Renewal Assessment Report

Dimethenamid-P

Volume 1

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Co-Rapporteur Member State: Bulgaria

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Level 1

Dimethenamid-P

1 Statement of subject matter and purpose for which this report has been prepared and background information on the application

1.1 Context in which the renewal assessment report was prepared

1.1.1 Purpose for which the renewal assessment report was prepared

This renewal assessment report has been prepared in accordance with Commission Regulation (EC) No 844/2012 and Guidance Document SANCO/2012/11251 rev. 4 in order to evaluate the application and the supplementary dossier submitted by BASF Corporation and to allow a decision on the renewal of the first approval of the active substance dimethenamid-P.

BASF submitted an application for the setting of MRLs in parallel. An amendment of MRLs is proposed in the RAR.

The proposed classification and labelling is in line with the ECHA harmonised classification.

1.1.2 Arrangements between rapporteur Member State and co-rapporteur Member State

According to Commission Regulation (EU) No 844/2012 Germany was assigned rapporteur Member State (RMS) and Bulgaria was assigned Co-rapporteur Member State (Co-RMS).

The Co-RMS did not have any comments on the draft RAR before it was sent to EFSA.

1.1.3 EU Regulatory history for use in plant protection products

Dimethenamid-P was first evaluated as new active substance according to Council Directive 91/414/EEC with Germany being the designated rapporteur Member State.

In 1999 BASF AG submitted the dossier for Annex I inclusion of Council Directive 91/414/EEC:

Following a peer review organised by the European Commission dimethenamid-P was included in Annex I of Council Directive 91/414/EEC with Commission Directive 2003/84/EC, entering into force on 1 January 2004. According to Regulation (EU) No 540/2011 dimethenamid-P is deemed to have been approved under Regulation (EC) No 1107/2009 as well.

The overall conclusions of the evaluation of glyphosate, as finalised by the Standing Committee on Plant Health on 25 September 2003, were provided in the Review Report (Dimethenamid-P; SANCO/1402/2001-Final, 3 July 2003).

The peer review concluded that only uses as herbicide may be authorised. These conclusions were reached within the framework of the following uses, which were supported by the main data submitters:

- herbicide against dicotyledonous weeds in maize and dicotyledonous weeds, *Echinochloa crus-galli*, *Setaria species* and *Digitaria species* in sugarbeet.

In agreement with Article 1 of Regulation (EC) No 844/2012 BASF submitted an application to Germany as RMS and Bulgaria as Co-RMS notifying the intention to renew the exsisting approval of dimethenamid-P on 20 October 2013.

A supplementary dossier from BASF was submitted on 29 April 2014.

1.1.4 Evaluations carried out under other regulatory contexts

The following evaluations are available:

- ECHA: Committee for Risk Assessment RAC, Opinion proposing harmonised classification and labelling at EU level of dimethenamid-P (ISO), CLH-0-0000003037-80-03/F, adopted 4 June 2013
- US-EPA: Toxicologicl Summary for: Dimethenamid and Dimethenamid-P, Health Based Guidance for WaterHealth Risk Assessment Unit, Environmental Health Division, 651-201-4899, November 2015
- Commission Regulation (EU) 2015/552 of 7 April 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards the maximum residue levels
- PMRL report: PMRL2013-105 Dimethenamid-P.

1.2 Applicant(s) information

1.2.1 Name and address of applicant(s) for approval of the active substance

BASF Corporation
100 Park Avenue
Florham Park, New Jersey 07932
United States

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D-67114 Limburgerhof
Germany

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Email: [redacted]

1.2.2 Producer or producers of the active substance

BASF Corporation
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United States

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BASF Nederland B.V.
APD/RH
P.O.Box 1019
NL-8601 MC Arnhem
The Netherlands

Name: [redacted]
Phone: [redacted]
Fax: [redacted]
Email: [redacted]

Alternative:

BASF SE
Agricultural Center
European Regulatory Affairs
P.O. Box 120
D-67114 Limburgerhof
Germany

Name: [redacted]
Phone: [redacted]
Fax: [redacted]
Email: [redacted]

Location of the manufacturing site:

Confidential information, see Annex C.

1.2.3 Information relating to the collective provision of dossiers

As BASF is the only applicant of the active substance dimethenamid-P, this point is not relevant.

1.3 Identity of the active substance

1.3.1 Common name proposed or ISO-accepted and synonyms

Dimethenamid-P

1.3.2 Chemical name (IUPAC and CA nomenclature)

IUPAC:	*S*-2-chloro-*N*-(2,4-dimethyl-3-thienyl)-*N*-(2-methoxy-1-methylethyl)-acetamide
CAS:	Acetamide, 2-chloro-*N*-(2,4-dimethyl-3-thienyl)-*N*-[(1*R*)-2-methoxy-1-methylethyl]-

1.3.3 Producer's development code numbers

BASF Code Number	BAS 656P H
BASF Registry Number	363851

1.3.4 CAS, EC and CIPAC numbers

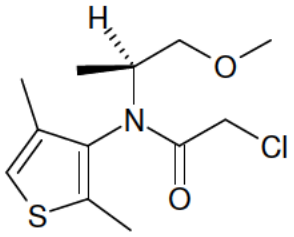
CAS	163515-14-8
EC (EEC)	n.a.
CIPAC	638

1.3.5 Molecular and structural formulae, molar mass

Molecular formular: $C_{12}H_{18}ClNO_2S$

Molar mass: 275.8 g/mol

Structural formula:



1.3.6 Method of manufacture (synthesis pathway) of the active substance

Confidential information, see Annex C.

1.3.7 Specification of purity of the active substance in g/kg

≥ 930 g/kg (commercial production)

1.3.8 Identity and content of additives (such as stabilisers) and impurities

Confidential information, see Annex C.

1.3.8.1 Additives

Confidential information, see Annex C.

1.3.8.2 Significant impurities

Confidential information, see Annex C.

1.3.8.3 Relevant impurities

1,1,1,2-Tetrachloroethane: < 1.0 g/kg
2,4-Dimethylthiophene-3-ol: ≤ 1.5 g/kg

1.3.9 Analytical profile of batches

Confidential information, see Annex C.

1.4 Information on the plant protection product

1.4.1 Applicant

BASF Corporation
100 Park Avenue
Florham Park, New Jersey 07932
United States

Contact:

BASF Nederland B.V.
APD/RH
P.O.Box 1019
NL-8601 MC Arnhem
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Name: [redacted]
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Alternative:

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Name: [redacted]
Phone: [redacted]
Fax: [redacted]
Email: [redacted]

1.4.2 Producer of the plant protection product

BASF Corporation
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Florham Park, New Jersey 07932
United States

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The Netherlands

Name: Klaas Jilderda
Phone: +31 26 3717286
Fax: +31 26 3717122
Email: klaas.jilderda@basf.com

Location of the manufacturing sites:

Confidential information, see Annex C.

1.4.3 Trade name or proposed trade name and producer's development code number of the plant protection product

Code number	BAS 656 12 H
Trade names	Spectrum, Isard, Frontier Optima, Frontier Optima New, Frontier Super, Outlook, Frontier X2, Frontier Elite, Spectrum ND New, Frontier Forte ND
Code number	BAS 830 01 H
Trade names	not yet defined

1.4.4 Detailed quantitative and qualitative information on the composition of the plant protection product

1.4.4.1 Composition of the plant protection product

Confidential information, see Annex C.

1.4.4.2 Information on the active substances

BAS 656 12 H

Content of pure active substance dimethenamid-P:	720 g/L	(64.46 % w/w)
Limits:	695.00 – 745.00 g/L	(62.22 – 66.70 % w/w)
Content of technical active substance dimethenamid-P: (min 93.0 %)	774.19 g/L	(69.31 % w/w)
Limits:	747.31 – 801.08 g/L	(66.90 – 71.72 % w/w)

BAS 830 01 H

Content of pure active substance dimethenamid-P:	333 g/L	(29.47 % w/w)
Limits:	316.35 – 349.65 g/L	(28.00 – 30.94 % w/w)
Content of pure active substance quinmerac:	167 g/L	(14.78 % w/w)
Limits:	156.98 – 177.02 g/L	(13.89 – 15.67 % w/w)
Content of technical active substance dimethenamid-P: (min 93.0 %)	358.06 g/L	(31.69 % w/w)
Limits:	340.16 – 375.97 g/L	(30.10 – 33.27 % w/w)
Content of technical active substance quinmerac: (min 98.0 %)	170.41 g/L	15.08 % w/w)
Limits:	160.18 – 180.63 g/L	(14.18 – 15.99 % w/w)

1.4.4.3 Information on safeners, synergists and co-formulants

Confidential information, see Annex C.

1.4.5 Type and code of the plant protection product

BAS 656 12 H Emulsifiable concentrate (EC)

BAS 830 01 H Suspo-emulsion (SE)

1.4.6 Function

Herbicide.

1.4.7 Field of use envisaged

BAS 656 12 H
Agriculture. The dimethenamid-P containg herbicide BAS 656 12 H is mainly a soil acting herbicide, which can be applied pre- and post-emergence of the crop to control a wide range of annual dicotyledonous weeds and annual monocotyledonous weeds in different crops.

BAS 830 01H
BAS 830 01 H is intended for post- end pre-emergence use in winter oilseed rape at a dose rate of 1.5 L/ha delivering 500 g/ha of dimethenamid-P and 250 g/ha of quinmerac.

1.4.8 Effects on harmful organisms

BAS 656 12 H
Dimethenamid-P is providing soil residual and, to little extend, foliar activity with application either before or shortly after weed emergence, leading to the inhibition of cell division. In germinating monocotyledonous weed species dimethenamid-P is predominantly absorbed via the emerging coleoptile. In dicotyledonous weed species dimethenamid-P enters the plant primarily via root uptake (radicule) and via the germinating shoots (hypocotyls). After uptake dimethenamid-P is hardly translocated within the plant. Typical symptoms of the aerial parts of broadleaf weed species that emerge include severe stunting, intense green colouration and a leathery appearance of the cotyledons. Emerged grasses are stunted and twisted.

BAS 830 01H
BAS 830 01 H contains dimethenamid-P and the second active substance quinmerac.
Quinmerac belongs to the chemical group of the quinolinecarboxylic acids. Due to its primary target site and its chemical family, in the HRAC mode of action classification, quinmerac is classified as group O. Quinmerac basically mimics the effects of supraoptimal endogenous auxin concentrations. The early effects in sensitive dicots are characterised by growth abnormalities, such as epinasty and growth inhibition with intensified green leaf pigmentation within 24 h. These phenomena are followed by chloroplast damage, leading to chlorosis and by the destruction of membrane and vascular system integrity, leading to desiccation, tissue necrosis and decay.

1.5 Detailed uses of the plant protection product

Please refer to point 1.5.1.

1.5.1 Details of representative uses

Table 1.5-1: GAP table for BAS 656 12 H

List of representative uses evaluated - BAS 656 12 H

GAP rev. 3, date: 2015-02-18

PPP (product name/code): BAS 656 12 H
Active substance: Dimethenamid-P
Formulation type: SE
Conc. of as 1: 720 g/L

Applicant: BASF
Zone(s): central/southern EU
Professional use: ☒
Non-professional use: ☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	EU	Maize - ZEAMX	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 00-09	a) 1 b) 1	a) 1.2 b) 1.2	a) 864 b) 864	100-400	F	Range 0.8-1.2 L/ha possible
2	EU	Maize - ZEAMX	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 10-16	a) 1 b) 1	a) 1.2 b) 1.2	a) 864 b) 864	100-400	F	Range 0.8-1.2 L/ha possible

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	EU	Sugar Maize - ZEAMS	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 00-09	a) 1 b) 1	a) 1.2 b) 1.2	a) 864 b) 864	100-400	F	Range 0.8-1.2 L/ha possible
4	EU	Sugar Maize - ZEAMS	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 10-16	a) 1 b) 1	a) 1.2 b) 1.2	a) 864 b) 864	100-400	F	Range 0.8-1.2 L/ha possible
5	EU	Soybean - GLXMA	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 00-09	a) 1 b) 1	a) 1.2 b) 1.2	a) 864 b) 864	100-400	F	Range 0.8-1.2 L/ha possible
6	EU	Sunflower - HELAN	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 00-09	a) 1 b) 1	a) 1.2 b) 1.2	a) 864 b) 864	100-400	F	Range 0.8-1.2 L/ha possible
7	EU	Sugar Beet - BEAVA	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 00-09	a) 1 b) 1	a) 1.2 b) 1.2	a) 864 b) 864	100-400	F	Range 0.8-1.2 L/ha possible
8	EU	Sugar Beet - BEAVA	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 16-18	a) 1 b) 1	a) 1.0 b) 1.0	a) 720 b) 720	100-400	F	Range 0.9-1.0 L/ha possible
9	EU	Sugar Beet - BEAVA	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 12-18	a) 2 (5-10d) b) 2	a1) 0.6 a2) 0.7 b) 1	a1) 432 a2) 504 b) 720	100-400	F	Max rate 1 L product/year Splitting: 2 applications BBCH 12 – BBCH 15: 0.3-0.6 L product/ha From BBCH 16: 0.3-0.7 L product/ha

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
10	EU	Sugar Beet - BEAVA	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 12-18	a) 3 (5-10 d) b) 3	a1) 0.4 a2) 0.4 a3) 0.4 b) 1	a1) 288 a2) 288 a3) 288 b) 720	100-400	F	Max rate 1 L product/year Splitting: 3 applications 0.3-0.4 L product/ha

Remarks:
(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(8) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

Table 1.5-2: GAP table for BAS 830 01 H

List of representative uses evaluated - BAS 830 01 H

PPP (product name/code): BAS 830 01 H
Active substance 1: Dimethenamid-P
Active substance 2: **Quinmerac**

Formulation type: SE
Conc. of as 1: 333 g/L
Conc. of as 2: 167 g/L

Applicant: BASF
Zone(s): northern/central/southern **EU**

Professional use: ☒
Non-professional use: ☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** (**crop destination / purpose of crop**)	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	EU	Winter Oilseed Rape - BRSNW	F	Annual monocotyledonous and dicotyledonous weeds	Spraying SP	BBCH 00-09	1	a) 1.5 b) 1.5	a) 500 [1] 250 [2] b) 500 [1] 250 [2]	100-400	F	Range 0.8-1.5 L/ha possible
2	EU	Winter Oilseed Rape - BRSNW	F	Annual monocotyledonous and dicotyledonous weeds	Spraying SP	BBCH 10-18	1	a) 1.5 b) 1.5	a) 500 [1] 250 [2] b) 500 [1] 250 [2]	100-400	F	Range 0.8-1.5 L/ha possible

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Remarks:
(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(8) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

1.5.2 Further information on representative uses

BAS 656 12 H
Method of application
The intended method of application is spraying by means of each type of spraying equipment which is normally used for applying herbicides in practical plant production. The diluent is water.

Number and timing of applications
The number of applications is 1 (maize, sugar maize, sunflower, soybean) and 1 up to 3 in sugar beet.

The timing of the application is from pre-emergence of weed/crop to early post-emergence (1st true leaf of annual monocotyledonous weeds, cotyledon stage of annual dicotyledonous weeds) at the latest. Growth stage of the crop ranges from BBCH 00 to 18, depending on crop species.

Waiting periods or other precautions to avoid phytotoxic effects on succeeding crops
After regular harvest of a crop treated with BAS 656 12 H all crops can be sown within the normal crop rotation. For grasses a deep tillage of 20 cm is required if seeded less than 4 months after application of BAS 656 12 H.
In the event of a crop failure certain precautions should be taken into account before a follow-crop is sown.
Maize, oilseed rape and related cruciferous crops can be replanted any time after application of BAS 656 12 H if either ploughing or thorough soil cultivation to a depth of approximately 15 - 20 cm ensures any residues are evenly dispersed throughout the soil. 30 - 45 days after application sowing should be safe with shallow cultivation.
Cereals and legume crops require a waiting period of 45 days with deep soil cultivation or 75 days with shallow soil cultivation.
A final recommendation in the event of a crop failure may vary between regions and adapted depending on cultural practices, climatic conditions, registered uses and dose rates, etc.

Proposed instructions for use
BAS 656 12 H is a herbicide for control of annual monocotyledonous and annual dicotyledonous weeds. It is absorbed through cotyledones, hypocotyl and roots. At pre-emergence applications, BAS 656 12 H is absorbed by germinating weeds and causes them to die off before or shortly after emergence. A fine-crumbled, moist seedbed supports efficacy.
In post-emergence, BAS 656 12 H will control weeds up to maximum 2-leaf stage. Good success is achieved when the active substance is diluted and consequently distributed in sufficient moisture in the soil and thus uptake of the active substance is also possible via the root system of the weeds. On highly organic soils, reduced efficacy may occur. If BAS 656 12 H is applied on dry surface soil, the main effect occurs after onset of precipitation. Weeds emerging from deeper soil layers under dry conditions may not be controlled satisfactorily.

BAS 830 01
Method of application
The intended method of application is spraying by means of each type of spraying equipment which is normally used for applying herbicides in practical plant production. The diluent is water.

Number and timing of applications
The maximum number of applications per cropping season is 1 (one).
Growth stages of crops or plants to be protected:
The timing of the application in winter oilseed rape is from BBCH 00-18, the product can be applied in pre- or in post-emergence of the crop.
Development stages of the harmful organism concerned:
The best application timing is depending on the development stages of the respective weeds (maximum 2 true leaves).

Normally one application will give a sufficient, season long control against harmful weeds.

Waiting periods or other precautions to avoid phytotoxic effects on succeeding crops
For all crops groups presented, the minimum waiting period is shorter than required for the typical cultivation period for a winter sown oilseed rape crop even with minimal soil cultivation.
Following crop failure, no special attention is needed for the planting of oilseed rape, cabbage, soybean, onion or maize. For oats (and via extrapolation, other winter cereals), replanting would require a minimum interval of 60 days, unless some form of cultivation is conducted. Spring crops of carrot, lettuce or tomato may be sown following cultivation to 5 cm after 120, 195 and 165 days, respectively. For ryegrass a waiting period of 165 days is required. The waiting period can be reduced if additional cultivation techniques are used.

Proposed instructions for use
The herbicide BAS 830 01H is used for the control of annual dicotyledonous and annual monocotyledonous weeds in winter oilseed rape pre (BBCH 00-09) and post emergence (BBCH 10-18) of the crop. The weeds that are controlled have to be between growth stages BBCH 00 and 12 (depending on the species). The product is to be used with a dose rate of 1.5 L/ha (active substance 1 dimethenamid-P 500 g/ha; active substance 2 quinmerac 250 g/ha). There is no PHI applicable; the product is applied once per season. BAS 830 01H is applied by spraying by using a water carrier system in a rate of 100 – 400 L/ha.
In general no special recommendations in addition to those already mentioned are found necessary.

1.5.3 Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Tree nuts	DE,AT	Spectrum	F	Annual grasses & Dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-55	1	N/A	0.864-0.216	100-400	0.864	F	From 1st year after planting, apply between rows with screen (PRNDA, PRNDU, CSNSS, CYLAV, CYLMA, IUGRE – almonds, chestnut, hazelnut, lambert nut, walnut)
Pome fruit	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-76	1	N/A	0.864-0.216	100-400	0.864	F	apply under trees (MABSD, PYUCO, CYDOB, ABOME, EIOJA, MSPGE – Apple, Pear, Quince, Black chokeberry, Loquat, Medlar)
Pome fruit	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 91-97	1	N/A	0.864-0.216	100-400	0.864	F	apply under trees (MABSD, PYUCO, CYDOB, ABOME, EIOJA, MSPGE – Apple, Pear, Quince, Black chokeberry, Loquat, Medlar)
Stone fruit	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-76	1	N/A	0.864-0.216	100-400	0.864	F	apply under trees (PRNAR, PRNAV, PRNCE, PRNPS, PRNPN, PRNDD, PRNDI, PRNDS – apricots, peaches, cherries, plums and others)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Stone fruit	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 91-97	1	N/A	0.864-0.216	100-400	0.864	F	apply under trees (PRNAR, PRNAV, PRNCE, PRNPS, PRNPN, PRNDD, PRNDI, PRNDS – apricots, peaches, cherries, plums and others)
Sugar beet, fodder beet, red beet	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.864-0.216	100-400	0.864	F	Range 0.8-1.2 L/ha possible
Sugar beet, fodder beet red beet	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-18	3 (5)	N/A	0.720-0.180	100-400	0.720	F	max of 720 g as/ha, season can be applied with max 3 times in split applications
Carrot, horse radish, turnip, swede	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-16	1	N/A	0.504-0.126	100-400	0.504	F	
Swedes and turnip	DE,PL,BE,NL	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 00-09	1	N/A	0.500-0.100	100-500	0.500	F	Pre emergence, intended minor use "F" = PHI is covered by the time period remaining between application and harvest
Spring, Welsh onions & similar	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-14	1	N/A	0.864-0.216	100-400	0.864	F	1.2 L/ha in pre-EM Or 0.4 L/ha in pre-EM + 2+ 0.4 L/ha in pot-EM

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Pumpkin hybr., cucumber, zucchini, patisson, melon (edible and inedible peel)	DE, AT, BE, BG, HR; CZ, FR,	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-16	1	N/A	0.850-0.212	100-400	0.864	F	
Oil pumpkin	DE, AT	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	Pre-planting	1	N/A	0.864-0.216	100-400	0.864	F	
Oil pumpkin	DE, AT	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.864-0.216	100-400	0.864	F	
Sweetcorn	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.864-0.216	100-400	0.864	F	Range 0.8-1.2 l/ha possible
Sweetcorn	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 10-16	1	N/A	0.864-0.216	100-400	0.864	F	Range 0.8-1.2 l/ha possible
Flowering brassica, (Cauliflower, Broccoli) transplanted	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 10-18	1	N/A	0.500-0.060	100-500	0.300-0.500	F	Post transplanting, not earlier than 5-7 days after transplanting

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Flowering brassica	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-16	1	N/A	0.720-0.180	100-400	0.720	35	seeded crop and planted crop, after taking roots
Brussels sprouts	DE, AT, BE, BG, HR; CZ, FR,	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-16	1	N/A	0.720-0.180	100-400	0.720	90	seeded crop and planted crop, after taking roots
Head cabbage (White, Red, Savoy, Spring cabbage) transplanted	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 10-18	1	N/A	0.500-0.060	100-500	0.300-0.500	F	Post transplanting, not earlier than 5-7 days after transplanting
Head cabbage (White, Red, Savoy, Spring cabbage) transplanted	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	After BBCH 14	1	N/A	0.300-0.060	100-500	0.300	N/A	Post transplanting, not earlier than 5-7 days after transplanting Intended minor use
Head cabbage (White, Red, Savoy, Spring cabbage) (seed plant) direct drilled	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 10-18	1	N/A	0.300-0.060	100-500	0.300	N/A	Post emergence direct drilled Intended minor use
Head cabbage (white, red, pointed head, savoy)	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-16	1	N/A	0.850-0.212	100-400	0.720	F	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Leafy brassica transplanted	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 10-18	1	N/A	0.500-0.060	100-500	0.300-0.500	F	Post transplanting, not earlier than 5-7 days after transplanting
Leafy brassica transplanted	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 10-18	1	N/A	0.500-0.100	100-500	0.500	F	Post transplanting, not earlier than 5-7 days after transplanting
Leafy brassica	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-16	1	N/A	0.720-0.180	100-400	0.720	60	seeded crop
Leafy brassica	DE, AT, BE, CZ, EE, FR, GR, HU, IT, LV, LT, LU, PL, ES, UK	Spring-bok	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-16	1	N/A	0.720-0.180	100-400	0.720	60	planted crop, after taking roots
Green beans with pods	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual weeds	EC	212.5 g/L	Spray	BBCH 00-09 (February-April)	1	N/A	0.425-0.213	200-400	0.850	F	
Green beans with pods	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.720-0.180	100-400	0.720	F	
Green beans with pods	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 11-14	1 N/A		0.720-0.180	100-400	0.720	F	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Climbing fresh beans with pods	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual weeds	EC	212.5 g/L	Spray	BBCH 00-09 or BBCH 10-14 (February-May)	1	N/A	0.425-0.213	200-400	0.850	F	
Climbing fresh beans with pods	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.720-0.180	100-400	0.720	F	
Climbing fresh beans with pods)	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 11-14	1	N/A	0.720-0.180	100-400	0.720	F	
Leek transplanted	DE,PL,BE,NL,FR,IT,ES, PT,GR	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 10-18	1	N/A	0.500-0.100	100-500	0.500	F	Post transplanting, not earlier than 5-7 days after transplanting
Leek transplanted	DE,PL,BE,NL,FR,IT,ES, PT,GR	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 10-18	1	N/A	0.500-0.060	100-500	0.300-0.500	F	Post transplanting, not earlier than 5-7 days after transplanting
Leek	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.864-0.216	100-400	0.864	F	1.2 L/ha in pre-EM Or 0.4 L/ha in pre-EM + 2+ 0.4 L/ha in pot-EM
Leek	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 10-18	1	N/A	0.864-0.216	100-400	0.864	F	1.2 L/ha in pre-EM Or 0.4 L/ha in pre-EM + 2+ 0.4 L/ha in pot-EM

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Vicia beans (dry)	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual weeds	EC	212.5 g/L	Spray	BBCH 00-09 or BBCH 10-14 (February-May)	1	N/A	0.425-0.213	200-400	0.850	F	
Vicia beans (dry)	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.720-0.180	100-400	0.720	F	Submitted as minor crop
Vicia beans (dry)	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 11-14	1	N/A	0.720-0.180	100-400	0.720	F	Submitted as minor crop
Lupine	DE, AT, BE, BG, CZ, FR, GR, HU, IT, NL, PL, PT, RO, SK, SE, GB	Wing P	F	Annual weeds	EC	212.5 g/L	Spray	BBCH 00-09 (February-March	1	N/A	0.425-0.213	200-400	0.850	F	Minor uses
Sunflower	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.864-0.216	100-400	0.864	F	Range 0.8-1.2 L/ha possible
Winter Oilseed Rape	,DE, AT, FR, UK, CZ, SK, HU, Pl, BG, RO, UA, BY, RU, SE, LT, EE, LV	BAS 830 01	F	Annual broadleaf weeds	SE	333 g/L	Spraying SP	BBCH 10-18	1	N/A	0.500-0.125	100-400	0.500	F	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Winter Oilseed Rape	,DE, AT, FR, UK, CZ, SK, HU, Pl, BG, RO, UA, BY, RU, SE, LT, EE, LV	BAS 830 01	F	Annual broadleaf weeds	SE	333 g/L	Spraying SP	BBCH 00-09	1	N/A	0.500-0.125	100-400	0.500	F	
Oilseed rape	DE, AT, BG, HR; CZ, EE, FR, HU, LV, LT, NL, PL, RO, SI, SK, SE, GB	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 00-09	1	N/A	0.500-0.100	100-500	0.500	F	Post emergence "f" = PHI is covered by the time remaining between application and harvest
Oilseed rape	DE, AT, BG, HR; CZ, EE, FR, HU, LV, LT, NL, PL, RO, SI, SK, SE, GB	Spring-bok	F	Weeds (general)	EC	200 g/L	Spraying SP	BBCH 10-18	1	N/A	0.500-0.100	100-500	0.500	F	Post emergence "f" = PHI is covered by the time remaining between application and harvest
Soybean	CZ, HU, RO, HR, BG, DE, AT	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 00-09	1	N/A	0.864-0.216	100-400	0.864	F	Range 0.8-1.2 L/ha possible
Maize	FR, NL, CZ, HU, RO, BE, BG, DE, AT, GR, IT, PT, ES, SI, HR , SK	Wing P	F	Annual weeds	EC	212.5 g/L	Spray	BBCH 00-09 or BBCH 10-16 (April-May)	1	N/A	0.425-0.213	200-400	0.850	F	
Maize	FR, NL, CZ, HU, RO, BE, BG, DE, AT, GR, IT, PT, ES, SI, HR , SK	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 10-16	1	N/A	0.864-0.216	100-400	0.864	F	Range 0.8-1.2 L/ha possible

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks**
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Maize	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 10-16	1	N/A	0.864-0.216	100-400	0.864	F	Range 0.8-1.2 L/ha possible
Millet	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 13-16	1	N/A	0.864-0.216	100-400	0.864	F	
Sorghum	DE, AT, BE, BG, HR; CZ, FR, GR, HU, IT, LU, NL, PT, RO, SI, ES	Spectrum	F	Annual monocotyle-donous and dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 13-16	1	N/A	0.864-0.216	100-400	0.864	F	
Witloof, Chicory root	FR	Spectrum	F	Annual grasses & Dicotyledo-nous weeds	EC	720 g/L	Spraying SP	BBCH 12-18	3 (5-10)	N/A	0.33-1.0	100-400	0.720	90	Split Application 3x0.33 L/ha

1.5.4 Overview on authorisations in EU Member States

Products containing dimethenamid-P are widely authorised in 21 of 28 EU Member States in a broad range of different crops including cereal crops, oilseed crops, beet roots, legume crops used as dry pulses or legume vegetables, vegetables, root & tuber vegetables, stem vegetables, fruiting vegetables, leafy vegetables & herbs, biannual / perennial crops and other crops.
Authorisations for a range of different formulation have been achieved in Europe. This includes different formulation types (EC, SC) of products including only dimethenamid-P as the active substance but also a range of combination products with different other active substances.

Level 2

Dimethenamid-P

2 Summary of active substance hazard and of product risk assessment

2.1 Identity

2.1.1 Summary of identity

All data concerning the identity address sufficiently the requirements of Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013.

2.2 Physical and chemical properties

2.2.1 Summary of physical and chemical properties of the active substance

Dimethenamid-P is a clear, slightly brown liquid with a faint, intrinsic odour. It has a solidification point below -50 °C and starts to decompose above approximately 101 °C, before reaching its boiling point. It is not flammable, not explosive and has no oxidising properties. It has an *n*-octanol/water partition coefficient (log P_{OW}) of 1.89. The log P_{OW} of metabolites included in the residue definition for risk assessment (see 2.13.1) are missing. Dimethenamid-P has a vapour pressure of 2.5 x 10^{-3} Pa at 25 °C and a surface tension of approximately 50 mN/m for 0.1 % and 0.5 % dilutions in water. It shows no dissociation in water and absorbs UV light with a maximum at 236 nm.

2.2.2 Summary of physical and chemical properties of the plant protection product

BAS 656 12 H is an EC formulation of a clear brown colour, with an aromatic odour. It is not explosive and has no oxidising properties. It has a corrected auto-ignition temperature of 391 °C. In aqueous solution, it has a pH value around 4.3 - 6.8.

The product BAS 830 01 H is an SE formulation. The appearance of the product is that of a light brown liquid, with a slightly aromatic odour. It is not explosive and has no oxidising properties. It has an auto-ignition temperature of 454 °C. In aqueous solution, it has a pH value around 3.5.

2.3 Data on application and efficacy

2.3.1 Summary of effectiveness

BAS 656 12 H

Dimethenamid-P as BAS 656 12 H achieves a good herbicidal activity when an appropriate concentration of the active substance reaches the important sites of uptake. Optimum constellation is influenced by the following factors:

- different binding characteristics to soil types with diverse texture and content of organic material
- activation of active substance by sufficient soil moisture or rainfall after application

- germination of weeds from deeper soil levels with less exposure of sensitive plant parts to the active substance
- different exposure of growing points to direct application due to morphological variation in plant architecture

Thus, depending on local or regional differences in weed spectrum, length of germination period of weeds, growing conditions, period of application, cultivation practices, soil types, soil moisture, rainfall, etc. the dose rate of BAS 656 12 H to provide the required activity can vary. However, effectiveness of dimethenamid-P is considered sufficient using the maximum recommended field rates as outlined in the GAP-tables.

BAS 830 01 H
The herbicide BAS 830 01 H containing dimethenamid-P and quinmerac has been tested in field development trials, which demonstrated efficacious activity of the product against weeds.
Dimethenamid-P acts as a selective herbicide against annual dicotyledonous and annual monocotyledonous weeds in many agricultural crops including oilseed rape. Quinmerac is used only in oilseed rape and sugar beet for the further increase of broadleaf weed control activity.

2.3.2 Summary of information on the development of resistance

BAS 656 12 H
Dimethenamid-P belongs to the Herbicide-Resistance Action Committee (HRAC) group K3 (inhibitors of very-long-chain-fatty-acids (VLCFA)). For dimethenamid-P no information on potential resistance mechanism is available.
No case of resistance to dimethenamid-P has so far been reported worldwide, but resistance of four grass weed species to other HRAC group K3 active substances are reported worldwide.
Herbicides with different mode of action are commonly applied in crop rotations which reduce the agronomic risk of herbicide resistance. The agronomic risk of dimethenamid-P can be assessed as being low.
Due to the low inherent and agronomic risk, the overall resistance risk of dimethenamid-P can be assessed as low.

BAS 830 01 H
Quinmerac belongs to the chemical group of the quinolinecarboxylic acids. Due to its primary target site and its chemical family, in the HRAC mode of action classification quinmerac is classified as group O. Although the mechanism of resistance of group O herbicides has not been determined, resistance may be due to an insensitive target site.
However, due to the low inherent and agronomic risk, the overall resistance risk of the herbicide containing dimethenamid-P and quinmerac can be assessed as low.

2.3.3 Summary of adverse effects on treated crops

BAS 656 12 H
BAS 656 12 H is selective in all tested maize, sunflower, soybean, sugarbeet varieties. Incompatibilities of BAS 656 12 H with certain varieties are not known.
Based on the long term experiences the risk of phytotoxicity is considered as acceptable.

BAS 830 01 H
BAS 830 01 H is selective in oilseed rape. Incompatibilities of BAS 830 01 H with certain varieties are not known.

2.3.4 Summary of observations on other undesirable or unintended side-effects

BAS 656 12 H
The most sensitive plants like lettuce may be affected in pre-emergence applications to a maximum distance of 5 m from the treated field, if no drift reducing application technique is used.
BAS 656 12 H can be considered as sufficiently safe for adjacent crops.

BAS 830 01 H
BAS 830 01 H can be considered as sufficiently safe for adjacent crops. The most sensitive plants like lettuce may be affected in pre-emergence applications to a maximum distance of 5 m from the treated field, if no drift reducing application technique is used.

2.4 Further information

2.4.1 Summary of methods and precautions concerning handling, storage, transport or fire

Precautions for safe handling
No special measures necessary if stored and handled correctly. Ensure thorough ventilation of stores and work areas. When using do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift.

Protection against fire and explosion:
Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy. Vapours may form ignitable mixture with air.

Conditions for safe storage, including any incompatibilities
Segregate from foods and animal feeds.
Further information on storage conditions: Keep away from heat. Protect from direct sunlight.
Protect from temperatures above: 30 °C.
Changes in the properties of the product may occur if substance/product is stored above indicated temperature for extended periods of time.

Description of first aid measures
If inhaled: Keep patient calm, remove to fresh air, seek medical attention.
On skin contact: Immediately wash thoroughly with soap and water, seek medical attention.
On contact with eyes: Wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.
On ingestion: Immediately rinse mouth and then drink 200 - 300 mL of water, seek medical attention. Do not induce vomiting due to aspiration hazard.
Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

Fire-Fighting Measures

Extinguishing media
Suitable extinguishing media:
Water spray, foam, dry powder, carbon dioxide

Special hazards arising from the substance or mixture
Carbon monoxide, hydrogen chloride, carbon dioxide, nitrogen oxides, organochloric compounds: The substances/groups of substances mentioned can be released in case of fire.

Advice for fire-fighters
Special protective equipment:
Wear self-contained breathing apparatus and chemical-protective clothing.

Further information:
In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire. Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Accidental Release Measures

Personal precautions, protective equipment and emergency procedures
Do not breathe vapour/spray. Use personal protective clothing. Avoid contact with the skin, eyes and clothing.

Environmental precautions
Do not discharge into drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

Methods and material for containment and cleaning up
Any spilled product or contaminated soil/water is to be absorbed and disposed of according to the use prescriptions.

For small amounts: Pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, kieselguhr).

For large amounts: Dike spillage. Pump off product. Dispose of absorbed material in accordance with regulations. Collect waste in suitable containers, which can be labelled and sealed. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations.

2.4.2 Summary of procedures for destruction or decontamination

For purposes of disposal of the active substance BAS 656 H and the formulated products BAS 656 12 H and BAS 830 01 H, combustion in a licensed incinerator is required. This method of disposal applies also to contaminated packages, which cannot be cleaned or reused.

Although it is possible to incinerate the product at lower temperatures, combustion at approximately 1100 °C with a residence time of about 2 seconds is advised.
By doing so, i.e., operating the incinerator according to the conditions laid down in Council Directive 94/67/EEC resp. directive 2000/76/EC of the European Parliament, one will achieve complete combustion and minimise the formation of undesired by-products in the off-gases.

Users are requested to triple rinse empty primary packages as described in the ECPA "Guidelines for the rinsing of agrochemical containers", 1993.

Pressure rinsing or integrated pressure rinsing of the packaging material achieves a similar or even better result. The rinsing water must be added to the spray liquid.

To minimise waste of packages it is recommended that empty and rinsed containers are delivered to local container collection stations. If these do not exist, empty and rinsed containers must be rendered unusable and disposed according to local regulations.

Immediately after use, clean the spray equipment thoroughly according to common agricultural

practice. Drain the system completely and rinse spray tank, boom and nozzles two to three times with clean water until the foam and all traces of product have been removed. This will remove any remainders of BAS 656 08 H (and thus BAS 656 12 H) as well as BAS 830 01 H so efficiently that no plant damage can be caused when the equipment is used subsequently for the treatment of different crops. It is not necessary to add cleaning agents. Protective clothing will be cleaned effectively when washed with usual laundry detergents.

Controlled incineration
Waste material and packaging should be disposed of at a suitable waste incineration plant in accordance with the official regulations. It is adviced to incinerate the products at 1100 °C with a residence time of about 2 seconds.

Others
No alternative to incineration for disposal of active substance has been identified.

2.4.3 Summary of emergency measures in case of an accident

Description of first aid measures

First aid personnel should pay attention to their own safety. If the patient is likely to become unconscious, place and transport in stable sideways position (recovery position). Immediately remove contaminated clothing.

If inhaled:
Keep patient calm, remove to fresh air, seek medical attention.

On skin contact:
Immediately wash thoroughly with soap and water, seek medical attention.

On contact with eyes:
Wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

On ingestion:
Immediately rinse mouth and then drink 200 - 300 mL of water, seek medical attention. Do not induce vomiting due to aspiration hazard.

Most important symptoms and effects, both acute and delayed
Symptoms: The most important known symptoms and effects are described in the labelling.

Further important symptoms and effects are so far not known.

Indication of any immediate medical attention and special treatment needed
Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

Accidental Release Measures

Personal precautions, protective equipment and emergency procedures
Do not breathe vapour/spray. Use personal protective clothing. Avoid contact with the skin, eyes and clothing.

Environmental precautions
Do not discharge into drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

Methods and material for containment and cleaning up
For small amounts: Pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, kieselgur).

For large amounts: Dike spillage. Pump off product. Dispose of absorbed material in accordance with regulations. Collect waste in suitable containers, which can be labelled and sealed. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations.

Sufficient information to address the respective data requirements is available.

2.5 Methods of analysis

2.5.1 Methods used for the generation of pre-authorisation data

Dimethenamid-P content in dimethenamid-P technical
Technical dimethenamid-P is dissolved in a mixture of heptane and 2-propanol and chromatographed on a normal phase HPLC system applying a chiral separation column. Quantitation of the active substance *S*-dimethenamid and its enantiomer *R*-dimethenamid is performed by UV detection and external standard calibration using authentic reference items of known purity.

Content of impurities in dimethenamid-P technical
Impurities in technical dimethenamid-P can be determined by HPLC-UV and GC-FID. Details of the methods are reported Volume 4 of the RAR.

Dimethenamid-P content in BAS 656 12 H
The active substance dimethenamid-P is dissolved in *n*-heptane/dichloromethane, chromatographed on an HPLC normal phase system and determined by UV detection using external calibration. This method has been developed and validated for the determination of dimethenamid-P in BAS 656 07 H. This method can also be used for the determination of dimethenamid-P in BAS 656 12 H, the related formulation "blank" does not show interference and the linearity range is respected.

Content of relevant impurities in BAS 656 12 H
The relevant impurities TCE and Keto-Enol can be determined in the formulation by GC-FID and HPLC-UV, respectively. Details of the methods are reported Volume 3 – B.5 of the RAR.

Dimethenamid-P and quinmerac in BAS 830 01 H
A correction factor for the P-enantiomer of dimethenamid is established by extraction of BAS 830 01 H in THF and *n*-heptane, and chiral separation by normal phase HPLC using a Regis (S,S) Whelk-O column, according to analytical method AFL0879/01.
The quinmerac and dimethenamid content of BAS 830 01 H (SE) formulation is then determined by extraction of the samples, and separation by reversed phase HPLC using a C18 column. Detection is by UV absorbance at 220 nm, and quantitation is by external standardisation.

Content of relevant impurities in BAS 830 01 H
Analytical methods for the determination of the relevant impurities in the product are missing.

Analytical methods for risk assessment
All methods submitted under B.5.1.2 were evaluated for compliance with SANCO/3029/99 rev 4. However, of the compliant studies provided by the applicant, only the method used for plants and plant products could be assigned to its use in field trials during the generation of pre-registration data. For all other methods the specific endpoints and/or studies where the method was used for during pre-registration could not be assigned.

Table 2.5-1: Method 1, BASF method L0179/02 (method used in field trials)

Matrix type	Matrix	Method	Limit of quantification		Reference	Owner
Crop	Maize whole plant Maize seed Sugar beet leaves Sugar beet roots Rape seed Strawberries Onions Dried beans	LC-MS/MS, XDB C18, ESI+, m/z 276→244, 276→168 (dimethenamid-P); 270→198, 270→166 (M23); 360→272, 360→142 (M26); 320→121, 320→80 (M27); 376→136, 376→270 (M30)	0.01	mg/kg per analyte	Lehmann, 2012 (ASB2014-3702)	BASF

2.5.2 Methods for post control and monitoring purposes

Methods to ensure the monitoring and enforcement of the respective limits are available.

2.5.2.1 Formulation analysis

See 2.5.1.

2.5.2.2 Residue analysis

Evaluation and Assessment

The submitted methods enable the enforcement of the following relevant residue definitions and limits (at the time of evaluation) are listed below:

Matrix	Limit		Comment
Plants and plant products			
Commodities with high water content	0.02	mg/kg	Residue definition: Sum of stereoisomers of dimethenamid + metabolite M30, expressed as dimethenamid-P
Commodities with high fat content	0.02	mg/kg	
Acidic commodities	0.02	mg/kg	
Dry commodities	0.02	mg/kg	
Animal products			
Milk, meat, egg, fat, liver/kidney	-	-	sum of stereoisomers of metabolite M30, expressed as dimethenamid-P (provisional)
Soil	0.01	mg/kg	The lowest ER_{50} found for non-target higher plants was determined for lettuce at 28.6 mL/ha (20.6 g/ha), which results according to SANCO 825/00 rev. 8.1 in a limit of quantification of 0.01 mg/kg. residue definition: sum of stereoisomers of dimethenamid
Drinking water	0.1	µg/L	EU drinking water limit; Residue definition: Sum of stereoisomers of dimethenamid
Surface water	6	µg/L	based on the E_yC_{50} for *L. gibba* (higher aquatic plant) residue definition: sum of stereoisomers of dimethenamid
Air	12	µg/m³	based on a proposed AOEL of 0.04 mg/kg bw/d residue definition: sum of stereoisomers of dimethenamid
Tissues	0.1	mg/kg	sum of stereoisomers of dimethenamid
Body fluids	0.05	mg/L	sum of stereoisomers of dimethenamid

For the assessment of the analytical methods for the determination of dimethenamid-P residues the following criteria were used:

- Mean recovery rates and standard deviation at each fortification level according to Table 1 of SANCO/825/00 rev. 8.1.
- No interfering blanks (<30 % of the LOQ).
- Methods must employ the simplest approach, involve the minimum cost, and require commonly available equipment.
- The enforcement method for food must be suitable for the determination of all compounds included in the residue definition and must be checked in an independent laboratory.
- The enforcement methods for environmental matrices must be able to analyse for all compounds of toxicological and/or ecotoxicological significance in soil, water and air.
- An additional confirmatory method for all matrices is supplied.

According to these criteria adequate analytical methods were identified and are listed in Table 2.5-2.

Table 2.5-2: Methods for the determination of residues

Matrix type	Matrix	Method	Limit of quantification		Reference	Owner
Crop	Maize whole plant Maize seed Sugar beet leaves Sugar beet roots Rape seed Strawberries Onions Dried beans	LC-MS/MS, XDB C18, ESI+, m/z 276→244, 276→168 (dimethenamid-p); 376→136, 376→270 (M30)	0.01	mg/kg per analyte	Lehmann, 2012 (ASB2014-3702)	BASF
Crop	Strawberries Dried beans Rape seed Maize forage Maize seed	LC-MS/MS, C18, ESI+, m/z 276→244, 276→168 (dimethenamid-P); 376→136, 376→270 (M30)	0.01	mg/kg per analyte	Rogers, 2014 (ASB2014-8333)	BASF
Crop	Grape Lettuce Barley grain	LC-MS/MS, ESI+, Atlantis T3 C18, m/z 276→244, 276→168 (dimethenamid-P); 376→91, 376→136 (M30)	0.01	mg/kg per analyte	Diamaduros, 2014 (ASB2014-8334)	BASF
Animal matrices	Muscle Kidney Liver Fat Milk Egg	LC-MS/MS, ESI-, Atlantis T3 C18 column, m/z 376→91, 376→136 (M30)	0.01	mg/kg	Gordon, 2014 (ASB2014-8335)	BASF
Soil	Lufa 5M Lufa 2.2	LC-MS/MS, C18, ESI+, m/z 276→168, 276→244 (dimethenamid-P)	0.005	mg/kg per analyte	Obermann, 2008 (ASB2010-4519)	BASF
Soil	Lufa 2.2 Lufa 5M Sediment	LC-MS/MS, C18, ESI+, m/z 276→244, 276→168 (dimethenamid-P)	0.005	mg/kg per analyte	Tilting, 2014 (ASB2014-8294)	BASF
Water	Drinking water surface water	LC-MS/MS, C18, ESI+, m/z 276→244, 276→168 (dimethenamid-P)	0.03	µg/L per analyte	Jooß, 2012 (ASB2014-8295)	BASF
Water	Drinking water	LC-MS/MS, C18, ESI+, m/z 276→244, 276→168 (dimethenamid-P)	0.03	µg/L per analyte	Liu & Shi, 2014 (ASB2014-8337)	BASF
Water	Drinking water surface water	LC-MS/MS, C18, ESI+, m/z 276→244, 276→168 (dimethenamid-P)	0.05	µg/L per analyte	Schulz & Meyer, 2007 (ASB2010-4520)	BASF
Water	Drinking water surface water	GC-MSD, HP-5MS, m/z 154, 203, 230 GC-NPD, SPB-5 (dimethenamid-P)	0.05	µg/L	Colin, 1998 (MET1999-540)	BASF

Matrix type	Matrix	Method	Limit of quantification		Reference	Owner
Air	Air, 35 °C, 81 % rel. humidity, 6 h	LC-MS/MS, C18, ESI+, m/z 276→168, 276→244 (dimethenamid-P)	1.5	µg/m³	Zangmeister, 2010 (ASB2013-9757)	BASF
Tissues	Muscle Kidney Liver Fat Milk Egg	LC-MS/MS, ESI-, Atlantis T3 C18 column, m/z 276→244, 276→186 (dimethenamid-P)	0.01	mg/kg	Gordon, 2014 (ASB2014-8335)	BASF

An overview of the accepted enforcement methods (incl. confirmatory methods and independent lab validation) submitted by the applicant is given in the following table.

Table 2.5-3: Studies submitted by the applicant, which describe appropriate analytical procedures (Completeness check of analytical methods for monitoring purposes and post-registration control in accordance to guidance document SANCO/825/00 rev. 8.1)

Matrix type/ crop group	Primary Method	Confirmatory method	Independent Lab Validation
Cereals and other dry crops	Lehmann/ 2012 ASB2014-3702 Diamaduros/ 2014 (QuEChERS-method) ASB2014-8334	Lehmann/ 2012 ASB2014-3702 Diamaduros/ 2014 (QuEChERS-method) ASB2014-8334	Rogers/ 2014 ASB2014-8333
Commodities with high water content	Lehmann/ 2012 ASB2014-3702 Diamaduros/ 2014 (QuEChERS-method) ASB2014-8334	Lehmann/ 2012 ASB2014-3702 Diamaduros/ 2014 (QuEChERS-method) ASB2014-8334	Rogers/ 2014 ASB2014-8333
Fruits with high acid content	Lehmann/ 2012 ASB2014-3702 Diamaduros/ 2014 (QuEChERS-method) ASB2014-8334	Lehmann/ 2012 ASB2014-3702 Diamaduros/ 2014 (QuEChERS-method) ASB2014-8334	Rogers/ 2014 ASB2014-8333
Commodities with high fat content	Lehmann/ 2012 ASB2014-3702 Diamaduros/ 2014 (QuEChERS-method) ASB2014-8334	Lehmann/ 2012 ASB2014-3702	Rogers/ 2014 ASB2014-8333
Commodities which are difficult to analyse	Not required (no intended use in difficult matrices)	Not required (no intended use in difficult matrices)	Not required (no intended use in difficult matrices)
Milk	Gordon/ 2014 ASB2014-8335	Gordon/ 2014 ASB2014-8335	Missing
Egg	Gordon/ 2014 ASB2014-8335	Gordon/ 2014 ASB2014-8335	Missing
Meat	Gordon/ 2014 ASB2014-8335	Gordon/ 2014 ASB2014-8335	Missing
Fat	Gordon/ 2014 ASB2014-8335	Gordon/ 2014 ASB2014-8335	Missing
Kidney/liver	Gordon/ 2014 ASB2014-8335	Gordon/ 2014 ASB2014-8335	Missing
Soil	Obermann/ 2008 ASB2010-4519 Tilting/ 2014 ASB2014-8294	Obermann/ 2008 ASB2010-4519 Tilting/ 2014 ASB2014-8294	Generally not required
Drinking water	Jooß/ 2012 ASB2014-8295 Schulz & Meyer/ 2007 ASB2010-4520 Colin/ 1998 MET1999-540	Jooß/ 2012 ASB2014-8295 Schulz & Meyer/ 2007 ASB2010-4520 Colin/ 1998 MET1999-540	Liu & Shi/ 2014 ASB2014-8337
Surface water	Jooß/ 2012 ASB2014-8295 Schulz & Meyer/ 2007	Jooß/ 2012 ASB2014-8295 Schulz & Meyer/ 2007	Generally not required

Matrix type/ crop group	Primary Method	Confirmatory method	Independent Lab Validation
	ASB2010-4520 Colin/ 1998 MET1999-540	ASB2010-4520 Colin/ 1998 MET1999-540	
Air	Zangmeister/ 2010 ASB2013-9757	Zangmeister/ 2010 ASB2013-9757	Generally not required
Tissues	Gordon/ 2014 ASB2014-8335	Gordon/ 2014 ASB2014-8335	
Body fluids	Missing	Missing	

This overview shows that for residues in all types of plant and plant products, for residues in soil, for residues in drinking and surface water as well as for residues in air sufficiently validated analytical methods and confirmatory methods are available. For body fluids no method has been provided. Moreover, for matrices of animal origin, an independent laboratory validation for metabolite M30 is missing. However, at this point no residues of metabolite M30 are expected in animal matrices. Thus, the ILV is not required until potential future uses relevant for animal feed further trigger the dietary burden.

2.6 Effects on human and animal health

The toxicological information on the Annex I inclusion of dimethenamid-P is provided as extracted from the original monograph of dimethenamid-P of September, 2000 (ASB2010-10566). It should be noted, that some tables or information were added, typos were corrected. The conclusions of the original monograph have not been revised. These toxicological studies were now re-evaluated by the RMS. In addition studies submitted with the dossier for the Renewal Assessment Report were evaluated. This information is provided under the respective chapters.

Comparative toxicological assessment of dimethenamid-P and racemic dimethenamid – the bridging concept:

A bridging concept was applied and accepted for the Annex I inclusion of dimethenamid-P.
Dimethenamid is one of many organic substances that occur as “racemic” 50/50 mixtures of stereoisomers. It was discovered that only the S-isomer (dimethenamid-P) has useful herbicidal activity, while the other isomer (R) is inactive as a pesticide that was nearly completely removed in the synthesis of dimethenamid-P.
For the inclusion of dimethenamid-P in Annex I of Directive 91/414/EEC, the long-term and reproductive toxicity studies submitted were not performed with dimethenamid-P. Instead, the effects of racemic (R, S)-dimethenamid were tested in these extensive studies, which had been completed prior to discovery of the superior properties of the S-isomer (dimethenamid-P). The so-called “bridging” concept was applied to avoid the additional conduct of the above mentioned studies with dimethenamid-P, and thus to avoid additional animal testing. By this bridging approach, results from toxicological studies available for both racemic dimethenamid and dimethenamid-P were compared.
All in all, the bridging studies that were available for assessment of acute toxicity, short-term toxicity, genotoxicity and developmental toxicity indicated that both test substances share the same toxicological profile, and that the effects established were observed at comparable dose levels (see table below). On this basis, it was the opinion that in principle the test substances racemic dimethenamid and dimethenamid-P are equivalent entities and that all studies available for racemic dimethenamid should be considered in the toxicological evaluation of dimethenamid-P. It is considered to be scientifically justifiable to accept relevant racemic dimethenamid studies for derivation of the ADI, ARfD and AOEL.

Table 2.6-1: Toxicological studies with dimethenamid-P and racemic dimethenamid including studies that support the bridging concept

Toxicity studies	Racemic dimethenamid	Dimethenamid-P
Absorption, distribution, metabolism and excretion		
Absorption, distribution, metabolism and excretion in rats and mice	+ (rat, mouse)	+ (rat)
Comparative *in-vitro* metabolism	+	+
Acute toxicity		
Oral, rat	+	+
Dermal, rabbit	+	+
Inhalation, rat	+	+
Dermal irritation, rabbit	+	+
Eye irritation, rabbit	+	+
Dermal sensitisation, guinea pig	+	+
Short term toxicity		
28-day/5-week oral range finding, rat	+	+
21-day dermal, rabbits	+	–
90-day oral, rat	+	+
90-day oral range finding, mice	+	–
90-day oral, dog	+	–
1-year oral, dog	+	–
Mutagenicity		
Bacterial gene mutation (*in vitro*)	+	+
Mammalian cell gene mutation (*in vitro*)	+	+
Chromosome aberration (*in vitro*)	–	+
Unscheduled DNA-synthesis (*in vitro/in vivo*)	+	+
Chromosome aberration (micronucleus test, *in vivo*)	+	+
Reproduction toxicity		
2-generation study, rat	+	–
Developmental. tox./teratogenicity, rat	+	+
Developmental. tox./teratogenicity, rabbit	+	–
Long term toxicity		
2-year oral, chronic tox./carcinogenicity, rat	+	–
94-week oral, carcinogenicity, mice	+	–
Neurotoxicity		
Acute neurotoxicity	–§	+
Subchronic (90-day) neuro-toxicity	–§	+

\+ = Study was submitted
– = No study conducted, evaluation is based on bridging concept
§ = Evaluation based on studies of the whole toxicological data package of dimethenamid racemate

In conclusion the bridging studies conducted with dimethenamid-P can be used in conjunction with the studies conducted with racemic dimethenamid to support a registration of the dimethenamid S-isomer (dimethenamid-P).

2.6.1 Summary of absorption, distribution, metabolism and excretion in mammals

The following already peer reviewed studies in rats and mice are briefly summarised below:

Table 2.6-2: Overview of studies evaluated for Annex I inclusion of dimethenamid-P

Table Title	Reference
Absorption, distribution and excretion in rats after single and multiple doses of [^{14}C] SAN 582-H	[redacted] 92/12428*[1,3] (TOX1999-406)
Absorption, distribution, metabolism and excretion of (^{14}C) SAN 582H in rats after single and multiple doses	[redacted] 1992; 1992/12428*[1,3] (TOX1999-406)
Qualitative investigations of the *in vitro* (liver and kidney) metabolism of Dimethenamid (SAN 582 H)	[redacted] 1993/11765*[1,3] (TOX1999-410)
SAN 582 H: Determination of the presence of plant metabolites in rat	[redacted] 1992/12448*[1,3] (TOX1999-409)
SAN 582 H: Determination of the presence of sulfonate metabolite in mice	[redacted] 1992/12445*[1,3] (TOX1999-407)
SAN 582 H: Addendum to determine sulfoxide of thioglycolic acid conjugate in mouse excreta	[redacted] 1992/12446*[1,3] (TOX1999-408)

* for Annex I inclusion of dimethenamid-P

1 The study has been evaluated as acceptable in the original monograph of dimethenamid-P by the RMS in September, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2015-1648).

2 The study has been evaluated as supplementary in the original monograph of dimethenamid-P by the RMS in September, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 ASB2015-1648).

3 The study has been evaluated as acceptable in the Renewal Assessment Report.

Absorption, distribution, metabolism and excretion in rats

A rat metabolism study was conducted using [3-thienyl-^{14}C] dimethenamid ([redacted] 1988; TOX1999-406). The test compound was administered by intravenous injection (i.v.) or by oral gavage (p.o.). The study was conducted in 5 groups. Group 1 was administered an oral dose at 10 mg/kg bw. Group 2 received an intravenous dose at 10 mg/kg bw. Group 3 was administered an oral dose at 1,000 mg/kg bw. Group 4 was orally administered with unlabelled dimethenamid for 14 days at 10 mg/kg bw/day followed by a ^{14}C oral dose at 10 mg/kg bw. The rats in group 5 were bile duct cannulated and received an oral dose at 10 mg/kg bw. Groups 1 to 4 consisted of 6 males and 6 females while group 5 consisted of 3 rats per sex. Excreta from each group and bile from group 5 were collected periodically until sacrifice at 168 h. Additional rat experiments to collect blood and tissue samples were conducted at 1, 4, 24, 72 and 168 h. Two dose groups (10 and 1000 mg/kg) and three rats per sex per time point per dose group were used.
A summary of excretion in urine, faeces and bile is presented in Table 2.6-3 [redacted] 1988; TOX1999-406). The blood radioactivity level decreased slowly over the experimental period of 168 h.

The radioactivity was mainly associated with red blood cells as radioactivity in plasma was much lower. Similar binding phenomenon was not observed in human blood as can be explained that the haemoglobin are different between rat and human. In general, tissue radioactivity levels were comparable in both sexes, showing a similar pattern of absorption, distribution and elimination. Radioactivity levels in kidney and liver were higher than in brain and heart. Residue levels decreased steadily over time with the exception of blood. Overall, tissue levels were small by 168 h after treatment. For the low dose treated rats, the concentration was less than 0.5 mg/kg in all organs and tissues.
It appeared that there was no significant difference in absorption, distribution, and elimination for dimethenamid between sexes. There was only a slight difference in elimination rate between single and multiple doses. Residue levels in tissues were similar for single dose and multiple dose groups. These data showed that dimethenamid and its metabolites had no tendency for bioaccumulation in animal systems.

Table 2.6-3: Excretion of total radioactivity following administration of ^{14}C-dimethenamid

Exp. No		Route	Dose level	% of administered dose at 168 h after treatment				
				Urine	Faeces	Bile	Carcass	Total
1	Male	p.o.	10 mg/kg	35.3	57.7	n.r.	6.7	99.7
	Female	p.o.	10 mg/kg	46.9	47.6	n.r.	8.0	102.5
2	Male	i.v.	10 mg/kg	31.2	56.4	n.r.	11.1	98.7
	Female	i.v.	10 mg/kg	49.4	36.6	n.r.	9.9	95.9
3	Male	p.o.	1,000 mg/kg	61.6	30.1	n.r.	3.4	95.1
	Female	p.o.	1,000 mg/kg	63.1	26.1	n.r.	3.7	92.9
4*	Male	Multiple p.o.	10 mg/kg	34.9	61.6	n.r.	4.4	100.9
	Female	Multiple p.o.	10 mg/kg	53.3	39.9	n.r.	3.6	96.8
5**	Male	p.o.	10 mg/kg	7.6	2.2	82.2	4.7	96.7
	Female	p.o.	10 mg/kg	12.4	3.7	75.1	5.3	96.5

* Rats received 10 mg/kg/day of unlabelled dimethenamid for 14 days, then received a ^{14}C dose at 10 mg/kg.
** Bile duct cannulated.
n.r. Not reported

Dimethenamid was well absorbed (>90 %), then rapidly and extensively metabolised in the rat. Only 1 - 2 % of unchanged dimethenamid was detected in excreta. Excretion was rapid primarily by bile. About 40 metabolites (20 identified) were found in organic extracts which were analysed by TLC. Metabolism occurred primarily via the glutathione conjugation pathways. Dimethenamid was rapidly conjugated with glutathione and then through several steps to form cysteine conjugate (M25) and mercapturate (M17). M25 was further oxidised to form additional metabolites (M1, M2, M10, M13, M14, M16, M18, M19, M21, M22, M26, M27, M30, and M31). Although the glutathione adduct was not found in the rat study, it was identified in the *in vitro* study. Other metabolites qualitatively identified in the *in vitro* study included the cysteine conjugate (M25), the mercapturate (M17), the sulfonate (M27), the sulfoxide of thiolactic acid (M30), the sulfoxide of thioglycolic acid (M31), and the thioglycolic acid (M32).
Dimethenamid was also metabolised via reductive dechlorination (M3), oxidation (M4, M23), hydroxylation (M5, M11, M15), O-demethylation (M7, M12) and cyclisation (M6, M8, M9, M15, M20).

Absorption, distribution, metabolism and excretion in mice

A metabolism study was conducted in mice using [3-thienyl-^{14}C] dimethenamid ([redacted], 1992; TOX1999-407; TOX1999-408). The study was conducted in 2 groups and each group (A

and B) consisted of 5 males and 5 females mice. Groups A and B were administered a single oral dose at 1 and 100 mg/kg bw, respectively. Urine and faeces samples were separately collected daily for 4 days and the animals were sacrificed at 96 h after dose administration.
A summary of radiocarbon in urine and faeces is presented in Table 2.6-4 ([redacted] 1992; TOX1999-407). Dimethenamid was rapidly metabolised and excreted in urine and faeces. The profile in mice was similar to the profile in rats.

Table 2.6-4: Summary of ^{14}C-dimethenamid material balance for dose groups A (1 mg/kg) and B (100 mg/kg) in mice administered orally

Dose group	Dose level	Sample	% of administered dose at 96 h after treatment*	
			Male	Female
A	1 mg/kg	Urine	43.99	46.25
		Faeces	47.26	42.12
		Cage wash	1.68	2.92
		Total	92.93	91.29
B	100 mg/kg	Urine	59.60	59.89
		Faeces	33.64	28.30
		Cage wash	0.99	0.62
		Total	94.23	88.81

* Data are the average of 5 animals per group and sex, except group B with 4 animals. Animals were sacrificed 96 h after ^{14}C-dimethenamid administration.

Table 2.6-5: Percentage of sulfonate in urine and faeces for groups A (1 mg/kg) and B (100 mg/kg) mice administered with ^{14}C-dimethenamid orally

Dose group	Urine	Faeces	Total
	% of sulfonate in urine and faeces		
A	0.060	0.25	0.31
B	0.069	0.25	0.319
	% of sulfoxide of thioglycolic acid in urine and faeces		
A	0.25	0.25	0.50
B	0.24	0.40	0.64

Dimethenamid was extensively metabolised and readily excreted by mice. Urinary radiocarbon accounted for approximately 44 % to 60 % while faeces accounted for approximately 28 % to 47 %. Total recovery varied from 88.81 to 94.23 %. Sulfonate was found to be 0.06 % (group A) and 0.069 % (group B) in urine and 0.25 % (both groups) in faeces. Sulfoxide of thioglycolic acid in urine accounted for 0.25 % (both groups). In faeces, this metabolite accounted for 0.25 % in group A and 0.40 % in group B.
The peer reviewed studies above were performed with racemic dimethenamid and metabolite identification was not performed using recent techniques. To augment these studies, a new rat metabolism study submitted for the Renewal Process was performed using dimethenamid-P and using state of the art identification ([redacted] 2014a; ASB2014-8383; [redacted] 2012a; ASB2014-8384). The study results of the new study confirm the absorption, distribution, metabolism and excretion of dimethenamid-P but there were some slight differences in metabolite identification. Therefore, the 2012 study expands upon the older studies for metabolite identification.
The following new studies with dimethenamid-P submitted within the Renewal Process are briefly summarised below:

Table 2.6-6: Overview of studies submitted with the dossier for the Renewal Assessment Report

Title	Reference
Excretion and metabolism of ^{14}C -dimethenamid-P (BAS 656 H) after oral administration in rats	[redacted] 2014; 2012/1194996#[3] (ASB2014-8383)
^{14}C -BAS 656 H - Study on bile excretion in rats	[redacted] 2012; 2012/1021081#[3] (ASB2014-8384)
Comparison of *in vitro* metabolism of enantiomers of BAS 656 H (dimethenamid)	[redacted] 2002/1004042#[3] (ASB2014-8385)
Comparative *in-vitro* metabolism with ^{14}C -BAS 656-PH	[redacted] 2014; 2013/1337274#[3] (ASB2014-8386)

\# Submitted with the dossier for the Renewal Assessment Report
[3] The study has been evaluated as acceptable in the Renewal Assessment Report.

The new rat metabolism study submitted within the Renewal Process was conducted with the isomer dimethenamid-P to further elucidate the detailed metabolism and excretion in male and female rats after oral administration ([redacted] 2014a; ASB2014-8383; [redacted] 2012a; ASB2014-8384).
In the new rat metabolism study the treated rats received an oral single dose (10 rats/sex, 250 mg/kg bw) and for bile excretion two oral single doses (10 mg/kg bw and 250 mg/kg bw male animals). All animals received the oral dose administered via gavage.
The bile excretion study showed high absorption of dimethenamid-P after single oral administration of the test item to male, bile catheterised rats. Absorption was slightly higher after administration of the low dose (approximately 94 % of the administered dose in the case of dose group RM (10 mg/kg bw)) compared to the high dose (approximately 85 % dose in the case of the high dose group SM (250 mg/kg bw)).
In the cases of the high dose groups (DXM, male, 250 mg/kg bw) and (DXF, female, 250 mg/kg bw) similar portions were eliminated via urine and faeces. Excretion via urine was nearly complete after 120 h after dosing, and excretion via faeces was nearly complete within 72 to 96 h after dosing.

Table 2.6-7: Route of excretion and total recovery of dimethenamid-P in rat (percent of radioactive dose)

Group	Target dose [mg/kg bw]	Route of administration	Sex of animal*	Urine [%]	Faeces [%]	Total [%]
Treated	250	Single oral	M	40.89	46.41	89.35
			F	54.87	32.20	89.44

Table 2.6-8: Route of excretion via bile and total recovery of dimethenamid-P in rat (percent of radioactive dose)

Group	Target dose [mg/kg bw]	Route of administration	Sex of animal	Bile [%]
Treated	10	Single oral	M*	79.62
	250		F1	21.61
			F2	56.84
			F3	72.57

* Mean of three animals

In the cases of the bile excretion dose groups RM (10 mg/kg bw) and SM (250 mg/kg bw), mean excretion of radioactive residues via bile within 72 h was 79.62 % and 50.34 % dose for the dose levels of 10 and 250 mg/kg bw, respectively. Biliary excretion was almost complete after 9 to 12 h in the case of the low dose group RM (10 mg/kg bw) or after 24 to 30 h in the case of the high dose group SM (250 mg/kg bw).
Dimethenamid-P was extensively metabolised in the rat. The main biotransformation steps of dimethenamid-P in rats are:

- Conjugation with glutathione and enzymatic cleavage of the tripeptide to the cysteine conjugate
- N-acetylation of the cysteine moiety
- Hydrolysis of S-conjugates to the mercaptan (followed by S-methylation)
- Oxidation of the sulphur atom to form sulphoxides and sulphones
- O-demethylation
- Hydroxylation
- Conjugation with glucuronic acid
- Replacement of the chlorine atom by hydrogen (reduction) or by a hydroxyl group (hydrolysis)
- Dimerisation of a mercaptan

In vitro incubations of racemic and dimethenamid-P in rat liver slices showed that the metabolism of the racemate and the S-isomer of dimethenamid is qualitatively and quantitatively comparable ([redacted] 2002a; ASB2014-8385).
A comparative *in-vitro* metabolism study shows that ^{14}C-dimethenamid-P is extensively metabolised by hepatocytes from dogs, rats and humans under the investigated conditions. All metabolites detected after incubation with human hepatocytes were also present in animal hepatocyte samples, except for the metabolite M656PH007 which has already been described in the *in-vivo* rat metabolism study with dimethenamid-P ([redacted] 2014b; ASB2014-8386).
No relevant differences between the absorption, distribution, excretion and metabolism in mammals of racemic dimethenamid and dimethenamid-P have been found in the submitted studies.
The new rat metabolism study (ASB2014-8383; ASB2014-8384) further supported the older metabolism studies for absorption, metabolism, distribution and excretion but also allowed for state of the art metabolite identification. No difference in metabolism between the older studies and the new study was observed except for the identification of additional metabolites.

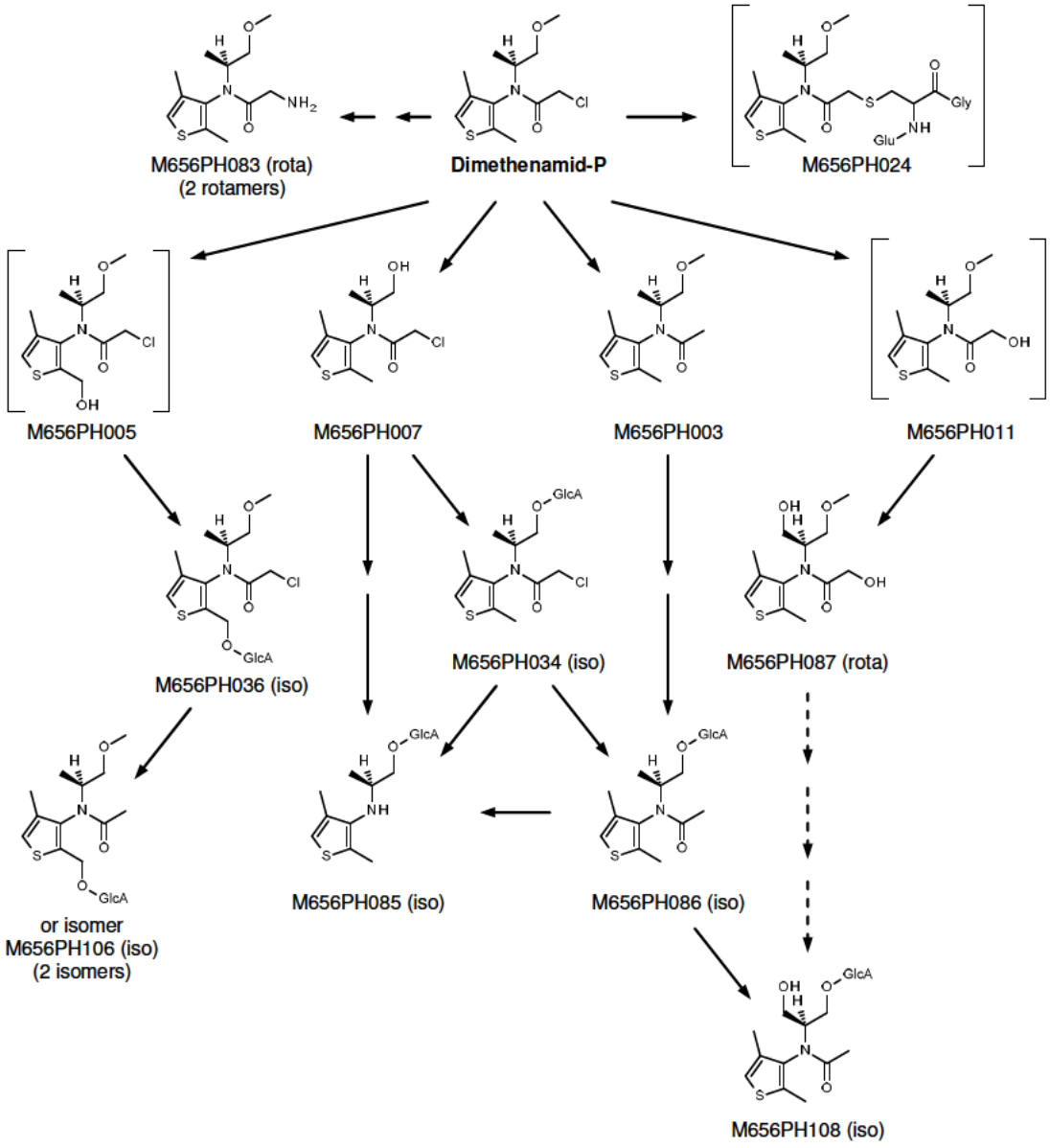


Figure 2.6-1: Proposed metabolic pathway of dimethenamid-P in rats (part 1)

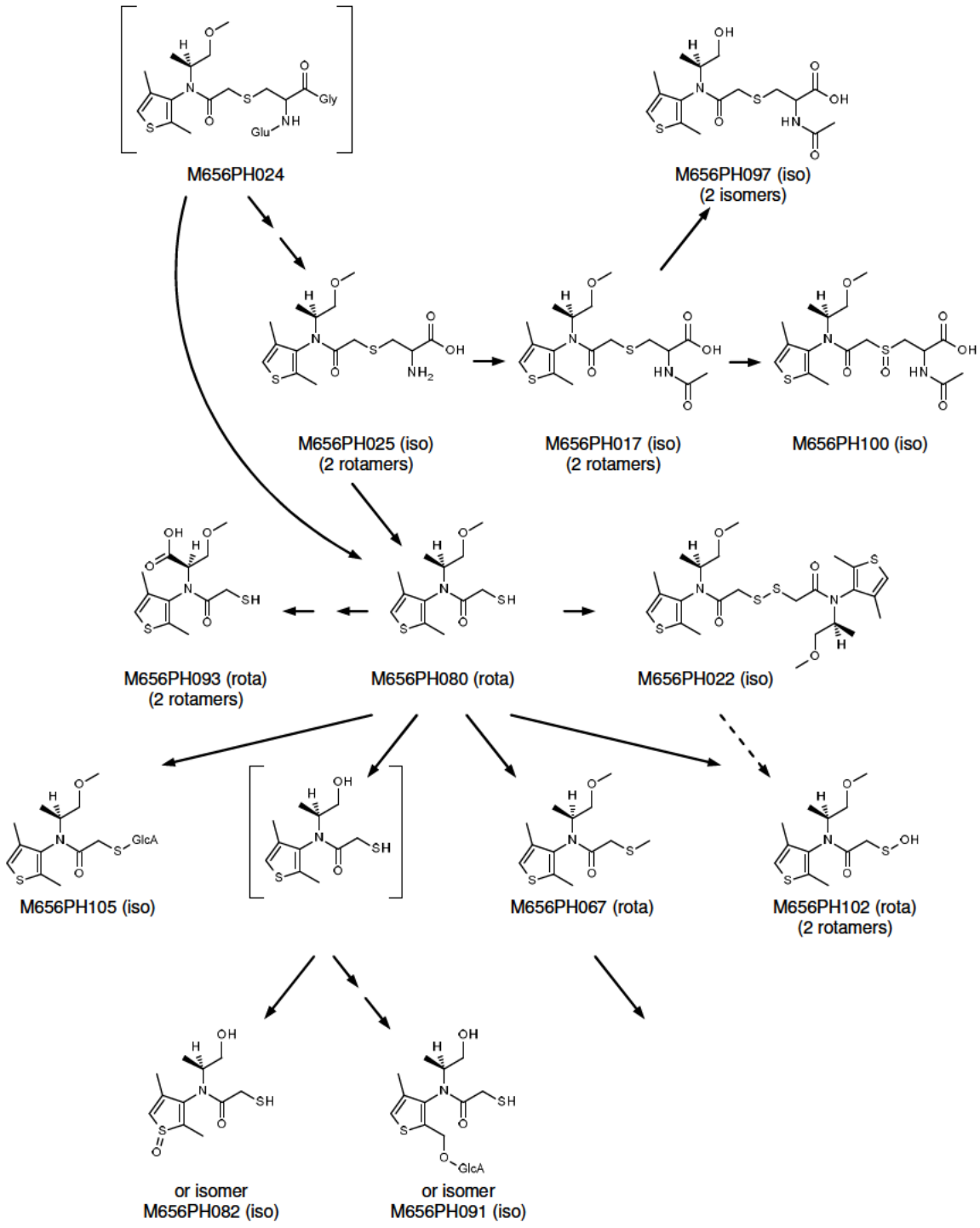


Figure 2.6-2: **Proposed metabolic pathway of dimethenamid-P (BAS 656 H) in rats (Part 2: derivatives after conjugation with glutathione)**

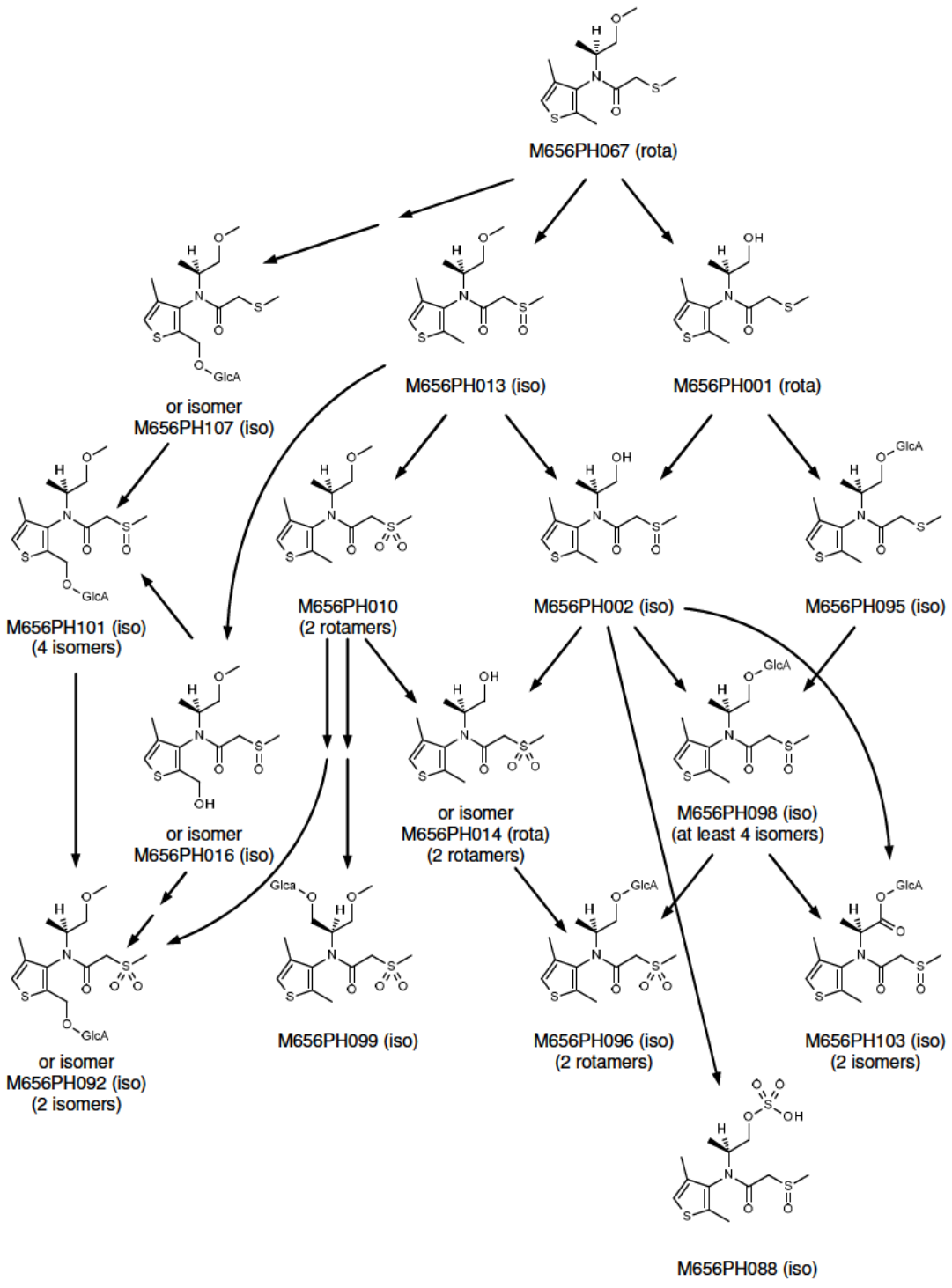


Figure 2.6-3: **Proposed metabolic pathway of dimethenamid-P (BAS 656 H) in rats (Part 3: Derivatives of the S-methyl metabolite M656PH067 (rota))**

2.6.2 Summary of acute toxicity

The chiral biologically active dimethenamid-P and the racemic dimethenamid have been tested in various species and via different routes of administration. Most studies are scientifically valid; however, partially the studies have been conducted before the release of study guidelines and are without GLP according to the usual practice in those days. These studies have been evaluated by European authorities and Germany as Rapporteur Member State (RMS) in the European Commission Peer Review Program. These toxicological studies were now re-evaluated by the RMS and are listed in Table 2.6-9.

Table 2.6-9: Summary of acute toxicity studies with dimethenamid and dimethenamid-P as available in the original monograph of dimethenamid-P

Study	Test substance/ Species/Sex	Dose range	Result	Reference
Acute toxicity Oral	Dimethenamid-P: Rat, Sprague-Dawley, m/f	350, 400 or 500 mg/kg bw	LD_{50}.(m): 429 mg/kg bw LD_{50} (f): 531 mg/kg bw	[redacted] 1996/11087*[1,3] TOX1999-413
	Racemic dimethenamid: Rat, Sprague-Dawley, m/f	150, 300 or 600 mg/kg bw	LD_{50}.(m): 371 mg/kg bw LD_{50} (f): 427 mg/kg bw	[redacted] 1991/11940*[1,3] TOX1999-451
Acute Toxicity Dermal	Dimethenamid-P: Rabbit, New Zealand White, m/f	2000 mg/kg bw	LD_{50} (m+f): >2,000 mg/kg bw	[redacted] 1996/5395*[1,3] TOX1999-414
	Racemic dimethenamid: Rabbit, New Zealand White, m/f	2000 mg/kg bw	LD_{50} (m+f): >2,000 mg/kg bw	[redacted] 91/11942*[1] TOX1999-452
Acute Toxicity Inhalation, 4 h nose-only	Dimethenamid-P: Rat, Sprague Dawley, m/f	2.2 mg/L (4 h)	LC_{50} (m+f): >2.2 mg/L	[redacted] 1996/5397*[1,3] TOX1999-415
	Racemic dimethenamid: Rat, Wistar m/f	4.99 mg/L	LC_{50} (m+f): >4.99 mg/L	[redacted] 1986/11166*[1,3] TOX1999-453
Skin irritation	Dimethenamid-P: Rabbit, New Zealand White	0.5 mL/animal	Not irritating	[redacted] 1996/5406 *[1 3] TOX1999-416
	Racemic dimethenamid: Rabbit, New Zealand White	0.5 mL/animal	Not irritating	[redacted] 1988/11363*[1,3] TOX1999-454
Eye irritation	Dimethenamid-P: Rabbit, New Zealand White	0.1 mL/animal	Not irritating	[redacted] 1996/5396*[1,3] TOX1999-417
	Racemic dimethenamid: Rabbit, New Zealand White	0.1 mL/animal	Not irritating	[redacted] 1988/11364*[1,3] TOX1999-455
Skin sensitisation	Dimethenamid-P: Buehler test Guinea pig, Dunkin Hartley	Induction and challenge with undiluted material	Sensitising	[redacted] 1996/11088*[1,3] TOX1999-418
	Racemic dimethenamid: Magnusson-Kligman test Guinea pig, Ibm: GOHI (Himalayan spotted)	Intracutaneous injections: 5 %	Sensitising	[redacted] 95/11324*[1,3] TOX2000-1560

Toxicological studies that are considered as not acceptable after re-evaluation by the RMS are not included in this table.

* Evaluated in the original monograph of dimethenamid-P by the RMS in September, 2000 (ASB2010-10566).

[1] The study has been evaluated as acceptable in the original monograph of dimethenamid-P by the RMS in September, 2000 (ASB2010-10566) or in Addendum 1 to the original monograph of the RMS Germany of July 03, 2001 (ASB2015-1648).

[2] The study has been evaluated as supplementary in the original monograph of dimethenamid-p by the RMS in September, 2000 (ASB2010-10566) or in the addendum 1 to the original monograph of rapporteur member state Germany of July 03, 2001 (ASB2015-1648).
[3] The study has been evaluated as acceptable in the Renewal Assessment Report.

Dimethenamid-P and racemic dimethenamid have a moderate acute toxicity after single oral application and show low toxicity after single dermal and inhalative exposure. The following clinical symptoms of acute dimethenamid-P intoxication in laboratory animals were observed after oral intake: decreased activity, lacrimation, excessive salivation, yellow ano-genital staining, black and/or brown staining on the snout, oral area, buccal area and/or extremities, lethargy, decreased food consumption and decreased faecal volume (TOX1999-413; TOX1999-451).
No mortality was observed after 4-h inhalative (nose-only) exposure of rats to a dimethenamid-P aerosol at a concentration of 2.2 mg/L air (TOX1999-415) or to an aerosol of racemic dimethenamid at a concentration of 4.99 mg/L air (TOX1999-453). In the study with dimethenamid-P clinical signs could be observed for up to 2 days in some animals including secretory (lacrimation, chromodacryorrhea, red and clear nasal discharge and dried red facial material) and respiratory (laboured breathing and moist rales) responses (TOX1999-415).
In the absence of irritation effects on rabbit skin, eyes and mucous membranes, dimethenamid-P proved to be a skin sensitiser in the Buehler test [redacted]., 1996; TOX1999-418). The result of a Magnusson and Kligman test with racemic dimethenamid was equivocal ([redacted] 1987; TOX1999-456). Due to deviations from the OECD Guideline No. 406 the study is considered to be unreliable and therefore not acceptable for the evaluation of skin sensitisation [redacted], 1987; TOX1999-456). A second Magnusson and Kligman test with racemic dimethenamid was negative [redacted] 1995; TOX2000-1560).
No relevant differences between the acute toxicity of racemic dimethenamid and dimethenamid-P have been found in the submitted studies.
A new acute inhalation study according to current criteria has been performed with dimethenamid-P for global registration (ASB2014-8387) as the former study was considered to have some limitations with regard to study design (TOX1999-415). This study is submitted within the Renewal Process. In accordance with the data requirements of Commission Regulation SANCO/11802/2010 an *in vitro* NRU-Phototoxicity study in Balb/c 3T3 cells has been performed (ASB2014-8388) and is given in detail in Vol. 3 section B.6.2. According to this study dimethenamid-P does not have a phototoxic potential.
New data available is tabulated in Table 2.6-10.

Table 2.6-10: Summary of newly available acute toxicity studies with dimethenamid-P

Type of study	Test substance	Result classification	Reference
Inhalation route - rat	Dimethenamid-P	LC_{50} (m+f) > 5.16 mg/L EU classification not required GHS classification not required	[redacted]., 2012a; 2011/1171036#[1] ASB2014-8387
In vitro NRU-Phototoxicity study in Balb/c 3T3 cells	Dimethenamid-P	Not phototoxic	[redacted] 2013/1110119#[1] ASB2014-8388

Submitted with the dossier for the Renewal Assessment Report
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Dimethenamid-P has moderate acute toxicity by the oral route and a low acute toxicity by the percutaneous, and inhalation routes of administration. Dimethenamid-P produces only slight reversible skin and eye irritation not requiring classification according to EU legislation. Dimethenamid-P is a skin sensitiser.

Therefore, a classification with *R22* and *R43* according to EU Dir. 67/548/EEC and *Acut. Tox. oral Cat. 4* and *Skin Sens. 1* according to CLP Reg. EC 1272/2008 classification criteria is warranted.

The ECHA risk assessment committee on classification and labelling has evaluated the data and concluded that classification for *Acute toxicity Category 4, H302* and *skin sensitisation Skin Sens. 1, H317* is warranted (see Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; CLH-O-0000003037-80-03/F; ASB2015-2797).
The newly available acute toxicity studies with dimethenamid-P of [redacted] 2012 (ASB2014-8387) and [redacted], 2013 (ASB2014-8388) have not been submitted to the ECHA risk assessment committee on classification and labelling. The results of these new studies would not change the classification and labelling of dimethenamid-P.

2.6.3 Summary of short-term toxicity

Short-term toxicity studies (28 - 90 days) with oral administration are available from three different species (rats, mice, dogs) for racemic dimethenamid. In addition a 1-year dog study is available for racemic dimethenamid. Furthermore 28 - 90 day studies in rat are available for dimethenamid-P. Short-term toxicity following dermal exposure was determined in a 21-day study in rabbits conducted with racemic dimethenamid. These studies have been evaluated by European authorities and Germany as Rapporteur member state (RMS) in the European Commission Peer Review Program and are now re-evaluated by the RMS (see Table 2.6-11).
After oral treatment, the signs of toxicity observed in rats, mice and dogs were overall similar with the liver as the target organ. The effects observed typically included the increase in one or more serum liver enzymes and changes in cholesterol levels. Increased liver weights were observed in all three species. Histologically, hepatocyte hypertrophy was observed in rats and hepatocyte vacuolation and dilatation of liver sinusoids occurred in dogs.
Feeding of racemic dimethenamid to dogs for 1 year resulted in decreased body weight gain and changes indicative of liver alteration at the high dose. Liver changes included increased alkaline phosphatase and cholesterol, increased liver weight and hepatocyte enlargement and vacuolation (TOX1999-433). The NOAEL was based on AP, cholesterol increase and body weight decrease in one animal at 250 ppm. Further details are reported in Vol. 3 (B.6.3).
In a 3-week dermal toxicity study in rabbits no substance related systemic findings were detected up to the highest dose level tested (1190 mg/kg bw/day) (TOX1999-420).
In order to assess the validity of the “bridging concept”, the toxicological effects observed in the 90-day oral studies conducted with either dimethenamid-P or racemic dimethenamid revealed only marginal differences between the two studies (TOX1999-421; TOX1999-467; TOX1999-457; TOX1999-467). The NOAELs and LOAELs were the same irrespective of the test substance administered. Therefore, on the basis of the available data at the time of Annex I inclusion of dimethenamid-P, the requirements were considered to have been met for a scientifically based justification of the “bridging concept” for dimethenamid-P/racemic dimethenamid.

Table 2.6-11: Summary of short-term toxicity studies conducted with dimethenamid-P and racemic dimethenamid

Study	Dosages (mg/kg bw/ day)	NOAEL (mg/kg bw/day)	Main adverse effect	Reference
Dimethenamid-P 4-week, diet, range-finder, Sprague-Dawley rat (constant diet concentrations: 0, "150", 500, 1500 and 3000 ppm)	M: 12, 50, 155 and 306 F: 12, 52, 143 and 290	Not established due to limited investigations performed	≥ 500 ppm: ↑ liver wt 3000 ppm: ↓ bw and bw gain No histopathology performed	[redacted]., 1996/11147*[1,4] TOX1999-419
Racemic dimethenamid 5-week, diet, range-finder, Wistar rat (constant diet concentrations: 0, 30, 100, 300, 1000 and 3000 ppm)	M: 2.92, 9.5, 28.8, 95.6 and 285 F: 3.32, 10.8, 35.7, 109 and 328	29 (300 ppm)	300 ppm: ↑ cholesterol, slight (m); not considered to represent an adverse effect ≥ 1000 ppm: ↑ liver wt, ↑ cholesterol, moderate (m) 3000 ppm: ↓ bw, bw gain and food intake, ↑ cholesterol (m+f), ↑ GGT, slight hepatocell. cytoplasmic swelling	[redacted] 1987/11227*[1,3] TOX1999-468
Dimethenamid-P 13-week, diet, Sprague-Dawley rat (constant diet 0, 500, 1500 and 3000 ppm)	M: 37, 110 and 222 F. 40, 125 and 256	37 (500 ppm)	≥ 1500 ppm: ↓ bw and bw gain, ↑ GGT (m); ↑ liver wt, hepatocellular hypertrophy (m+f). 3000 ppm: ↑ cholesterol (m+f)	[redacted] 1996/5420*[1,3] TOX1999-421 [redacted] 1999/10270*[1,3] TOX1999-467
Racemic dimethenamid 13-week + 4- week recovery , diet, Sprague-Dawley rat (constant diet 0, 50, 150, 500, 1500 and 3000 ppm)	M: 3.5, 10, 34, 98 and 204 F. 3.9, 11.8, 40,1, 119 and 238	34 (500 ppm)	≥ 1500 ppm: ↓ bw and bw gain, ↓ feed intake; ↑ protein, ↑ cholesterol (f) ↑ liver wt (f); ↑ hepatocell. hypertrophy (f) 3000 ppm: ↑ GGT (m), cholesterol (m+f); ↑ liver wt (m)	[redacted] 1987 1986/11183*[1,3] TOX1999-457 1995/11323 [redacted] 1999/10270*[1,3] TOX1999-467
Racemic dimethenamid 13-week, diet, CD-1 mice (constant diet concentrations: 0, 300, 700, 2000, 5000 ppm)	M: 46, 105, 301 and 805 F: 60, 137, 383 and 972	Not established due to limited investigations performed	≥700 ppm: ↑ liver wt ≥ 2000 ppm: subdued behaviour; ↑ rel. kidney wt; 5000 ppm: ↓ bw gain and food intake no ophthalmology, haematological or clinical chemistry investigations performd; histopathological assessment confined to liver and kidney	[redacted] 1988/11360*[1,4] TOX1999-422
Racemic dimethenamid 13-week, diet, Beagle dog (constant diet concentration 9, 91.5, 750, 2000 ppm)	M: 4.3, 34 and 90 F: 4.6, 40 and 87	4.3 (91.5 ppm)	≥ 750 ppm: ↓ bw gain; ↑ liver wt; hepatocyte periportal vacuolation and dilatation of liver sinusoids 2000 ppm: ↑ AP and cholesterol	[redacted] 1986/11159*[1,3] TOX1999-423 [redacted]

Study	Dosages (mg/kg bw/ day)	NOAEL (mg/kg bw/day)	Main adverse effect	Reference
				[redacted]., 1986/11178*[1,3] TOX1999-424
Racemic dimethenamid 52-week, diet, Beagle dog (constant diet concentration 0, 50, 250, 1500 ppm)	2, 10, 49	2 (50 ppm)	250 ppm: bw gain ↓, AP ↑, cholesterol ↑ 1500 ppm: bw gain ↓, AP ↑, cholesterol ↑, liver weight ↑, hepatocyte enlargement, hepatocyte vacuolation	[redacted] 1988/11361 1988/11362 (TOX1999-433)
Racemic dimethenamid 3-week, dermal, New Zealand White rabbit (6 h/day/5 days a week) Limit-test 1000 µL/kg	0, 1190	Systemic NOAEL: 1190	Dermal irritation, No systemic findings	[redacted] 1990/11142*[1,3] TOX1999-420

Toxicological studies that are considered as not acceptable after reevaluation by the RMS are not included in this table.

* Evaluated for Annex I inclusion of dimethenamid-p

[1] The study has been evaluated as acceptable in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2015-1648)

[3] The study has been evaluated as acceptable in the Renewal Assessment Report.

[4] The study has been evaluated as supplementary in the Renewal Assessment Report.

The only new studies to consider whether they could affect the short-term relevant NOAEL/NOEL would be the 90-day neurotoxicity study in rats (see Vol. 3) and the 28-day immunotoxicity study in mice (see Vol. 3). However the determined study NOAELs were clearly above the derived lowest relevant oral NOAEL of the 90-day dog study and no additional targets/critical effects were determined.
The ECHA risk assessment committee on classification and labelling has evaluated the data and concluded that no classification for systemic toxicity is warranted (see Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; CLH-O-0000003037-80-03/F; ASB2015-2797).

2.6.4 Summary of genotoxicity

An extended data package of *in vitro* genotoxicity studies in bacterial and mammalian cell systems and of *in vivo* genotoxicity studies conducted with racemic dimethenamid and dimethenamid-P is available in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) and in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2015-1648). These studies have been evaluated by European authorities and Germany as Rapporteur Member State (RMS) in the European Commission Peer Review Program and are now re-evaluated by the RMS.
The different types of mutagenicity assays and the test results obtained in the various genotoxicity endpoints are presented in tabular form in Table 2.6-12 and Table 2.6-13.

Dimethenamid-P:
Dimethenamid-P was evaluated for its potential genotoxicity *in vitro* using bacterial and mammalian cell mutagenicity tests, a chromosome damage (clastogenicity) test and an unscheduled DNA synthesis test. The mutagenicity tests were negative, with the exception of a single positive result obtained in the Ames Test with *S.typhimurium* strain TA-100 in the absence of an exogenous metabolic activation system (TOX1999-425). This result could not be reproduced in several repeat assays. The *in vitro* chromosome aberration study gave equivocal test results both in the presence and absence of an exogenous metabolic activation system (TOX1999-430). However, the result of the corresponding *in vivo* assay for chromosomal aberration, *i.e.* the mouse micronucleus test, gave a

clearly negative result (TOX1999-432; ASB2014-8390), indicating that dimethenamid-P has no chromosome damaging potential. The results of the toxicokinetic studies (see Vol. 3, section B.6.4) confirmed that the test compound reached the bone marrow after oral treatment.

Racemic dimethenamid:
In addition to the studies mentioned above, additional genotoxicity studies conducted with racemic dimethenamid were submitted for comparative evaluation. The test results obtained in bacterial and mammalian mutagenicity testing were negative. An *in vitro* chromosome aberration assay with racemic dimethenamid was submitted but not performed according to currently accepted guidelines (TOX1999-430). Three *in vitro* assays for unscheduled DNA synthesis conducted with racemic dimethenamid were submitted. One study gave a positive test result (TOX1999-463); the other two tests gave inconclusive results due to poor experimental design or reporting (TOX1999-464; TOX1999-462). An *in vivo* UDS assay with rats (TOX2001-472) and *in vivo* micronucleus tests with mice gave negative results (TOX1999-465; TOX1999-466).

Overall, the results do not indicate that dimethenamid-P possesses a genotoxic potential. The database has been extended with an *in vitro* mouse lymphoma assay (ASB2014-8389) to fulfil the new data requirement and with an *in vivo* micronucleus test in mice (ASB2014-8390). Both studies did not provide any evidence for genotoxicity of dimethenamid-P and thus clearly support the weight of evidence approach that dimethenamid-P is not genotoxic. A summary of the *in vitro* genotoxicity studies evaluated for Annex I inclusion of dimethenamid-P and submitted within the Renewal Process for the Renewal Assessment Report is summarised in Table 2.6-12 below.

Table 2.6-12: Summary of genotoxicity studies *in vitro* conducted with dimethenamid-P and racemic dimethenamid

Study type	Test System	Test material / Purity	With S-9 mix	Result	Reference
In vitro mutagenicity in bacterial cells (Ames test)	*Salmonella thyphimurium* (TA 1535, 100, 1537, 98); *Escherichia coli* (WP2 uvrA)	Dimethenamid-P /93.3 % (total dimethenamid), 91.1 % (S-isomer)	No Yes	Positive with TA 100 Negative all strains	Wagner V.O. and Coffman N., 1996/5403*[1,3] TOX1999-425
	Salmonella thyphimurium (TA 1535, 100, 1537, 98); *Escherichia coli* (WP2 uvrA)	Dimethenamid-P /91.1 %	No Yes	Negative Negative	Engelhardt G., Hoffmann H., 1997/10622*[1,3] TOX1999-426
	Salmonella thyphimurium (TA 1535, 100, 1537, 98); *Escherichia coli* (WP2 uvrA)	Dimethenamid-P /99.4 %	No Yes	Negative Negative	Engelhardt G. and Hoffman H., 1997/10621*[1,3] TOX1999-427
	Salmonella thyphimurium (TA 100)	Dimethenamid-P /91.1 %	No	Negative	Wagner V.O. and Klug M.L., 1997/5271*[2,4] TOX1999-428
	Salmonella thyphimurium (TA 1535, 1537, 1538, 98, 100)	Racemic dimethenamid (91.4 %)	No Yes	Negative Negative	Haworth L. and Lawlor T.E., 1989/11032*[1,3] TOX1999-459
In vitro mutagenicity in mammalian cells	CHO/HGPRT	Dimethenamid-P /96.3 % (total dimethenamid technical); 91.1 % (S-dimethenamid)	No Yes	Negative Negative	[redacted]., 1996/5404*[1,4] TOX1999-429
	V79/HGPRT	Racemic dimethenamid /92 %	No Yes	Negative Negative	[redacted] 1986/11167*[1,3] TOX1999-460
	Forward mutations in L5178Y mouse lymphoma cells (TK +/- locus assay)	Dimethenamid-P (BAS 656-PH) /95.9 %	No Yes	Negative Negative	[redacted] 2013/1003738 #[3] ASB2014-8389

Study type	Test System	Test material / Purity	With S-9 mix	Result	Reference
In vitro DNA damage and repair	UDS, rat primary hepatocytes	Dimethenamid-P /96.3 % (total dimethenamid technical); 91.1 % (S-dimethenamid)	No	Negative	[redacted] 1996/5399*[1,4] TOX1999-431
	UDS, rat primary hepatocytes	Racemic dimethenamid /91.4 %	No	Positive	[redacted] 1989/11033*[1,3] TOX1999-463

Toxicological studies that are considered as not acceptable after re-evaluation by the RMS are not included in this table.
* Evaluated for Annex I inclusion of dimethenamid-P
\# Submitted within the Renewal Process for the Renewal Assessment Report
1 The study has been evaluated as acceptable in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2010-10566).
2 The study has been evaluated as supplementary in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2010-10566).
3 The study has been evaluated as acceptable in the Renewal Assessment Report.
4 The study has been evaluated as supplementary in the Renewal Assessment Report.

A summary of the *in vivo* genotoxicity studies evaluated for Annex I inclusion of dimethenamid-P and submitted within the Renewal Process for the Renewal Assessment Report is summarised in Table 2.6-13 below.

Table 2.6-13: Summary of genotoxicity studies *in vivo* conducted with dimethenamid-P and racemic dimethenamid

Study type	Test System	Test material / Purity	Result	Reference
In vivo Clastogenicity	Mouse Micronucleus test (103-205-410 mg/kg bw (i.p. injection)	Dimethenamid-P/96.3 % (total dimethenamid technical); 91.1 % (S-dimethenamid)	Negative	[redacted] 1996/5401*[1,4] TOX1999-432
	Mouse micronucleus test (1000 mg/kg bw, oral gavage)	Racemic dimethenamid/ not specified	Negative	[redacted] 1986/11168*[2,4] TOX1999-465
	Mouse micronucleus test (125-250-500 mg/kg bw/d, 2 day, oral)	Dimethenamid-P/97.6 %	Negative	[redacted] 2014/1038343#[3] ASB2014-8390
	In vivo UDS, rat primary hepatocytes (500 and 158 mg/kg bw, oral gavage)	Racemic dimethenamid/ 97.6 %	Negative	[redacted] 1993/11757*[1,3] TOX2001-472

Toxicological studies that have been considered as not acceptable after re-evaluation by the RMS are not included in this table.
* Evaluated for Annex I inclusion of dimethenamid-P
\# Submitted within the Renewal Process for the Renewal Assessment Report
1 The study has been evaluated as acceptable in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2010-10566).
2 The study has been evaluated as supplementary in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2010-10566).
3 The study has been evaluated as acceptable in the Renewal Assessment Report.
4 The study has been evaluated as supplementary in the Renewal Assessment Report.

According to Part A, Section 5 of Commission Regulation (EU) No 283/2013 of 1 March 2013 special testing requirements in relation to photomutagenicity may be indicated by the structure of a molecule. If the ultraviolet/visible molar extinction/absorption coefficient of the active substance and its major metabolites is less than 1,000 $L \times mol^{-1} \times cm^{-1}$, photomutagenicity testing is not required. No data

have been submitted to decide if special testing requirements in relation to photomutagenicity may be indicated for dimethenamid-P.
The ECHA risk assessment committee on classification and labelling has evaluated the data and concluded that no classification for mutagenicity is warranted (see Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; CLH-O-0000003037-80-03/F; ASB2015-2797). The newly available studies, the *in vitro* mouse lymphoma assay (ASB2014-8389) and the *in vivo* micronucleus test in mice (ASB2014-8390), have not been submitted to the ECHA risk assessment committee on classification and labelling. The results of these studies would not change the classification and labelling of dimethenamid-P.

2.6.5 Summary of long-term toxicity and carcinogenicity

Chronic toxicity and oncogenicity studies were only conducted with racemic dimethenamid. Long-term toxicity feeding studies (94 - 104 weeks) are available from two different species (rat, mice) for racemic dimethenamid. These studies were already evaluated in the initial review programme.

Table 2.6-14: Summary of long-term toxicity/carcinogenicity studies conducted with and racemic dimethenamid

Study	Dosages (mg/kg bw/day)	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Main adverse effect	Reference and year
Racemic dimethenamid 104-week, diet, Sprague-Dawley rat (diet concentrations: 0, 100, 700 and 1500 ppm)	M: 5, 36 and 80 F: 7, 49 and 109	5	36	Systemic toxicity: 1500 ppm: ↓ food consumption and ↓ bw gain, lenticular opacities; ↑ serum γ-GGT (m) and cholesterol (f), ↑ urinary ketones (m); ↑ rel. liver wt (f) epithelial hyperplasia of the stomach (m), altered eosinophilic hepatocytes (m), bile duct hyperplasia (f), cystically dilated bile ducts (f), hyperplasia of parathyroid (m) 700 ppm: ↓ food consumption ↓ bw gain (f); ↑ rel. liver wt; bile duct hyperplasia (f), hyperplasia of parathyroid (m) Oncogenicity: Increased incidences of hepatic and ovarian tumors; no classification according to RAC	[redacted] 1990/11138 1990/11179 1993/11798 TOX1999-435*[1,3] TOX1999-436* TOX1999-437*
Racemic dimethenamid 94-week, diet, CD-1 mice (diet concentrations: 0, 30, 300, 1500 and 3000 ppm)	M: 3.8, 41, 205 and 431 F: 4.1, 40, 200 and 411	40	200	Systemic toxicity: ≥1500 ppm: ↓ bw gain, ↑ rel. liver wt, ↑ rel. kidney wt (f) and enlarged hepatocytes 3000 ppm: ↑ incidence of stomach hyperkeratosis Oncogenicity: No increased incidences of tumours reported	[redacted] 1990/11139 TOX1999-438*[1,3]

* Evaluated for Annex I inclusion of dimethenamid-p

1 The study has been evaluated as acceptable in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2010-10566).

3 The study has been evaluated as acceptable in the Renewal Assessment Report.

The results of a 2-year chronic/oncogenicity study in rats indicated that a maximum tolerated dose was met at the high dose of 1500 ppm (approx. 80 mg/kg bw/d males; 109 mg/kg bw/d females). This is demonstrated by a body weight gain depression for the first 80 weeks of treatment in males and females.

The liver was a target organ for dimethenamid in the rat. Observations included an increase in serum γ-glutamyltransferase (γ-GGT) and cholesterol, an increase in liver weight and liver pathology including altered eosinophilic hepatocytes, bile duct hyperplasia and cystically dilated bile ducts.

Other effects noted in high dose males were an increase in epithelial hyperplasia of the limiting ridge of the stomach and hyperplasia in the parathyroid. The mid dose of 700 ppm produced body weight gain decreases and liver alterations in females. The incidence of liver tumours was slightly increased. However, they were within historical control range and not significant. In contrast ovarian tubular adenomas were significantly elevated but just outsight historical control ranges.
A carcinogenicity study in mice was conducted with doses up to 3000 ppm, which represented the maximum tolerated dose as evidenced by significant body weight gain depression. Similar to the results in rats, the liver was the apparent target organ in mice. Liver weights were increased and hepatocyte enlargement was observed at the 2 highest dose levels. An additional finding in mice was hyperkeratosis of the limiting ridge of the stomach. There was no evidence of a treatment related increase in neoplasms.
In summary, long-term feeding studies with racemic dimethenamid in rats and mice demonstrated that the primary target organ was the liver. The increased incidences of ovarian tubular adenomas and liver tumours observed in rats were not regarded sufficient for classification.
ECHA's RAC evaluated the available data and concluded that no classification for systemic toxicity or carcinogenicity is warranted (see Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; CLH-O-0000003037-80-03/F; ASB2015-2797).
Since the publication of the RAC opinion no new studies on long-term toxicity or carcinogenicity were submitted with either racemic dimethenamid or dimethenamid-P.

2.6.6 Summary of reproductive toxicity

A two-generation study is available for racemic dimethenamid in rats. Furthermore, prenatal toxicity studies in rats are available for both dimethenamid-P and racemic dimethenamid, and a prenatal toxicity study in rabbits with racemic dimethenamid. These studies have been evaluated by European authorities and Germany as Rapporteur Member State (RMS) in the European Commission Peer Review Program. All studies on reproductive toxicity were considered acceptable with the exception of the prenatal toxicity study for racemic dimethenamid in rats, now considered supplementary. The studies are summarised below.

Table 2.6-15: Summary of reproduction toxicity studies conducted with and racemic dimethenamid and dimethenamid-P

Study	Dosages (mg/kg bw/day)	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Main adverse effect	Reference and year
Racemic dimethenamid 2-generation, oral, feed Wistar rats (constant diet concentrations: 0, 100, 500 and 2000 ppm)	7. 5, 37.5 [75 lactation] and 151 (average values)	Parental toxicity: approx. 7.5 Developmental toxicity: approx. 75 Reproduction: approx. 150	Parental toxicity: approx. 38 Develop-mental toxicity: approx. 150	Parental toxicity: 2000 ppm: ↓ food intake, ↓ bw gain (m), ↑ liver wt 500 ppm: ↑ liver wt (F0 females) Developmental toxicity: 2000 ppm: ↓ bw gain during lactation	[redacted] 1990/11140 TOX1999-439*[1,3]
Dimethenamid-P Developmental toxicity, gavage, Sprague-Dawley rats	0, 25, 150 and 300	Maternal toxicity: <25 Developmental toxicity: 25	Maternal toxicity: 25 Develop-mental toxicity: 150	Maternal toxicity: 300 mg/kg bw/d: ↓ bw gain and food consumption; clinical signs, ↑ liver wt 150 mg/kg bw/d: ↓ bw gain and food consumption 25 mg/kg bw/d: ↓ body weight gain and food consumption Developmental toxicity: ≥150 mg/kg bw/d: ↑ delayed skeletal ossifications, marginal ↓ fetal body weights	[redacted] 1997/5274 TOX1999-440*[1,3]
Racemic dimethenamid Developmental toxicity, gavage, CD rats	0, 50, 215 and 425	Maternal toxicity: 50 Developmental toxicity: 50	Maternal toxicity: 215 Develop-mental toxicity: 215	Maternal toxicity: ≥215 mg/kg bw/d: ↓ bw gain, ↓ feed consumption, clinical signs, ↑ liver wt Developmental toxicity: ≥215 mg/kg bw/d: ↑ early resorptions 425 mg/kg bw/d: ↓ live litter size	[redacted] 1987/11225 TOX1999-458*[1,4]

Study	Dosages (mg/kg bw/day)	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Main adverse effect	Reference and year
Racemic dimethenamid, Developmental toxicity, gavage, New-Zealand-White rabbits	0, 37.5, 75 and 150	Maternal toxicity: 37.5 Developmental toxicity: 75	Maternal toxicity: 75 Develop-mental toxicity: 150	Maternal toxicity: ≥75 mg/kg bw/d: ↓ bw gain, clinical signs 150 mg/kg bw/d: ↓ food intake, ↓ bw loss Developmental toxicity: 150 mg/kg bw/d: abortions in 2 animals, resorptions	[redacted] 1988/11376 TOX1999-441*[1,3]

* Evaluated for Annex I inclusion of dimethenamid-P
1 The study has been evaluated as acceptable in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2010-10566).
3 The study has been evaluated as acceptable in the Renewal Assessment Report.
4 The study has been evaluated as supplementary in the Renewal Assessment Report.

In a 2-generation reproductive toxicity study no evidence for impairment of fertility and reproduction was observed. Therefore, the NOAEL for reproduction toxicity was 2000 ppm (approx. 150 mg/kg bw/d), the highest dose tested. The NOAEL concerning systemic toxicity for parental animals in the 2-generation study was 100 ppm (approx. 7.5 mg/kg bw/d) based on significant increased liver weight in F0 females. The only pup effect was decreased body weight gain during lactation at the high dose level, therefore the NOAEL for developmental toxicity in the F1 and F2 litters was 500 ppm (approx. 75 mg/kg bw/d).

The developmental toxicity study in rats using dimethenamid-P, revealed delayed ossification at the two highest doses groups (150 and 300 mg/kg bw/d) and resulted in an NOAEL of 25 mg/kg bw/d for developmental toxicity. Maternal toxicity was observed and characterised by decreased body weight gain, and food consumption at all dose levels and clinical signs and liver weight increases in the high dose group of 300 mg/kg bw/d. The NOAEL for maternal toxicity was <25 mg/kg bw/d.

The current re-evaluation revealed that due to reporting deficiencies, the prenatal toxicity study in rats using racemic dimethenamid is now considered supplementary. Under the conditions of this study maternal and developmental toxicity were observed at the two highest doses tested (215 and 425 mg/kg bw/d). Therefore, the NOAEL for both, maternal and developmental toxicity was 50 mg/kg bw/d.

In prenatal toxicity study in rabbits, significant maternal toxicity (reduced food consumption, body weight loss, clinical signs) was observed at the high dose and less severe at mid dose level. Abortions in 2 high-dose animals were considered treatment related, but attributed to the marked maternal toxicity. Early resorptions at 215 mg/kg bw/d and above were statistically not significant but outside historical control data. The NOAEL for maternal toxicity was 37.5 mg/kg bw/d and 75 mg/kg bw/d for developmental toxicity.

The lowest NOAEL for developmental toxicity was 25 mg/kg bw/d in the rat (prenatal toxicity study, dimethenamid-P). During the previous evaluation, it was considered to derive an overall NOAEL of 50 mg/kg bw/day in the rat based on dose spacing in the above mentioned rat study and only slight effects at next dose level of 150 mg/kg bw/d (6 fold higher) and taking into account results of the study conducted with racemic dimethenamid. However, since the current re-evaluation considered the prenatal toxicity study with racemic dimethenamid in rats to be supplementary, no overall NOAEL can be driven.

There are no new studies on reproduction and developmental toxicity available with either racemic dimethenamid or dimethenamid-P.

The ECHA risk assessment committee on classification and labelling has evaluated the data and concluded that no classification for reproduction toxicity or developmental toxicity is warranted. (see Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; CLH-O-0000003037-80-03/F; ASB2015-2797).

2.6.7 Summary of neurotoxicity

There were no studies available for Annex I inclusion of dimethenamid-P and no studies were considered necessary for dimethenamid-P as the data package on acute studies in rats and subchronic and chronic exposure studies in three species conducted with either dimethenamid-P or racemic dimethenamid gave no evidence of a neurotoxic effect. A study on delayed neurotoxicity in hens being only required for organophosphorous or carbamate compounds was also not considered warranted as neither dimethenamid nor any of the metabolites are belonging to these chemical classes.
In order to satisfy an US EPA requirement an acute neurotoxicity study and a 90-day neurotoxicity study were conducted and are thus now presented as further information within the Renewal Process for the Renewal Assessment Report. The results of these studies are summarised in Table 2.6-16.

Table 2.6-16: Summary of neurotoxicity studies with dimethenamid-P

Study Dose levels (Batch / purity)		NOAEL mg/kg bw/d (ppm)	LOAEL mg/kg bw/d (ppm)	Adverse effects at LOAEL	Reference
Acute neurotoxicity study Rat (Wistar, Crl:WI(Han), 0, 60, 200 and 600 mg/kg bw/d (COD-001509/95.9 %)	M	600 (neurotoxicity) 600 (systemic)	not obtained (neurotoxicity) not obtained (systemic)	no signs of neurotoxicity and systemic toxicity observed	[redacted] 2013/1028330 ASB2014-8392#[1]
	F	600 (neurotoxicity) 200 (systemic)	not obtained (neurotoxicity) 600 (systemic)	no signs of neurotoxicity observed clinical findings in females	
Subchronic (90-day) neurotoxicity study Rat (Wistar, Crl:WI(Han), 0, 300, 1000 and 4500 ppm (COD-001509/95.9 %)	M	323 (4500) (neurotoxicity) 63 (1000) (systemic)	not obtained (neurotoxicity) 323 (4500) (systemic)	no signs of neurotoxicity observed 4500 ppm: ↓ bw gain, ↑ liver wt, ↑ kidney wt (males only)	[redacted] 2013/1165818 ASB2014-8393#[1]
	F	390 (4500) (neurotoxicity) 72 (1000) (systemic)	not obtained (neurotoxicity) 390 (4500) (systemic)		

\# Submitted within the AIR III process for the Renewal Assessment Report
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

In the acute neurotoxicity single animals (1 or 2 out of 10) of all male dose groups showed strongly contracted pupils under incidence of light. There was however no dose-response relationship and it was not seen in females which showed treatment related toxicity while no other toxicity effects were noticed in males. The effect was noted as a transient effect only on the day of administration. Additionally, no treatment related neuropathological findings were determined, i.e. no brain weight changes or neurohistopathological findings were observed. Therefore, the observed pupillary reaction under light was considered to represent a transient neurotoxicological effect rather than to be indicative for adverse neurotoxicity.
The observed systemic toxicity in females at 600 mg/kg bw/day is in line with the toxicity observed in other acute oral studies in rats conducted with either dimethenamid-P or racemic dimethenamid.
Oral administration of dimethenamid-P to rats over 3 month revealed no adverse neurobehavioural effects and did not show any alterations in neuropathology investigations. Effects indicating a certain level of systemic toxicity were given at least for the high concentration of 4500 ppm, i.e. impairment of body weight development in male and female Wistar rats accompanied by an increase of liver (males and females) and kidney (males only) weights and were in line with findings in other repeated dose administrations of either dimethenamid-P or racemic dimethenamid to rats.

The newly available neurotoxicity studies have not been submitted to the ECHA risk assessment committee on classification and labelling. The results of these studies would not change the classification and labelling of dimethenamid-P (see Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; CLH-O-0000003037-80-03/F; ASB2015-2797).

2.6.8 Summary of further toxicological studies on the active substance

Supplementary studies on the active substance

A plasma-protein binding study conducted with racemic dimethenamid done in rat and human blood cells and an enzyme induction study with racemic dimethenamid in rats are available. These studies have been evaluated by European authorities and Germany as Rapporteur Member State (European Commission Peer Review Program) and were considered to be acceptable.

Table 2.6-17: Summary of supplementary studies conducted with dimethenamid-P and racemic dimethenamid

Study	Main effects	Reference
Investigation of the Potential of a Covalent Binding of [^{14}C]-dimethenamid (SAN 582 H) or its Derivatives to Rat and Human Haemoglobin	No increase in methaemoglobin in rats. Strong binding of dimethenamid to rat haemoglobin, primarily to globin protein, but no incorporation of dimethenamid to human haemoglobin.	[redacted] 1992*[1,3] TOX1999-448
Investigation of Liver Enzyme Induction by dimethenamid (SAN 582 H) in Rats	Metabolism of dimethenamid involves oxidation steps mainly by cytochrome P450 dependent enzymes and glutathione conjugation and glucuronidation.	[redacted] 1994*[1,3] TOX1999-449
Investigation of the immunotoxicity in female C57BL/6J Rj mice - Administration of dimethenamid-p via the diet for 4 weeks	No signs of immunotoxicity (by T-cell dependent antigen response) NOAEL: 500 ppm (120 mg/kg bw/day)	[redacted] 2013f#[3] ASB2014-8422

* Evaluated for Annex I inclusion of dimethenamid-p.
\# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the original monograph of the RMS Germany of Sep. 12, 2000 (ASB2010-10566) or in Addendum 1 to the monograph of the RMS Germany of July 03, 2001 (ASB2015-1648).
[3] The study has been evaluated as acceptable in the Renewal Assessment Report.

The pharmacokinetic studies (TOX1999-448) indicated that dimethenamid may bind to blood components in rats. This was based on 3 % of the radiolabelled material administered remaining in the blood fraction. Therefore, the nature of the interaction between dimethenamid and rat blood was investigated. The results of the study showed that racemic dimethenamid did not produce methaemoglobin in rat blood following a four day treatment. Dimethenamid was shown to bind to rat haemoglobin, primarily to the globin portion, but no binding was demonstrated using human blood.
The difference in haemoglobin binding between humans and rats is explained by the difference in three dimensional structures between the 2 species. It is known from the literature that the cysteine residue β-125 in rat haemoglobin is accessible for chemical substitution, but in human haemoglobin, the sequence does not contain a cysteine residue in position 125. In summary, it can be concluded that the interaction between dimethenamid and haemoglobin is a species specific reaction. This binding is irrelevant for humans.
In a further *in vivo* study with rats, the qualitative and quantitative effects of racemic dimethenamid on liver enzymes, blood and urine parameters were investigated (TOX1999-449). Oral administration of racemic dimethenamid to rats for 4 days induced several liver enzyme systems. It was demonstrated that the metabolism of racemic dimethenamid involves oxidation steps mainly by cytochrome P450

dependent enzymes, and glutathione conjugation and glucuronidation. Upon removal from treatment, there is a recovery from the liver changes.
In addition to these studies already evaluated an immunotoxicity study has been conducted to fulfil data requirements of the US-EPA.
The study conducted with dimethenamid-P in female mice in the presence of systemic toxicity, did not reveal any signs of immunotoxicity (by T-cell dependent antigen response) when administered via the diet over a period of 4-weeks.
The newly available study of [redacted] 2013 (ASB2014-8422) has not been submitted to the ECHA risk assessment committee on classification and labelling. The results of this study would not change the classification and labelling of dimethenamid-P (see Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; ASB2015-2797).

Studies on endocrine disruption

A separate evaluation of potential endocrine disruption was not a data requirement at the time of Annex I inclusion of dimethenamid-P. However, this endpoint is considered intrinsically covered by the respective pivotal toxicity studies on racemic dimethenamid and dimethenamid-P.
The data package of dimethenamid-P does not indicate a potential of dimethenamid-P to affect the oestrogen or androgen system.
There is no indication for adverse alterations in the thyroidal hormonal system from the available database for dimethenamid-P. The noticed parathyroidal hyperplasia in the long-term rat study is not related to any indication of adverse effects due to parathyroidal hormonal imbalance i.e. altered ossification.
Racemic dimethenamid is part of the ToxCast program (ASB2014-8446; ASB2014-8447; ASB2014-8448). Several assay react to varying doses of racemic dimethenamid, however, no conclusive picture has emerged. For example dimethenamid is positive for androgen receptor antagonism but negative for other assays on the androgen receptor system (ASB2014-8446). Also dimethenamid does not activate any assays indicating a linkage to the oestrogen receptor system (ASB2014-8446; ASB2014-8447).
There is some evidence that link dimethenamid to the activation of the CAR/PXR-system (ASB2014-8446), which would be in line with the known pattern of liver enzyme induction and observed liver effects in the short- and long-term toxicity studies.
In addition to the pivotal toxicity studies the following literature was taken into consideration.

Table 2.6-18: Summary of literature studies indicating endocrine disruption with dimethenamid-P

Study Dose levels (Batch/purity)	Endpoint	NOAEL ppm (mg/kg bw/d)	LOAEL ppm (mg/kg bw/d)	Effects	Reference BASF DocID
Literature: Reporter gene assays (not reported)	Multiple transcriptional targets			Activation of some transactivation systems, contradictory information for androgen receptor signaling no indication for estrogen receptor signalling, some indications of activation of the CAR/PXR axis.	Shah I. et al., 2011a#[1] ASB2014-8446
Literature: Reporter gene assays (not reported)	Multiple transcriptional targets			Limited indication for androgen receptor pathway, no indication for estrogen receptor pathway, no indication for thyroid axis	Reif D.M. et al., 2010a#[1] ASB2014-8447
Literature: Reporter gene assays (not reported)	Multiple transcriptional targets			Unclear linkage	Sipes N.S. et al., 2013a#[1] ASB2014-8448

Submitted within the AIR III process for the Renewal Assessment Report
[1] Study has been evaluated as supplementary in the Renewal Assessment Report.

The presented *in vitro* studies provide some evidence of interaction between dimethenamid-P and PXR pathway and to a lesser degree androgen receptor and PPAR in highly artificial cell systems (ASB2014-8446; ASB2014-8447; ASB2014-8448). These are in general lacking any form of metabolic competence which is especially critical in a setting where the substance is rapidly and nearly completely metabolised as is the case for dimethenamid-P.
In a recent evaluation of the predictivity of the high-throughput *in vitro* screening battery used in ToxCast, Thomas et al. (Toxicological Sciences; 128(2), 398-417 (2012); ASB2015-1115) tested 84 statistical classification models (JMP Genomics software 5.0) with chemical descriptors (QSAR analysis) or *in vitro* assays as variables. After multiple iterations and cross validations, they identified balanced accuracy scores to be <0.55 (or 55 % predictivity) for 56 of the 60 endpoints. There was little to no predictive advantages of the cell based assays in comparison to QSAR tools, which are generally deemed to have low predictivity for complex endpoints (<70 % accuracy, evaluation of multiple endpoints by EPA and EFSA).
This indicates that *in vitro* studies only provide an initial step in the evaluation of the toxicological properties of a compound.
A full set of higher tier studies is available for racemic dimethenamid and dimethenamid-P. This includes carcinogenicity studies in mouse and rats with no effect in oestrogen or androgen related organs either as neoplastic or non-neoplastic lesions. Furthermore a 1 year study in dogs and teratogenicity studies in rats and rabbits and are available.
In a two generation study in rats no indication of estrogenic or androgenic activity were observable. This includes no effect on time to pregnancy, pregnancy rate, gestation length, or any pup effects related to an estrogenic or androgenic activity.

No spermatology investigation was performed. However, male fertility was indirectly assessed in the breedings in each generation which indicated no evidence of an effect on male fertility.
It is considered to be highly unlikely that dimethenamid-P has estrogenic, androgenic, or anti-androgenic properties up to the maximum dose testable in mammalian systems.
There might be an enzyme induction related higher excretion of thyroid hormones considered, related to dimethenamid treatment in the rat. This potential increased excretion is considered an indirect effect not related to endocrine activity. Moreover, although there is evidence for enzyme induction, there is no indication that thyroid might be a target organ.
It is considered to be highly unlikely that dimethenamid-P does affect the thyroidal system up to the maximum dose testable in mammalian systems.
In conclusion, there is no evidence that dimethenamid-P has a human relevant endocrine related effect.
The newly available literature has not been submitted to the ECHA risk assessment committee on classification and labelling. The results of the literature studies would not change the classification and labelling of dimethenamid-P (see Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; CLH-O-0000003037-80-03/F; ASB2015-2797).

2.6.9 Summary of toxicological data on impurities and metabolites

Dimethenamid-P as is the racemic dimethenamid are extensively metabolised in all matrices (mammal, plant and soil/water) resulting in numerous metabolites identified. Meanwhile further insights into behaviour of dimethenamid-P in plants and in the environment has been obtained. Consequently, the database for the above mentioned metabolites now considered as significant ground-water metabolites has been extended and additional metabolites that were determined at significant levels in plants or groundwater were included into the evaluation.
Due to the extensive number of metabolites and the close structural relationship a grouping approach has been applied for the assessment. The grouping strategy stems mainly from the results of the lysimeter study, but is meant to align with toxicological testing strategies. Note that grouping approach and naming took into account related rat or plant metabolites leading to group names not always congruent with the concerned significant metabolites (for further details see Vol. 3, B.6.8 or B.6.9).
Thus, the conclusion for relevant endpoints for the current re-registration was drawn as follows:

The metabolic pathways in soil, water, mammals, and plants are equivalent for the racemic dimethenamid and dimethenamid-P (S-enantiomer). The metabolites derived from either racemic or enantio-enriched source are considered toxicologically equivalent and were taken into account for the assessment below.

For all metabolites identified with potential relevance or as corresponding group members presence for potential structural alerts was evaluated with different SAR/QSAR models. Models used, were the OECD toolbox, OASIS TIMES, DEREK (partly) and VEGA. These evaluations were in particular taken into account for those metabolites in the grouping approach presented in Vol. 3 where toxicological data are not available (for further details see Vol. 3, B.6.8 or B.6.9). However, the QSAR predictions obtained are limited by the reliability as most of the structures evaluated were not in the prediction domain. Thus, given the structural relationship of the metabolites evaluated inter alia and in relation to the parent molecule dimethenamid-P, the predicted alerts were compared to those for the parent and those metabolites were toxicological data were available in order to overcome the limitations of the predictions made. Moreover, the systems used do not distinguish chiral structures. Thus, any prediction made applies generally to the racemic molecules as well as to the S-enantiomer metabolites considered for dimethenamid-P.
Racemic dimethenamid and dimethenamid-P have been tested for genotoxic potential in 17 assays using both *in vitro* and *in vivo* techniques. Considering all 17 tests with dimethenamid, the weight of the evidence assessment is that this compound is not genotoxic. Specifically for chromosome aberration potential, four assays have been conducted including an *in vitro* study using Chinese Hamster Ovary (CHO) cells and three *in vivo* mouse micronucleus assays. All four studies indicated that dimethenamid has no clastogenic activity.
Based on the structural activity analysis conducted for dimethenamid and the metabolites structural alerts for chromosomal aberration *in vitro* based on formation of alpha, beta polarised carbonyls had been identified for several of the structures considered including the parent molecule dimethenamid.

These structural alerts were determined in several of the *in vitro* studies for chromosomal aberration conducted. However, in none of the *in vivo* tests on clastogenicity conducted, neither for the parent compound nor for the metabolites there was evidence for chromosomal aberration. Thus, the conclusion drawn that this alert for clastogenicity is related to the *in vitro* situation only was confirmed by the toxicological studies conducted.

Toxicological evaluation of metabolite M656PH023:
M656PH023 (Reg. No. 5886780) is a metabolite of dimethenamid-P that was determined in soil, surface water, groundwater and plants. An exposure level in groundwater of 0.1 µg/L < M656PH023 ≤ 0.75 µg/L was predicted by the applicant. In plants it was not determined in edible commodities.

Table 2.6-19: Summary of the toxicity studies of M656PH023

Study	Test system	Result	Reference
Acute oral	Rat	LD_{50}>5000 mg/kg bw	[redacted] (1995)*[1] TOX1999-442
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 102, 1535 and 1537	Negative	Clare C., (1995)*[1] TOX1999-444
Gene Mutation Assay	Chinese hamster V79 cells *in vitro* (V79 / HPRT)	Negative	[redacted] (2000)#[1] TOX2002-1990
Micronucleus test	Mouse	Negative	[redacted] (1998)* TOX1999-446
28-day	Rat, administration via the diet, 1200, 4000 and 12000 ppm	No adverse signs of toxicity NOAEL: 12000 ppm (1057 mg/kg bw/d)	[redacted] 2014b# ASB2014-8415

* Reported in the original DAR Dimethenamid-P – Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

The limited toxicological alert for chromosomal aberration *in vitro* identified for M656PH023 was not confirmed by the genotoxicological testing conducted. There was no evidence for genotoxicity of M656PH023 in the *in vitro* and *in vivo* genotoxicity studies conducted fulfilling the requirements for evaluation of groundwater metabolites. The available data on systemic toxicity – acute oral toxicity and short-term toxicity study in rats - clearly demonstrated that the compound is of low toxicity and thus less toxic than the parent molecule dimethenamid-P.

Toxicological evaluation of metabolite M656PH026:
M656PH026 is a metabolite of dimethenamid-P determined in rat, goat (dosed with M565PH030), plant and soil. The determined levels of M656H026 in rats and mice were at trace levels but M656PH026 was up to 68 % of the applied dose in urine when dosed with M656PH030. In plants, the only human consumable it was measured in was bulb onions at a level near the LOQ. It was measured in animal feed items. As there might be potential human consumer exposure via the food chain this metabolite was considered for toxicological relevance assessment. Exposure estimates for consumer of 0.0025 µg/kg bw/day < M656PH026 ≤ 1.5 µg/kg bw/day were predicted by the applicant.
The limited alert for chromosomal aberration *in vitro* identified for M656PH026 was considered to be of no relevance *in vivo* in comparison to the parent molecule dimethenamid-P and the closely related metabolites M656PH030, M656PH031 and M656PH032 for which genotoxicity data are available leading to the conclusion M656PH026 not to be genotoxic.

Toxicological evaluation of metabolite M656PH027:
M656PH027 is a metabolite of dimethenamid-P determined in rat, hen, goat, mice, plant and groundwater and surface water. The determined levels of M656H023 in rats, mice, and goat were at trace levels and were previously reviewed under Annex I.
Exposure levels in groundwater of $0.75\ \mu g/L < M656PH027 \leq 4.5\ \mu g/L$ were predicted by the applicant.
The toxicological alert for chromosomal aberration *in vitro* identified for M656PH027 was not confirmed by the genotoxicological testing conducted. There was no evidence for genotoxicity of M656PH027 in the studies conducted fulfilling the requirements for evaluation of groundwater metabolites. The available data on general toxicity – acute oral toxicity and short-term toxicity study in rats - clearly demonstrated that the compound is of low toxicity and thus less toxic than the parent molecule dimethenamid-P.

Table 2.6-20: Summary of the toxicity studies of M656PH027

Study	Test system	Result	Reference
Acute oral	Rat	LD_{50}>5000 mg/kg bw	[redacted], 1992*[1] TOX1999-443
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 102, 1535 and 1537	Negative	Clare C., (1995)*[1] TOX1999-445
Gene Mutation Assay	Chinese hamster V79 cells *in vitro* (V79 / HPRT)	Negative	[redacted] 2000*[1] TOX2002-1991
Micronucleus test	Mouse	Negative	[redacted] 1998*[1] TOX1999-447
28-day	Rat, administration via the diet, 1200, 4000 and 12000 ppm	No adverse signs of toxicity NOAEL: 12000 ppm (1064 mg/kg bw/d)	[redacted] 2014#[1] ASB2014-8416

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Toxicological evaluation of metabolite M656PH030:
M656PH030 a metabolite identified in rat, hen, and goats dosed with M656PH030. The determined levels of M656H030 in rats and mice were at trace levels but M656PH030 reached 4 % of the applied dose in goats that were dosed with 12 mg/kg of M656PH030. In plants it was only determined in edible commodities of bulb and spring onions, kale, Chinese cabbage, and head cabbage as well as several animal feed items. As there might be potential human consumer exposure via the food chain this metabolite was considered for toxicological relevance assessment.
No relevant toxicological alert (QSAR) was identified for M656PH030. By weight of evidence M656PH030 is not considered to be genotoxic based on the in the *in vitro* and *in vivo* studies conducted.

Table 2.6-21: Summary of the toxicity studies of M656PH030

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537; *E. coli* WP2 uvrA	Negative	Woitkowiak C., 2014#[1] ASB2014-8451
Gene Mutation Assay	*In vitro* cell mutation assay at the Thimidine Kinase Locus (TK+/-) in mouse lymphoma L5178Y cells	Negative	[redacted], 2014#[1] ASB2014-8458
In vitro Micronucleus test	Chinese hamster V79 cells	Positive	[redacted]., 2014#[1] ASB2014-8465
In vivo Micronucleus test	Micronuclei in polychromatic erythrocytes (PCE) in the bone marrow of the mouse 500, 1000 and 2000 mg/kg bw by oral gavage	Negative	[redacted] 2014#[1] ASB2014-8470

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Toxicological evaluation of metabolite M656PH031:

M656PH031 is a metabolite of dimethenamid-P determined in maize and soybean metabolism studies but not observed edible commodities as well as in soil, surface water and groundwater. The applicant predicted an exposure for groundwater of M656PH031 < 0.1µg/L.

The toxicological evaluation of M656PH031 was based on studies conducted with M656H031. No conclusive, relevant toxicological alerts were identified for M656PH031. There was no evidence for genotoxicity of M656PH031 in the *in vitro* genotoxicity studies conducted fulfilling the requirements for evaluation of groundwater metabolites. The available data on systemic toxicity – short-term toxicity study in rats - clearly demonstrated that the compound is of low toxicity and thus less toxic than the parent molecule dimethenamid-P.

Table 2.6-22: Summary of the toxicity studies of M656PH031

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537; *E. coli* WP2 uvrA	Negative	Schulz M., Landsiedel R., 2008a#[1] ASB2010-6897
Gene Mutation Assay	Chinese hamster CHO cells (sub-strain K3); HPRT locus assay	Negative	[redacted] 2008b#[1] ASB2008-7224 [redacted] 2000#[1] TOX2002-1991
In vitro chromosome aberration assay	Chinese hamster V79 cells	Negative	[redacted] 2008c#[1] ASB2008-7223
28-day	Rat, administration via the diet, 1200, 4000 and 12000 ppm	No adverse signs of toxicity NOAEL: 12000 ppm (1068 mg/kg bw/d)	[redacted]., 2013#[1] ASB2014-8417

* Reported in the original DAR Dimethenamid-P - Volume 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
# Submitted within the AIR III process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Toxicological evaluation of metabolite M656PH032

M656PH032 is a metabolite of dimethenamid-P determined in hen and groundwater. In the hen metabolism study M656H032 was observed at 1.05 mg/kg in excreta.

M656PH032 is not mutagenic in the Ames test. M656PH032 is a presumed metabolite of M656PH031.

Table 2.6-23: Summary of the toxicity studies of M656PH032

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537; *E. coli* WP2 uvrA	Negative	Woitkowiak C., 2013a # [1] ASB2014-8452

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Toxicological evaluation of metabolite M656PH043 former assigned M43/M44:
M656PH043 is a metabolite of dimethenamid-P determined in groundwater.
No relevant toxicological alert (QSAR) was identified for M656PH043.

Table 2.6-24: Summary of the toxicity studies of M656PH043

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537 *E. coli* WP2 uvrA	Negative	Woitkowiak C., 2014a#[1] ASB2014-8453
Gene Mutation Assay	*In vitro* cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells	Negative	[redacted] 2013a#[1] ASB2014-8459
In vitro micronucleus test	Chinese hamster V79 cells	Positive	[redacted] 2013#[1] ASB2014-8466
In vivo micronucleus test	Polychromatic erythrocytes (PCE) in the bone marrow of the mouse oral gavage ≤2000 mg/kg bw	Negative	[redacted] 2013b#[1] ASB2014-8471

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Overall, with regard to *in vitro* genotoxicity testing there was no indication for mutagenicity neither in the bacterial Ames test nor in the mammalian Mouse Lymphoma test. However, in the *in vitro* micronucleus test in V79 cells conducted with M656PH043 a potential chromosomal aberration effect was observed in the absence of metabolic activation. In contrast in the subsequently conducted *in vivo* micronucleus test in mice no treatment related induction of micronuclei could be determined up to the limit dose of 2000 mg/kg a dose level that demonstrated clinical signs of toxicity in the pre-test. Plasma analytics confirmed that M656PH043 was systemically available. Thus, the *in vivo* study conducted for the same endpoint did not demonstrate a treatment related effect. By weight of evidence M656PH043 was not considered to be genotoxic in the *in vitro* and *in vivo* genotoxicity studies conducted for evaluation of groundwater metabolites.

Toxicological evaluation of metabolite M656PH045 formerly assigned M45/M46:
M656PH045 is a metabolite of dimethenamid-P determined in groundwater. The exposure levels in groundwater, predicted by the applicant, are 0.75 µg/L < M656PH045 ≤ 4.5 µg/L.
No conclusive, relevant toxicological alerts (QSAR) were identified for M656PH045. There was no evidence for genotoxicity of M656PH045 in the *in vitro* genotoxicity studies conducted fulfilling the requirements for evaluation of groundwater metabolites. The available data on systemic toxicity - short-term toxicity study in rats - clearly demonstrated that the compound is of low toxicity and thus less toxic than the parent molecule dimethenamid-P.

Table 2.6-25: Summary of the toxicity studies of M656PH045

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537 *E. coli* WP2 uvrA	Negative	Woitcowiak C., 2013#[1] ASB2014-8487
Gene Mutation Assay	*In vitro* cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells	Negative	[redacted] 2013b#[1] ASB2014-8460
In vitro micronucleus test	Chinese hamster V79 cells	Negative	[redacted] 2013#[1] ASB2014-8467
28-day	Rat 1200, 4000 and 12000 ppm administered via diet	No adverse signs of toxicity NOAEL 12000 ppm (1174 mg/kg bw/d)	[redacted] 2014#[1] ASB2014-8418

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Toxicological evaluation of metabolite M656PH047 formerly assigned M47/M48:
M656PH047 is a metabolite of dimethenamid-P determined in groundwater. The human exposure levels via groundwater, predicted by the applicant, are 0.1 µg/L < M656PH047 ≤ 0.75 µg/L.
No conclusive, relevant toxicological alerts were identified for M656PH047. By weight of evidence M656PH047 was considered not to be genotoxic in the *in vitro* and *in vivo* genotoxicity studies conducted for evaluation of groundwater metabolites.

Table 2.6-26: Summary of the toxicity studies of M656PH047

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537 *E. coli* WP2 uvrA	Negative	Woitcowiak C., 2014b#[1] ASB2014-8454
Gene Mutation Assay	*In vitro* cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells	Negative	[redacted] 2014a#[1] ASB2014-8461
In vivo micronucleus test	Polychromatic erythrocytes (PCE) in the bone marrow of the mouse	Negative	[redacted] 2014a #[1] ASB2014-8472
28-day	Rat 1320, 4400 and 13200 ppm administered via diet	No adverse signs of toxicity NOAEL 13200 ppm (967 mg/kg bw/d)	[redacted] 2014d#[1] ASB2014-8419

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Toxicological evaluation of metabolite M656PH049 formerly assigned M49:
M656PH049 is a groundwater metabolite. The exposure in groundwater, predicted by the applicant, is 0.1 µg/L < M656PH049 ≤ 0.75 µg/L.
A structural alert for *in vitro* chromosomal aberration (QSAR) was identified that was considered of low relevance for mammals *in vivo*. The structural alert identified was considered to be covered by the toxicological testing conducted with dimethenamid-P, M656PH023 and M656PH054. According to the applicant any efforts to synthesise M656PH049 were not successful (Jilderda, K., 2014 (ASB2014-8610)). The toxicological evaluation is made based on the grouping proposal presented and discussed in Vol. 3.

Toxicological evaluation of metabolite M656PH050 formerly assigned M50:
M656PH050 is a groundwater and soybean metabolite, but was not determined in edible commodities. The toxicological evaluation is made based on the grouping proposal (member of the M23 group) presented and discussed in Vol. 3.

Toxicological evaluation of metabolite M656PH051 former assigned M51:
M656PH051 is a metabolite observed in soybean and rotational crop metabolism but was not observed in any edible commodity. It is also a groundwater metabolite.
In conclusion in one of the structure activity evaluation tools employed there was a limited alert for chromosomal aberration *in vitro* with metabolic activation considered of low relevance for the *in vivo* situation. The toxicological evaluation is made based on the grouping proposal (member of the M31-group) presented and discussed in Vol. 3.

Toxicological evaluation of metabolite M656PH052 former assigned M52:
M656PH052 is a groundwater metabolite. The exposure in groundwater, predicted by the applicant, is 0.1 µg/L < M656PH052 ≤ 0.75 µg/L.
A structural alert (QSAR) for *in vitro* chromosomal aberration was identified that was considered of low relevance for mammals *in vivo*. The structural alert identified was considered to be covered by the

toxicological testing conducted with M656PH027, M656H031 and M656PH054. Any efforts to synthesise M656PH052 were not successful (Jilderda, K., 2014 (ASB2014-8610). Consequently the toxicological evaluation is made based on the grouping proposal presented and discussed in Vol. 3.

Toxicological evaluation of metabolite M656PH053 former assigned M53/M57:
M656PH053 is a groundwater metabolite. The exposure levels in groundwater, predicted by the applicant, are 0.75 µg/L < M656PH053 ≤ 4.5 µg/L.
Based on the failure of synthesis efforts experienced with M656PH049 and M656PH052, synthesis of M656PH053 was not considered feasible.
The toxicological evaluation is made based on the grouping proposal presented and discussed in Vol. 3.
No conclusive toxicological alert has been identified.

Toxicological evaluation of metabolite M656PH054 former assigned M54/M58:
M656PH054 is a groundwater metabolite. Exposure levels via groundwater, predicted by the applicant, are 0.75 µg/L < M656PH054 ≤ 4.5 µg/L.
Overall, with regard to *in vitro* genotoxicity testing there was no indication for mutagenicity neither in the bacterial Ames test nor in the mammalian Mouse Lymphoma test.

Table 2.6-27: Summary of the toxicity studies of M656PH054

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537 *E. coli* WP2 uvrA	Negative	Woitcowiak C., 2014c#[1] ASB2014-8455
Gene Mutation Assay	*In vitro* cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells	Negative	[redacted] 2013a#[1] ASB2014-8462
In vitro micronucleus test	Chinese hamster V79 cells	Positive	[redacted] 2013#[1] ASB2014-8468
In vivo micronucleus test	Polychromatic erythrocytes (PCE) in the bone marrow of the mouse	Negative	[redacted] 2014b#[1] ASB2014-8473
28-day	Rat 1200, 4000 and 12000/9250 ppm administered via diet	12000/9250 ppm: food consumption in males ↓, bw development in male and female ↓ NOAEL 4000 ppm (346 mg/kg bw/d, corrected for 86.5 % purity)	[redacted] 2014e#[1] ASB2014-8420

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

However, in the *in vitro* micronucleus test in in V79 cells conducted with M656PH054 a potential chromosomal aberration effect was observed with metabolic activation. In contrast, in the subsequently conducted *in vivo* micronucleus test in mice no treatment related induction of

micronuclei could be determined up to the limit dose of 2000 mg/kg, a dose level with clear clinical signs of toxicity. Plasma analytics confirmed that M656PH054 was systemically available. Thus, the *in vivo* study conducted for the same endpoint did not demonstrate a treatment related effect. By weight of evidence M656PH054 was not considered to be genotoxic.
The available data on systemic toxicity – short-term toxicity study in rats – clearly demonstrated that the compound is of low toxicity and thus less toxic than the parent molecule dimethenamid-P.

Toxicological evaluation of metabolite M656H055 former assigned M55:
M656H055 is a groundwater metabolite. Exposure levels via groundwater, predicted by the applicant, are 0.1 µg/L < M656H055 ≤ 0.75 µg/L.
For M656H055 structural alerts (QSAR) for presumed degradates were identified for chromosomal aberration *in vitro*. M656H055 was, however, not genotoxic in the *in vitro* and *in vivo* genotoxicity studies conducted fulfilling the requirements for evaluation of groundwater metabolites.

Table 2.6-28: Summary of the toxicity studies of M656H055

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537 *E. coli* WP2 uvrA	Negative	Woitcowiak C., 2012a#[1] ASB2014-8456
Gene Mutation Assay	Chinese Hamster CHO cells (HPRT locus assay)	Negative	[redacted] 2013a#[1] ASB2014-8488
In vivo micronucleus test	Polychromatic erythrocytes (PCE) in the bone marrow of the mouse	Negative	[redacted] 2014a#[1] ASB2014-8474

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

Toxicological evaluation of metabolite M656PH059 former assigned M59/M60/M61:
M656PH059 is a groundwater metabolite. Exposure levels via groundwater, predicted by the applicant, are 0.75 µg/L < M656PH059 ≤ 4.5 µg/L.
Based on the failure of synthesis efforts experienced with M656PH049 and M656PH052, synthesis of M656PH059 was not considered feasible (Jilderda, K., 2014; ASB2014-8610).
No conclusive toxicological alert (QSAR) is identified and the toxicological evaluation is made based on the grouping proposal (member of the M27 group) presented and discussed in Vol. 3.

Toxicological evaluation of metabolite M656PH062 former assigned M62:
M656PH062 is a groundwater metabolite. The exposure levels in groundwater, predicted by the applicant, are 0.75 µg/L < M656PH062 ≤ 4.5 µg/L.
Studies were conducted with the ethylester derivative of M656PH062 as M656PH062 could not be stably synthetised. Overall, with regard to *in vitro* genotoxicity testing there was no indication for mutagenicity neither in the bacterial Ames test nor in the mammalian Mouse Lymphoma test from the studies conducted with ethylester derivative of M656PH062. However, in the *in vitro* micronucleus test in in V79 cells conducted with ethylester derivative of M656PH062 a potential chromosomal aberration effect was observed without and with metabolic activation. In contrast, in the subsequently conducted *in vivo* micronucleus test in mice no treatment related induction of micronuclei could be determined up to the limit dose of 2000 mg/kg a dose level with clear clinical signs of toxicity. Plasma analytics confirmed that ethylester derivative of M656PH062 was systemically available. Thus, the *in*

vivo study conducted for the same endpoint did not demonstrate a treatment related effect. By weight of evidence M656PH062 was not considered to be genotoxic.
The available data on systemic toxicity - short-term toxicity study in rats - demonstrated that M656PH062 is of no higher toxicity than the parent molecule dimethenamid-P.

Table 2.6-29: Summary of the toxicity studies of ethylester derivate of M656PH062

Study	Test system	Result	Reference
Bacterial mutagenicity	Reverse mutation assay *Salmonella typhimurium* strains TA 98, 100, 1535 and 1537 *E. coli* WP2 uvrA	Negative	Woitcowiak C., 2012b#[1] ASB2014-8457
Gene Mutation Assay	*In vitro* cell mutation assay at the Thymidine Kinase Locus (TK+/-) in mouse lymphoma L5178Y cells	Negative	[redacted] 2013c#[1] ASB2014-8464
In vitro micronucleus test	Chinese hamster V79 cells	Positive	[redacted] 2014#[1] ASB2014-8469
In vivo micronucleus test	Polychromatic erythrocytes (PCE) in the bone marrow of the mouse	Negative	[redacted] 2014c#[1] ASB2014-8475
28-day	Rat 1200, 4000, 8000 and 12000/8000 ppm	12000/8000 ppm: bw gain ↓, food consumption ↓ altered clinical chemistry parameters, absolute and relative liver weights ↑, moderate centrilobular liver cell hypertrophy in females, follicular hypertrophy/hyperplasia of the thyroid 4000 ppm: bw gain ↓, absolute and relative liver weight ↑, low incidence of minimal centrilobular liver cell hypertrophy in females, considered treatment related but not adverse NOAEL: 4000 ppm (323 mg/kg bw/d)	[redacted] 2014f#[1] ASB2014-8421

* Reported in the original DAR Dimethenamid-P - Vol. 3, Annex B.6: Toxicology and Metabolism September 2000 (ASB2010-10566).
\# Submitted within the Renewal Process for the Renewal Assessment Report.
[1] The study has been evaluated as acceptable in the Renewal Assessment Report.

2.6.10 Summary of medical data and information

A survey was conducted in 1992 that did not report any cases of skin irritation, skin sensitisation or other adverse health effects in personnel handling racemic dimethenamid and dimethenamid products. Furthermore no direct observation of e.g. clinical cases or poisoning incidents, no observations on exposure of the general population and no epidemiology studies were reported. Specific signs of

poisoning or clinical tests were not known.
This information was already reported in the original monograph of the RMS Germany of Sep. 12, 2000 has been evaluated by European authorities and Germany as RMS (European Commission Peer Review Program).
Information on medical data obtained since then has been collected and evaluated and a literature search has been conducted to extend the evaluation basis.
Thus, it can be concluded that there were no adverse health effects during research, production and use of dimethenamid-P and its formulations.

2.6.11 Toxicological end point for assessment of risk following long-term dietary exposure - ADI

For Annex I inclusion of dimethenamid-P as laid down in the review report for the active substance dimethenamid-P (SANCO/1402/2001-Final of 3 July 2003) and approved in the Commission Directive 2003/84/EC of 25 September 2003 an Acceptable Daily Intake (ADI) was established on the basis obtained from the 1 year dog study, representing the lowest NOAEL (2 mg/kg bw/day) in comparison to the chronic and carcinogenicity studies in rat and mice and thus the highest dose not causing harmful effects. An ADI value of 0.02 mg/kg bw/day was calculated taking into account a total safety factor of 100.
Considering the toxicological profiles of dimethenamid-P and racemic dimethenamid, a risk for the consumer of treated crops in terms of acute toxicity, organotoxicity, genotoxicity, and carcinogenicity is not discernable. There is no evidence for bioaccumulation. The 2-generation study in rats and the oral developmental studies in rats and rabbits have shown that dimethenamid-P has no primary reproductive toxicity.
No additional data have been provided for re-evaluation of dimethenamid-P that would affect the basis of the derived reference value agreed upon for Annex I inclusion of dimethenamid-P as laid down in the review report for the active substance dimethenamid-P (SANCO/1402/2001-Final of 3 July 2003) and approved in the Commission Directive 2003/84/EC of 25 September 2003.

Table 2.6-30: Summary of toxicity studies conducted with dimethenamid-P and racemic dimethenamid relevant for deriving an ADI

Study	Test substance	NOAEL [mg/kg bw/day]	LOAEL [mg/kg bw/day]
104-week, diet, Sprague-Dawley rat	Racemic dimethenamid	5 (100 ppm)	36 (700 ppm)
94-week, diet, CD-1 mice	Racemic dimethenamid	40 (300 ppm)	200 (1500 ppm)
13-week, diet, Beagle dog	Racemic dimethenamid	4.3 (91.5 ppm)	34 (750 ppm)
52-week, diet, Beagle dog	Racemic dimethenamid	2 (50 ppm)	10 (250 ppm)

However, considering the end points that have been addressed in the toxicological studies it is obvious that the same end points have been addressed in the 13-week and 1 year dog studies (TOX1999-423; TOX1999-424; TOX1999-433). In both dog studies body weight gain and the liver were affected at the lowest-observed-adverse-effect level (LOAEL). It can be assumed that the different dose spacing in both dog studies resulted in different no-observed-adverse-effect levels (NOAELs) and lowest-observed-adverse-effect levels (LOAELs). Therefore, it seems to be appropriate to consider the studies together. The two dog studies are comparable, including consideration of study design, end points addressed, and strain of animal. In such a situation an ‘overall NOAEL’ can be derived. The ‘overall NOAEL’ should be the highest value identified in the available studies that provides a reasonable margin (≥2) over the lowest LOAEL (World Health Organisation and Food and Agriculture Organisation of the United Nations Rome, 2004, FAO Plant Production and Protection Paper, 178 Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004.
Therefore an Acceptable Daily Intake (ADI) is proposed on the basis of an ‘overall NOAEL’ obtained

from the 13-week and 1 year dog studies, representing the lowest NOAEL in comparison to the chronic and carcinogenicity studies in rat and mice and thus the highest dose not causing harmful effects.
In consideration of the quality, extent and consistency of the toxicological data base and the absence of specific effects of concern, a total safety factor of 100 is proposed, which takes into account differences attributable to inter- and intra-species variability.

Thus an ADI of 0.04 mg/kg bw/d based on the 'overall NOAEL' of the 13-week and the 52-week dog studies is proposed.

2.6.12 Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

No additional data have been provided for re-evaluation of dimethenamid-P that would affect the derived reference value agreed upon for Annex I inclusion of dimethenamid-P as laid down in the review report for the active substance dimethenamid-P (SANCO/1402/2001-Final of 3 July 2003) and approved in the Commission Directive 2003/84/EC of 25 September 2003.
For the determination of an ARfD, results from oral studies that used acute or sub-acute (up to 28-day) short-term exposure are the most relevant studies to be considered, provided the study design is sufficient to derive a NOAEL. Consequently the acute neurotoxicity study conducted with dimethenamid-P as well as the 4-day short-term mechanistic study conducted with racemic dimethenamid in addition to the 28-day studies in rats and the prenatal toxicity studies in rats and rabbits need to be considered. The table below (see Table 2.6-31) summarises the NOAELs and LOAELs of these studies. The acute oral toxicity studies aiming to derive a LD_{50} conducted with either dimethenamid-P or dimethenamid are not considered to be applicable to derive an ARfD.

Table 2.6-31: NOAELs and LOAELs from oral acute and sub-acute studies

Study	Test substance	NOAEL [mg/kg bw/day]	LOAEL [mg/kg bw/day]
Acute neurotoxicity study, rat	Dimethenamid-P	200	600
4-day - Liver enzyme induction study, rat	Racemic dimethenamid	25	100
5-week study, rat	Racemic dimethenamid	29	96
Developmental toxicity, rat	Dimethenamid-P	<25	25
	Racemic dimethenamid	50	215
Developmental toxicity, rabbit	Racemic dimethenamid	37.5	75

The overall lowest NOAEL relevant for use in ARfD calculations was 25 mg/kg bw/day in the 4 day liver enzyme induction study in rats conducted with racemic dimethenamid ([redacted] 1994; TOX1999-449) supported by 5-week study in rats conducted with racemic dimethenamid ([redacted] 1987; TOX1999-468) and the developmental toxicity study conducted with dimethenamid-P ([redacted] 199; TOX1999-440). It should however be noted that due to the dose spacing in the developmental toxicity studies in rats an overall NOAEL of 50 mg/kg bw/day was derived which is by factor 2 higher. An extensive and reliable toxicological database evaluating all major endpoints of toxicity has been developed for dimethenamid-P, and clear no adverse effect levels have been determined for all treatment related effects. As for ADI and AOEL calculation, an assessment factor of 100 was applied for derivation of the ARfD.

Thus, the proposed ARfD is 0.25 mg/kg bw.

2.6.13 Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

No additional data have been provided for re-registration of dimethenamid-P that would affect the derived reference value agreed upon for Annex I inclusion of dimethenamid-P as laid down in the review report for the active substance dimethenamid-P (SANCO/1402/2001-Final of 3 July 2003) and approved in the Commission Directive 2003/84/EC of 25 September 2003.
According to the principles of Annex VI to Directive 91/414 EEC, the proposed AOEL should be based on the highest level at which no adverse effect is observed in tests in the most sensitive relevant animal species.
For the risk assessment of the operator or worker as well as bystander and resident the results of the short-term toxicity including neurotoxicity and immunotoxicity studies and reproduction/ developmental toxicity studies are considered the most relevant in order to calculate an AOEL. Given the application practice of an early growth stage applied herbicide the exposure period to be considered is adequately covered by up to 90-day studies.
The NOAELs and LOAELs of up to 90-day repeated-dose studies including endpoint specific studies for neurotoxicity and immunotoxicity and reproductive toxicity studies are summarised in the following table:

Table 2.6-32: NOAELs and LOAELs from oral repeat-dose endpoint specific and reproductive toxicity studies

Study	Test substance	NOAEL [mg/kg bw/day]	LOAEL [mg/kg bw/day]
5-week, oral rat, range-finder	Racemic dimethenamid	29	95.6
13-week, oral rat	Dimethenamid-P	37	110
	Racemic dimethenamid	34	98
13-week, oral dog	Racemic dimethenamid	4.3	34
1-year, oral dog	Racemic dimethenamid	2	10
2-generation rat	Racemic dimethenamid	50	150
Developmental toxicity, rat	Dimethenamid-P	<25	25
	Racemic dimethenamid	50	215
Developmental toxicity, rabbit	Racemic dimethenamid	37.5	75
90-day neurotoxicity study, rats	Dimethenamid-P	63	323
28-day immunotoxicity study, mice (females)	Dimethenamid-P	120	385

In the case of dimethenamid, systemic effects are considered to be of primary significance, since in the studies submitted for assessment of reproductive and developmental toxicity; all the relevant findings (reduced pup or foetal weight, increased incidence of abortions, etc.) were associated with pronounced systemic paternal and maternal toxicity.
The signs of toxicity observed in short-term toxicity studies with rats, mice and dogs were overall similar with the liver as the target organ. The effects observed typically included the increase in one or more serum liver enzymes and changes in cholesterol. Pathology confirmed the liver to be a target organ. Increased liver weights were observed in all three species probably indicative of an adaptive response to exposure. Histologically, hepatocyte hypertrophy was observed in rats and hepatocyte vacuolation and dilation of liver sinusoids occurred in dogs.
The most sensitive species is the dog. Considering the end points that have been addressed in the toxicological studies it is obvious that the same end points have been addressed in the 13-week and 1 year dog studies (TOX1999-423; TOX1999-424; TOX1999-433). In both dog studies body weight gain and the liver were affected at the lowest-observed-adverse-effect level (LOAEL). It can be assumed that the different dose spacing in both dog studies resulted in different no-observed-adverse-

effect levels (NOAELs) and lowest-observed-adverse-effect levels (LOAELs). Therefore it seems to be appropriate to consider the studies together. The two dog studies are comparable, including consideration of study design, end points addressed, and strain of animal. In such a situation an 'overall NOAEL' can be derived. The 'overall NOAEL' should be the highest value identified in the available studies that provides a reasonable margin (≥2) over the lowest LOAEL (World Health Organisation and Food and Agriculture Organisation of the United Nations Rome, 2004, FAO Plant Production and Protection Paper, 178 Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004).
Therefore an AOEL is proposed on the basis of an 'overall NOAEL' obtained from the 13-week and 1 year dog studies, representing the lowest NOAEL in comparison to other relevant oral repeat-dose studies and thus the highest dose not causing harmful effects.
In consideration of the quality, extent and consistency of the toxicological data base and the absence of specific effects of concern, a total safety factor of 100 is proposed, which takes into account differences attributable to inter- and intra-species variability.

Thus an AOEL of 0.04 mg/kg bw/d based on an 'overall NOAEL' obtained from the 13-week and 1 year dog studies is proposed.

2.6.14 Summary of product exposure and risk assessment

BAS 656 12 H containing 720 g/L dimethenamid-P is a herbicide used for foliar spray application on maize, soybean, sunflower and sugar beet at a maximum rate of 1.2 L product/ha. The estimated operator exposure calculated with the German model and the AOEM is below the systemic AOEL when PPE is considered (German model: 498 % of the $AOEL_{syst}$ without PPE; 36 % of the $AOEL_{syst}$ with gloves during mixing/loading and application and coverall during application; AOEM: 189 % of the $AOEL_{syst}$ without PPE; 11 % of the $AOEL_{syst}$ with gloves during mixing/loading and application) whereas no safe use could be demonstrated when exposure was calculated with the UK POEM and the use of gloves was considered (4695 % of the $AOEL_{syst}$ without PPE; 745 % of the $AOEL_{syst}$ with gloves during mixing/loading and application). The estimated exposure of workers, bystanders and residents does not exceed the systemic AOEL.

BAS 830 01 H containing 333 g/L dimethenamid-P and 167 g/L quinmerac is used for the treatment of winter oilseed rape at an application rate of 1.5 L product/ha. The risk assessment for dimethenamid-P revealed that the estimated operator exposure will not exceed the systemic AOEL according to the German model if the operator wears gloves during mixing/loading and a coverall during application (331 % of the $AOEL_{syst}$ without PPE; 81 % of the $AOEL_{syst}$ with PPE) and to the AOEM if the operator wears gloves during mixing/loading (184 % of the $AOEL_{syst}$ without PPE; 71 % of the $AOEL_{syst}$ with PPE). However, according to the UK POEM the estimated operator exposure will exceed the systemic AOEL of dimethenamid-P even if gloves are used during mixing/loading and application (3842 % of the $AOEL_{syst}$ without PPE; 595 % of the $AOEL_{syst}$ with PPE). No unacceptable risk was identified for workers, bystanders and residents.

The detailed calculations are presented in Volume 3, B.6 (product level).

2.7 Residues

2.7.1 Summary of storage stability of residues

Storage stability in frozen crop matrices was evaluated during the initial EU Review of the active substance dimethenamid-P by the RMS Germany (DAR, 2000, ASB2010-10566). It was considered applicable to extrapolate data on the stability of dimethenamid-P residues from the data on dimethenamid, the racemic mixture of S-dimethenamid (dimethenamid-P) and R-dimethenamid. However re-evaluation revealed that it is not possible to determine storage stabilities based on neither

nominal recoveries nor day 0 standardised recoveries due to the analytical variability of the data. If however the stability recoveries are adjusted for concurrent recoveries, a storage stability of 21 and 12 months can be set in maize forage, silage, grain and fodder for dimethenamid and M23, respectively. In conclusion, the study can be considered as supplementary only.
A new storage stability study was submitted with the renewal dossier for dimethenamid-P and its metabolites M23, M26, M27 and M30. All analytes are stable under deep frozen conditions (<-20 °C) for at least 24 months in commodities with high acid content (strawberry), high water content (maize whole plant), high starch content (maize seed) and high protein content (dry beans). Shorter storage times are determined for M26 in strawberry and whole maize plant with 12 and 3 months, respectively, and for M30 in strawberry with 18 months. Additionally, storage stability could not be proven for M27 in maize seed (recoveries after 45 days at 60 %). Since M27 is not included in the residue definition, this is considered not relevant.
In high oil content matrices (oilseed rape) neither dimethenamid-P nor its metabolites are found to be stable with recoveries ranging between 44 and 69 % after 31 days of storage. The applicant argued that problems with the extraction could have been the reason for these low recoveries, despite of acceptable concurrent recoveries. Consequently an additional storage stability study using the identical extraction method was provided by the applicant for high oil matrices only (oilseed rape seed, soya bean seed and sunflower seed). In this interim report a storage stability of dimethenamid and it metabolites could be proven for up to 3 months. The improved stability recoveries in oily matrices compared to the study by Lehmann (2014, ASB2014-8339) were explained by the applicant by the use of a high speed homogeniser instead of a low speed homogeniser. Assuming a smaller particle size when using the high speed homogeniser, the RMS considered this as an acceptable explanation, as it is known that extraction efficiency increases with smaller particles size.
The storage stability of dimethenamid in various organic solvents could be demonstrated up to 12 days.

2.7.2 Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

2.7.2.1 Metabolism in plants

Plant metabolism studies have been provided for the crop categories cereal (maize), pulses and oilseeds (soya bean) and root crops (sugar beet) covering all representative uses. During and following the initial EU review of dimethenamid-P studies were evaluated for maize, sugar beet and soya bean (DAR, 2000, ASB2010-10566). For the renewal, new studies were provided additionally for maize and soya beans, confirming the findings of the previous evaluated studies for these crops. Due to analytical limitations with regards to analyte identification, the older studies for maize and soya bean were therefore considered as supplementary only.
The main route of metabolism was similar in all crops investigated. It involves rapid glutathione conjugation of dimethenamid-P, enzymatic cleavage of the tripeptide and subsequent metabolic reactions on the resulting cysteine conjugate (loss of the amino group of the cysteine moiety and S-oxidation). Various sulphur containing secondary metabolism products (modified cysteine conjugates) M30, M31 (or isomer), M26 and M37 (or isomer) represented the major part of the extractable radioactive residues. A second metabolic route is hydrolytic/oxidative displacement of the chlorine atom, followed by glycosylation (to form one to several isomers of the metabolite M40) or further transformation (e.g. oxidation, leading to the oxalamide M23, or cleavage of the acetamide to form the amine metabolite M39).
Residues in edible parts of the plants were all below 0.01 mg eq/kg. The only metabolites contributing to more than 10 % TRR were M26 and M30 in maize forage (DAT 30) and M26 in soya bean leaves. No parent was detected all crops investigated.

2.7.2.2 Metabolism in poultry

During the initial EU Review of the active substance dimethenamid-P the metabolism was investigated in laying hen (DAR, 2000, ASB2010-10566). After administration of racemic ^{14}C-dimethenamid to laying hens, the radioactivity was rapidly excreted (77 % of the total applied dose at sacrifice) while only a minor fraction of the TRR was found in edible tissues and egg. No individual metabolites were detected in edible tissues and egg, with the exception of dimethenamid in fat and M3 and M8 in liver. Metabolite M30, which is the major plant metabolite, was detected in excreta equal to 3.5 % TRR. Dimethenamid was rapidly and extensively metabolised and excreted. The metabolic pathway was via glutathione conjugation, reductive dechlorination followed by the formations of cysteine and mercapturate conjugations, and dimerisation of a mercaptan intermediate as can be seen in excreta. The other pathways included O-demethylation and reductive dechlorination. Metabolism in hen is similar to metabolism in rats. As the study was performed with the parent dimethenamid, which was not detected in any of the plant metabolism studies, it does not reflect the actual exposure scenario if poultry is fed with feed treated with dimethenamid. However, the study can still be considered acceptable since M30 was detected in excreta and is therefore bioavailable in poultry.

2.7.2.3 Metabolism in lactating ruminants

A metabolism study on lactating goat was evaluated during the initial process of Annex 1 listing under Directive 91/414/EEC (DAR, 2000, ASB2010-10566). This study was conducted using racemic dimethenamid. Therefore, the metabolism of the dimethenamid-P was covered since the racemic mixture contained 50 % of the herbicidal active R-enantiomer (dimethenamid-P). The radioactivity was also rapidly excreted after the administration of ^{14}C-dimethenamid to lactating goats. More than 59 % and 28 % of the dose was excreted in the urine and faeces, respectively. The residue concentrations in milk were below 0.98 mg/kg and kidney, fat, muscle and liver were 9.92, 0.97, 0.97 and 16.62 mg/kg, respectively. Dimethenamid was rapidly and extensively metabolised in the goat study. The major metabolic pathway was through glutathione conjugation, followed by the formations of cysteine, mercapturate, sulfoxide of thioglycolic acid conjugations, and dimerisation of a mercaptan intermediate. The other pathways included O-demethylation and reductive dechlorination. In liver, M22 (dimer), M17 (mercapturate conjugate), M24 (glutathione conjugate) and M25 (cysteine conjugate) were found. In kidney, M7 (O-demethylated parent), M17, M24 and M25 were found. The analysis of milk indicated M17, M24 and M25. For muscle, the main metabolites were: M17, M24 and M25. Metabolites in fat were M7 and M17. In urine and faeces, metabolites M3 (reductive dechlorinated), M7, M17, M24, M25, and M31 (sulfoxide of thioglycolic acid) were identified.
However, this study was considered supplementary only; as metabolism studies in plant and from field trials showed no residue of parent dimethenamid-P at all. Thus, it can be assumed that livestock is not exposed to dimethenamid-P. On the other hand metabolite M30 is found in plant metabolism studies and is most frequently detected in controlled field trials. Therefore the applicant submitted a metabolism study performed with M30 in the lactating goat.

In this study one lactating goat was administered ten consecutive daily oral doses of ^{14}C-M30. The average actual dose was 0.5663 mg/kg body weight/day. The majority of the radioactive residue was present in the urine (51.7 %), faeces (36.8 %) and GI tract contents (11.7 %). The total radioactive residues in milk, muscle and fat were very low and accounted for a maximum of 0.018 mg/kg. The residues in the other edible matrices accounted for 0.219 mg/kg (liver) and 0.243 mg/kg (kidney). In total, the radioactivity associated with edible portions (milk and tissues) accounted for 0.2 % of the administered dose. M30 was extensively metabolised in the lactating goat. The unchanged M30 was found in portions below 24 % TRR in matrices except in bile where M30 comprised 40 % TRR. The main component in urine and faeces was M26, indicating that urinary and faecal excretion is the major elimination pathway accounting for 89 % of the administered dose. In extracts of milk, liver, kidney, loin muscle and renal fat the main components were M26 and M30. The metabolite M2 was formed by demethylation of the ether group and substitution of the 2-hydroxypropanoic acid with a methyl group, followed by oxidation of the sulphur group to sulfoxide and subsequent conjugation with glucuronic acid leading to M98. Further oxidation of M2 to the corresponding sulfone led to M14 followed by

glucuronidation yielding M96. M2, M14, and M96 were present in some tissue extracts, generally at lower levels.

2.7.3 Definition of the residue

In the process of Annex 1 listing under Directive 91/414/EEC (DAR, 2000, ASB2010-10566) the residue definition (monitoring and risk assessment) for food of plant and animal origin was proposed as:

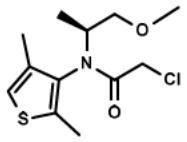
"dimethenamid, dimethenamid-P sum expressed as dimethenamid".

The current legal residue definition for monitoring and the one proposed for MRL setting under Reg. (EU) 396/2005 (EFSA 2013, ASB2013-6081) is:

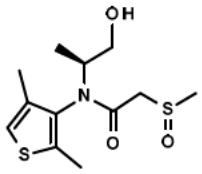
"*dimethenamid-P (dimethenamid-P including other mixtures of constituent isomers (sum of isomers))*".

The additionally submitted metabolism studies (maize, soya bean, and lactating goat) and a new rotational crop metabolism study make a re-assessment of the residue definition necessary. A list of identified residues including their relative and absolute levels is given in the following tables.

(1) Dimethenamid-P
Parent dimethenamid-P is relevant for inclusion into the residue definition for plants by default. In a laying hen metabolism study using dimethenamid, the parent was detected equal to 0.075 mg/kg (26 % TRR) in fat. However, the study was overdosed and moreover, as the parent was not detected in any of the plant metabolism studies, exposure via feed can be excluded. A validated analytical method from residue field trials is available.

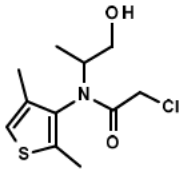
No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
Dimethenamid-P BAS 656P H 363851 For dimethenamid: BAS 656 H 360720 S-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)-acetamide		Dosed as dimethenamid: Laying hen fat: 0.075 mg/kg, 26.23 % TRR Rat urine: <0.1-0.7 % of administered dose Rat faeces: 0.8-2.1 % of administered dose

(2) M2
Not relevant for inclusion into the residue definition for plant or animal matrices. Minor metabolite only found in animals. M2 was also found in the rat metabolism and therefore its toxicological properties are covered by parent dimethenamid-P. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M2 For dimethenamid-P M656PH002		Dosed as dimethenamid-P: Lactating goat liver: 0.010 mg/kg, 4.5 % TRR Lactating goat kidney: 0.014 mg/kg, 5.9 % TRR Rat urine: 2.4-9.9 % of administered dose Rat faeces: <0.1 % of administered dose

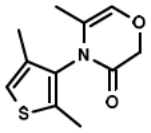
(3) M7

Not relevant for inclusion into the residue definition for plant or animal matrices. This metabolite only occurs in overdosed animal metabolism study performed with racemic dimethenamid. As the metabolite is directly formed from the parent dimethenamid, and neither the metabolite nor the parent were detectable in any plant metabolism studies, exposure of animals via feed can be excluded. Moreover, the metabolite was not detected in the goat metabolism study performed with M30. M7 was also found in the rat metabolism. However, as M7 levels are reported together with M1 and do not occur at levels >10 % of the administered dose, its toxicological properties are not covered by the parent dimethenamid-P. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M7 For dimethenamid M656H007 360718		Dosed as dimethenamid: Laying hen liver: 0.429 mg/kg, 5.1 % TRR Lactating goat kidney: 2.388 mg/kg, 24.1 % TRR Rat urine: 0.4-5.9 % of administered dose together with M1 Rat faeces: 0.1-4.5 % of administered dose together with M1

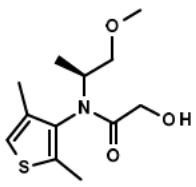
(4) M8

Metabolite only occurs in overdosed laying hen metabolism study performed with racemic dimethenamid. The metabolite is directly formed from the parent via M7. Since neither the metabolites nor the parent were detectable in any plant metabolism studies, exposure of animals via feed can be excluded. Moreover, the metabolite was not detected in the goat metabolism study performed with M30. M8 was only found in minor amounts and its toxicological properties are not covered by parent dimethenamid. Therefore it is not relevant for inclusion into the residue definition for plant or animals. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M8 For dimethenamid M656H008		Dosed as dimethenamid: Laying hen liver: 0.650 mg/kg, 7.8 % TRR Rat urine: <0.1-0.3 % of administered dose Rat faeces: <0.1-0.2 % of administered dose

(5) M11

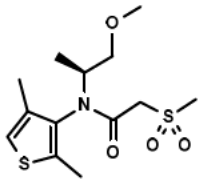
Minor plant metabolite found in soya bean leaves only. Since soya bean leaves are an inedible commodity and its contribution to the dietary burden is also minor, the metabolite is not considered relevant for an inclusion into the residue definition for plants. M11 was only found in minor amounts and its toxicological properties are not covered by parent dimethenamid. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M11 For dimethenamid-P M656PH011 5886786		Dosed as dimethenamid-p: Soya bean leaf: 0.038 mg/kg, 1.5 % TRR[1] Rat urine: <0.1-0.4 % of administered dose Rat faeces: <0.1-1.5 % of administered dose

[1] Together with M26

(6) M14

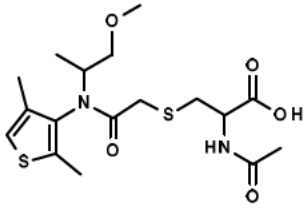
Metabolite found in animals and non-edible soya matrices only. As its contribution to the dietary burden is considered minor, the metabolite is not considered relevant for an inclusion into the residue definition for plants. M14 was only found in minor amounts and its toxicological properties are not covered by parent dimethenamid. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M14 For dimethenamid-P M656PH014		Dosed as dimethenamid-P: Soya bean leaf: 0.135 mg/kg, 5.2 % TRR[1] Soya bean hull: 0.010 mg/kg, 1.2 % TRR[1] Soya bean rest of plant: 0.007 mg/kg, 1.2 % TRR[1] Lactating goat milk: 0.001 mg/kg, 5.8 % TRR Lactating goat liver: 0.013 mg/kg, 6.1 % TRR Lactating goat kidney: 0.011 mg/kg, 4.6 % TRR Lactating goat muscle: 0.001 mg/kg, 7.3 % TRR Rat urine: 0.9-3.9 % of administered dose Rat faeces: 0.1-2.1 % of administered dose

[1] Combination of M14 isomer A/M14 isomer B/M30/others

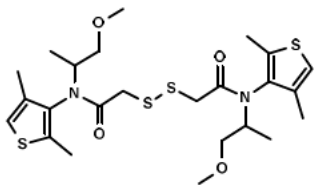
(7) M17

Not relevant for inclusion into the residue definition for plant or animal matrices. The metabolite only occurred in an overdosed goat metabolism study performed with racemic dimethenamid. Since neither the metabolites nor the parent were detectable in any plant metabolism studies, exposure of animals via feed can be excluded. Moreover, the metabolite was not detected in the goat metabolism study performed with M30. M17 was only found in minor amounts and its toxicological properties are not covered by parent dimethenamid. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M17 For dimethenamid M656H017		Dosed as dimethenamid: Lactating goat kidney: 0.889 mg/kg, 9.0 % TRR Lactating goat liver: 0.445 mg/kg, 2.7 % TRR Rat urine: 0.2-3.7 % of administered dose Rat faeces: <0.1-0.2 % of administered dose

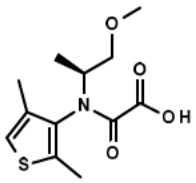
(8) M22

Not relevant for inclusion into the residue definition for plant or animal matrices. The metabolite only occurred in an overdosed goat metabolism study performed with racemic dimethenamid. Since neither the metabolites nor the parent were detectable in any plant metabolism studies, exposure of animals via feed can be excluded. Moreover, the metabolite was not detected in the goat metabolism study performed with M30. M22 was only found in minor amounts and its toxicological properties are not covered by parent dimethenamid. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M22 For dimethenamid M656H022		Dosed as dimethenamid: Lactating goat liver: 1.016 mg/kg, 6.1 % TRR Rat faeces: 0.1-1.0 % of administered dose

(9) M23

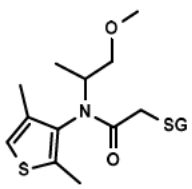
With the exception of sugar beet root, the metabolite was found in non-edible plant matrices only. As significant amounts were detected only in an older, less reliable metabolism study in soya bean, the metabolite is not considered relevant for an inclusion into the residue definition for plants. M23 was also found in the rat metabolism and therefore its toxicological properties are covered by parent dimethenamid-P. A validated analytical method from residue field trials is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M23 For dimethenamid-P M656PH023 5886780 For dimethenamid M656H023 360715		Dosed as dimethenamid-P: Soya bean leaf: 0.053 mg/kg, 2.1 % TRR[1] Soya bean hull: 0.015 mg/kg, 1.9 % TRR[1] Soya bean rest of plant: 0.005 mg/kg, 0.7 % TRR[1] Dosed as dimethenamid: Maize forage: 0.011 mg/kg, 3.6 % TRR Maize silage: 0.002-0.014 mg/kg, 0.6-3.6 % TRR Maize fodder: 0.007 mg/kg, 1.4 % TRR Soya bean forage: 0.47 mg/kg, 16.8 % TRR Soya bean hay: 0.14 mg/kg, 5.3 % TRR Soya bean seed: 0.03 mg/kg, 6.6 % TRR Sugar beet roots: 0.001 mg/kg, 1.1 % TRR RC carrot top: 0.001 mg/kg, 2.2 % TRR

[1] Together with M51

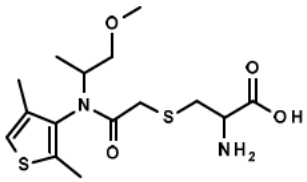
(10) M24

Not relevant for inclusion into the residue definition for plant or animal matrices. The metabolite only occurs in overdosed goat metabolism study performed with racemic dimethenamid. The metabolite is directly formed from parent dimethenamid by conjugation with glutathione. Since neither the metabolite nor the parent were detectable in any plant metabolism studies, exposure of animals via feed can be excluded. Moreover, the metabolite was not detected in the goat metabolism study performed with M30. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M24 For dimethenamid M656H024		Dosed as dimethenamid: Lactating goat kidney: 0.516 mg/kg, 5.2 % TRR Lactating goat liver: 0.366 mg/kg, 6.1 % TRR

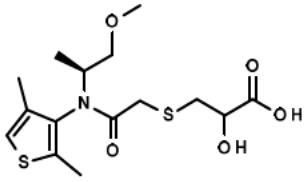
(11) M25

Not relevant for inclusion into the residue definition for plant or animal matrices. The metabolite only occurs in overdosed goat metabolism study performed with racemic dimethenamid. The metabolite is directly formed from the parent dimethenamid by conjugation with glutathione. Since neither the metabolite nor the parent were detectable in any plant metabolism studies, exposure to animals via feed can be excluded. Moreover, the metabolite was not detected in the goat metabolism study performed with M30. M25 was only found in minor amounts and its toxicological properties are not covered by the parent dimethenamid. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M25 For dimethenamid M656H025		Dosed as dimethenamid: Lactating goat kidney: 0.122 mg/kg, 1.23 % TRR Lactating goat liver: 1.198 mg/kg, 7.2 % TRR Rat urine: <0.1-0.9 % of administered dose Rat faeces: <0.1-0.2 % of administered dose

(12) M26

The metabolite is relevant for inclusion into the residue definition for plant matrices. Significant residues occurred in plant (maize forage). This is considered relevant as field trials for leafy crops were provided by the applicant for MRL setting purposes (trials not yet reported here), but no metabolism study for this crop category. Consequently maize forage can be considered as a substitute for leafy crops. In the context of MRL setting, M26 was also detected in the edible parts of commodities from additional field trials (not reported yet). With regards to animal matrices, M26 occurred in significant amounts in liver and kidney of a goat metabolism study performed with M30. If however, these residues are extrapolated to the calculated dietary burden, the theoretical residues are <0.01 mg/kg. M26 was only found in minor amounts and its toxicological properties are not covered by the parent dimethenamid. Consequently M26 does not require the inclusion into the residue definition for food of animal origin. A validated analytical method from residue field trials is available.

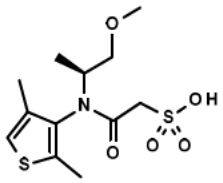
No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M26 For dimethenamid-P M656PH026 5886781 For dimethenamid M656H026 360716		Dosed as dimethenamid-P: Maize forage: 0.077 mg/kg, 10.8 % TRR Maize forage/husk: 0.002 mg/kg, 1.3 % TRR Maize grain/cobs: <0.0005 mg/kg, 0.6 % TRR Maize straw: 0.006 mg/kg, 1.2 % TRR Maize cobs: <0.0005 mg/kg, 0.4 %TRR Soya bean leaf: 0.038 mg/kg, 1.5 % TRR[1] Lactating goat milk: 0.002 mg/kg, 13.2 % TRR Lactating goat liver: 0.011 mg/kg, 5.0 % TRR Lactating goat kidney: 0.060 mg/kg, 24.8 % TRR Lactating goat muscle: 0.002 mg/kg, 12.2 % TRR Lactating goat fat: 0.002 mg/kg, 16.5 % TRR Dosed as dimethenamid Maize forage: 0.007 mg/kg, 2.3 % TRR Maize silage: 0.005-0.017 mg/kg, 1.2-4.2 % TRR

[1] Together with M11

(13) M27

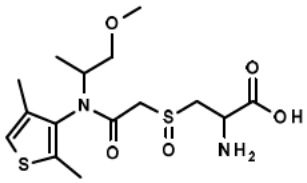
The metabolite is not relevant for inclusion into the residue definition for plant matrices. Significant

residues occurred in inedible plant matrices (soya bean leaves and hay). Toxicity studies performed with M27 were available and it was concluded the metabolite is not of toxicological relevance. A validated analytical method from residue field trials is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M27 For dimethenamid-P M656PH027 5912598 For dimethenamid M656H027		Dosed as dimethenamid-P: Soya bean leaf: 0.321 mg/kg, 12.4 % TRR Soya bean hull: 0.009 mg/kg, 1.1 % TRR Soya bean rest of plant: 0.016 mg/kg, 2.6 % TRR Dosed as dimethenamid: Maize forage: 0.019 mg/kg, 6.1 % TRR Maize silage: 0.030 mg/kg, 7.4 % TRR Maize fodder: 0.013 mg/kg, 2.5 % TRR Soya bean forage: 0.2 mg/kg, 7.0 % TRR Soya bean hay: 0.28 mg/kg, 10.6 % TRR Soya bean seed: 0.03 mg/kg, 7.5 % TRR Sugar beet roots: 0.005 mg/kg, 6.0 % TRR Sugar beet leaves: 0.019 mg/kg, 6.5 % TRR RC spring wheat immature: 0.002-0.008 mg/kg, 6.6-12.5 % TRR

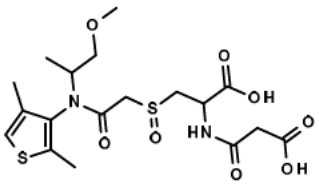
(14) M28

Not relevant for inclusion into the residue definition for plant matrices. M28 is a minor metabolite occurring in insignificant amounts only in sugar beet. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M28 For dimethenamid M656H028		Dosed as dimethenamid: Sugar beet roots: 0.002 mg/kg, 2.3 % TRR

(15) M29

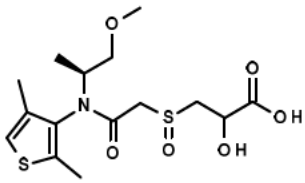
Not relevant for inclusion into the residue definition for plant matrices. M29 is a minor metabolite occurring in insignificant amounts only in sugar beet. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M29 For dimethenamid M656H029		Dosed as dimethenamid: Sugar beet roots: 0.004 mg/kg, 5.7 % TRR Sugar beet leaves: 0.003 mg/kg, 1.0 % TRR

(16) M30

The metabolite is relevant for inclusion into the residue definition for plant matrices. Significant residues occurred in plant (maize forage, soya bean leaves). This is considered relevant as field trials

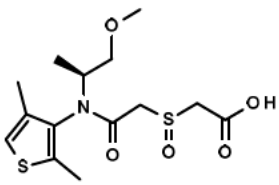
for leafy crops were provided by the applicant for MRL setting purposes, but no metabolism study for this crop category. Consequently maize forage and soya beans can be considered as a substitute for leafy crops. In the context of MRL setting M30 was also detected in green onions and curly kale. Additionally, significant residues were detected in the liver and kidney of a lactating goat metabolism studies. Since M30 is a major residue in potential feed items, a significant carry-over into animal commodities cannot be excluded. If however, these residues are extrapolated to the calculated dietary burden, the theoretical residues are <0.01 mg/kg. Toxicity studies performed with M30 were available and it was concluded the metabolite is not of toxicological relevance. Consequently M30 does not require the inclusion into the residue definition for food of animal origin. A validated analytical method from residue field trials is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M30 For dimethenamid-P M656PH030 5296352 For dimethenamid M656H030		Dosed as dimethenamid-P: Maize forage: 0.128 mg/kg, 17.9 % TRR Maize forage/husk: 0.008 mg/kg, 4.6 % TRR Maize grain/cobs: <0.0005 mg/kg, 0.6 % TRR Maize straw: 0.031 mg/kg, 6.4 % TRR Maize husks: 0.001 mg/kg, 2.2 % TRR Maize cobs: <0.0005 mg/kg, 0.8 %TRR Soya bean leaf: 0.135 mg/kg, 5.2 % TRR[1] Soya bean hull: 0.010 mg/kg, 1.2 % TRR[1] Soya bean rest of plant: 0.007 mg/kg, 1.2 % TRR[1] Lactating goat milk: 0.001 mg/kg, 7.6 % TRR Lactating goat liver: 0.027 mg/kg, 12.4 % TRR Lactating goat kidney: 0.048 mg/kg, 19.8 % TRR Lactating goat muscle: 0.002 mg/kg, 14.1 % TRR Lactating goat fat: 0.003 mg/kg, 23.7 % TRR Dosed as dimethenamid: Maize forage: 0.005 mg/kg, 1.7 % TRR Maize silage: 0.012 mg/kg, 2.9 % TRR Maize fodder: 0.003 mg/kg, 0.7 % TRR Soya bean forage: 0.17 mg/kg, 6.0 % TRR[2] Soya bean hay: 0.20 mg/kg, 7.8 % TRR[2] Soya bean seed: 0.04 mg/kg, 11.7 % TRR[2] Sugar beet leaves: 0.027 mg/kg, 9.4 % TRR RC winter wheat straw: 0.01 mg/kg, 5.7 % TRR RC lettuce: 0.004 mg/kg, 10.7 % TRR RC spring wheat straw: 0.004 mg/kg, 3.1 % TRR RC carrot tops: 0.002-0.003 mg/kg, 3.1-4.1 % TRR Rat urine: <0.1-0.2 % of administered dose Rat faeces: <0.1-0.1 % of administered dose

[1] Combination of M14 isomer A/M14 isomer B/M30/others
[2] Combination of M30 and M31

(17) M31

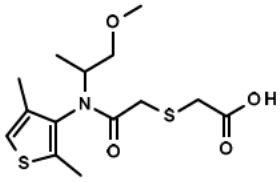
With the exception of soya bean seed, the metabolite was found in insignificant amounts in non-edible plant matrices only. As the significant amounts found in soya bean were detected only in an older, less reliable metabolism study, the metabolite is not considered relevant for an inclusion into the residue definition for plants. M31 was also found in the rat metabolism and therefore its toxicological properties are covered by parent dimethenamid-P. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M31 For dimethenamid-P M656PH031 5886777 For dimethenamid M656H031 360712		Dosed as dimethenamid-P: Maize forage: 0.031 mg/kg, 4.4 % TRR Maize forage/husk: 0.005 mg/kg, 2.6 % TRR Maize grain/cobs: <0.0005 mg/kg, 0.6 % TRR Maize straw: 0.012 mg/kg, 2.5 % TRR Maize husks: <0.0005 mg/kg, 0.4 % TRR Maize cobs: <0.0005 mg/kg, 0.4 %TRR Maize grain: <0.0005 mg/kg, 0.2 %TRR Soya bean leaf: 0.025 mg/kg, 1.0 % TRR Soya bean hull: 0.006 mg/kg, 0.8 % TRR Soya bean rest of plant: 0.010 mg/kg, 1.6 % TRR Dosed as dimethenamid Maize forage: 0.005 mg/kg, 1.4 % TRR Maize silage: 0.015 mg/kg, 3.7 % TRR Maize fodder: 0.010 mg/kg, 2.0 % TRR Soya bean forage: 0.17 mg/kg, 6.0 % TRR[1] Soya bean hay: 0.20 mg/kg, 7.8 % TRR[1] Soya bean seed: 0.04 mg/kg, 11.7 % TRR[1]

[1] Combination of M30 and M31

(18) M32

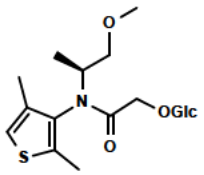
Not relevant for inclusion into the residue definition for plant matrices. M32 is a minor metabolite occurring in insignificant amounts only. M31 was also found in the rat metabolism and therefore its toxicological properties are covered by parent dimethenamid-P. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M32[1] For dimethenamid M656H032 395234		Dosed as dimethenamid: Maize forage: 0.011 mg/kg, 3.7 % TRR Maize silage: 0.002-0.015 mg/kg, 0.6-3.6 % TRR Maize fodder: 0.028 mg/kg, 5.6 % TRR

[1] Thioglycolic acid M32 plus M11 plus other unknowns which additional TLC analysis of soil demonstrated this band to be a multi-component as found also in maize seedlings (non-GLP study).

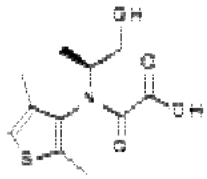
(19) M40

Not relevant for inclusion into the residue definition as plant metabolite. M40 was detected at 11.7 % TRR in maize forage/husks, but the residue concentration was only 0.021 mg/kg and is about 10 times lower compared to M26 and M30 in maize forage. M40 is the glucuronidated metabolite of M11, which was also identified in the rat metabolism. Since M11 is covered by the toxicological reference values of the parent substance, the contribution of M40 is insignificant to the overall exposure. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M40 For dimethenamid-P M656PH040		Dosed as dimethenamid-P: Maize forage: 0.017 mg/kg, 2.3 % TRR Maize forage/husk: 0.021 mg/kg, 11.7 % TRR Maize grain/cobs: <0.0005 mg/kg, 2.7 % TRR Maize straw: 0.023 mg/kg, 4.7 % TRR Maize husks: 0.001 mg/kg, 2.3 % TRR Maize cobs: <0.0005 mg/kg, 1.1 % TRR Maize grain: <0.0005 mg/kg, 1.1 % TRR Soya bean leaf: 0.034 mg/kg, 1.3 % TRR

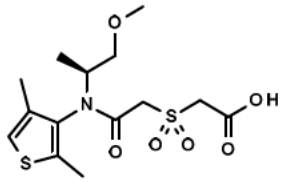
(20) M50

Not relevant for inclusion into the residue definition for plant matrices. M50 is a minor metabolite occurring in non-edible parts of soya beans only. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M50 For dimethenamid-P M656PH081		Dosed as dimethenamid-P: Soya bean leaf: 0.093 mg/kg, 3.6 % TRR Soya bean rest of plant: 0.011 mg/kg, 1.7 % TRR

(21) M51

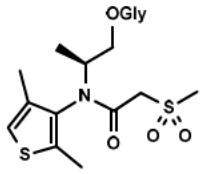
Not relevant for inclusion into the residue definition for plant matrices. M51 is a minor metabolite occurring in non-edible plant parts only. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M51 For dimethenamid-P M656PH051 SES16802		Dosed as dimethenamid-P: Soya bean leaf: 0.053 mg/kg, 2.1 % TRR[1] Soya bean hull: 0.015 mg/kg, 1.9 % TRR[1] Soya bean rest of plant: 0.005 mg/kg, 0.7 % TRR[1] RC white radish top: <0.001 mg/kg, 1.3 % TRR RC spring wheat forage: 0.001-0.005 mg/kg, 2.8-4.2 % TRR RC spring wheat hay: 0.003-0.021 mg/kg, 2.6-2.9 % TRR RC spring wheat straw: 0.002-0.008 mg/kg, 1.5 % TRR

[1] Together with M23

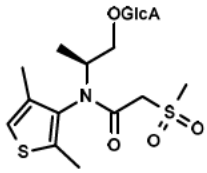
(22) M81

M81 is a metabolite occurring in edible plant parts (radish tops are considered a surrogate for leafy brassica). Being the glycosylated metabolite of M14, M81 was also identified in the rat metabolism. However, M14 did occur in very small amounts only and can therefore not be considered as toxicologically covered by the parent substance. Therefore the metabolite is considered as provisionally relevant for inclusion into the residue definition for plant matrices**. The applicant has proposed to perform a grouping approach of metabolite M14, as well as a QSAR evaluation as this is considered a data gap.** No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M81 For dimethenamid-P M656PH050		Dosed as dimethenamid-P: Soya bean leaf: 0.019 mg/kg, 0.7 % TRR RC white radish top: <0.001-0.1 mg/kg, 1.7-11.2 % TRR RC spring wheat forage: 0.001-0.006 mg/kg, 4.4-5.3 % TRR RC spring wheat hay: 0.004-0.026 mg/kg, 3.2-3.4 % TRR RC spring wheat straw: 0.005-0.014 mg/kg, 2.8-3.3 % TRR

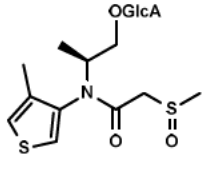
(23) M96

Not relevant for inclusion into the residue definition for plant or animal matrices. M96 occurred in significant amounts in the kidney of a goat metabolism study performed with M30. If however, these residues are extrapolated to the calculated dietary burden, the theoretical residues are <0.01 mg/kg. M96 was also found in the rat metabolism and therefore its toxicological properties are covered by the parent dimethenamid-P. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M656PH096		Dosed as dimethenamid-P: Lactating goat liver: 0.001 mg/kg, 0.6 % TRR Lactating goat kidney: 0.035 mg/kg, 14.4 % TRR Lactating goat muscle: 0.001 mg/kg, 3.5 % TRR

(24) M98

Not relevant for inclusion into the residue definition for plant or animal matrices. M98 occurred in significant amounts in the kidney of a goat metabolism study performed with M30. If however, these residues are extrapolated to the calculated dietary burden, the theoretical residues are <0.01 mg/kg. M98 was also found in the rat metabolism and therefore its toxicological properties are covered by parent dimethenamid-P. No validated analytical method is available.

No., codes and chemical names	Structure	Occurence in metabolism (plant and amimal) and rotational crop metabolism studies
M656PH098		Dosed as dimethenamid-P: Lactating goat milk: 0.002 mg/kg, 13.4 % TRR Lactating goat liver: 0.011 mg/kg, 5.3 % TRR Lactating goat kidney: 0.032 mg/kg, 13.4 % TRR Lactating goat muscle: 0.002 mg/kg, 12.8 % TRR Lactating goat fat: 0.002 mg/kg, 14.1 % TRR

2.7.3.1 Proposed residue definition for plants

Residue definition for risk assessment:
The parent dimethenamid-P was not detected in primary and rotational crop metabolism studies, but is considered relevant by default. Additionally the metabolites M26 and M30 are included in the residue definition. The decision to include the metabolites was based on the fact that
i) these metabolites were detected in significant amounts (>10 % TRR) in soya bean leaves (M30) and maize forage (M26) and
ii) were detected in field trials.
Additionally, the applicant provided for MRL setting purposes supplementary field trials where M26 and M30 detected in the edible parts of green onions and curly kale.

In addition, metabolite M81 was detected in edible plant parts (radish tops are considered a surrogate for leafy brassica) during a rotational crop study. M81 is the glycosylated metabolite of M14, which was also identified in the rat metabolism. However, M14 did occur in very small amounts only and cannot be considered as toxicologically covered by parent substance. Hence, until a conclusion on the relevance of M81 can be made, the following residue definition for risk assessment has to be considered as provisional.

Sum of dimethenamid-P + metabolite M26, and M30, expressed as dimethenamid-P (provisional)

Residue definition for monitoring:
The parent dimethenamid-P was not detected in primary and rotational crop metabolism studies, but is considered relevant by default. Additionally, in supplementary field trials with spring onions and leafy cabbage M30 was detected in the edible parts. Consequently it is proposed to set the residue definition for monitoring as:

Sum of stereoisomers of dimethenamid + metabolite M30, expressed as dimethenamid-P

Validated monitoring methods for the analysis of dimethenamid-P and metabolite M30 in plants are available.

2.7.3.2 Proposed residue definition for animal matrices

Residue definition for risk assessment:
As no residues of dimethenamid-P arise in metabolism studies or residue trials in any feed item at relevant harvest intervals, it is unlikely that livestock animals will be exposed to the parent compound. However, since livestock animals may be exposed via animal feeds to residues of M30, a new goat metabolism study with this metabolite was included in this submission. In this study a goat was dosed with metabolite M30 at 0.5663 mg/kg bw/day, which resulted in residues up to 0.048 and 0.027 mg eq/kg in liver and kidney, respectively (see B.7.2.3). Extrapolation of these residues to the calculated dietary burden resulted in theoretical residues of 0.005 mg/kg in kidney and 0.003 mg/kg in liver.
Therefore neither a consideration in risk assessment nor MRLs are required. It has to be kept in mind however, that due to additional uses in the future the dietary burden could increase, thereby making a feeding study and consequently the setting of a residue definition indispensable. It is therefore concluded to propose the residue definition for risk assessment as:

Sum of metabolites M26 and M30, expressed as dimethenamid-P (provisional)

Residue definition for monitoring:
As metabolite M30 was identified as the main metabolite in liver and kidney, the residue definition for monitoring is proposed as:

Sum of stereoisomers of metabolite M30, expressed as dimethenamid-P (provisional)

2.7.4 Representative uses

Maize

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at early post-emergence stage up to BBCH 16. PHI is covered by the growing period between application and harvest.

Table 2.7-1: Overview of the selected supervised residue trials for dimethenamid-P in maize

Commodity	Region[a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[b]	HR (mg/kg)[c]	Median CF[d]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Maize grain	NEU	Outdoor	<0.017 (7)	<u><0.025</u> (7)	0.025	0.025	n/a
Maize plant (forage)	NEU	Outdoor	<0.017 (6), 0.020, 0.025	<u><0.025</u> (6), 0.028, 0.033	0.025	0.033	<u>1.3, 1.4</u>
Maize grain	SEU	Outdoor	<0.017 (8)	<u><0.025</u> (8)	0.025	0.025	n/a
Maize plant (forage)	SEU	Outdoor	<0.017 (4), 0.025, 0.047, 0.18. 0.81	<u><0.025 (4), 0.032</u>, 0.054, 0.21, 0.98	0.029	0.82	<u>1.2 (3), 1.3</u>

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A sufficient number of acceptable trials for NEU and SEU was provided by the applicant. It should be noted however, that sample storage time of metabolite M26 in high water content commodities (forage) was not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR.

Soya bean

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at pre-emergence stage up to BBCH 09. PHI is covered by the growing period between application and harvest.

Table 2.7-2: Overview of the selected supervised residue trials for dimethenamid-P in soya bean

Commodity	Region[a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[b]	HR (mg/kg)[c]	Median CF[d]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Soya bean seed	NEU	Outdoor	<0.017 (8)	<u><0.025</u> (8)	0.025	0.025	n/a
Soya bean plant	NEU	Outdoor	<0.017 (8)	<u><0.025</u> (8)	0.025	0.025	n/a
Soya bean seed	SEU	Outdoor	<0.017 (8)	<u><0.025</u> (8)	0.025	0.025	n/a
Soya bean plant	SEU	Outdoor	<0.017 (7), 0.020	<u><0.025</u> (8), 0.028	0.025	0.028	1.4

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A sufficient number of acceptable trials for NEU and SEU was provided by the applicant. It should be noted however, that sample storage time of metabolite M26 in high water content commodities (plant) was not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR.

Sunflower

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at pre-emergence stage up to BBCH 09. PHI is covered by the growing period between application and harvest.

Table 2.7-3: Overview of the selected supervised residue trials for dimethenamid-P in sunflower

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Sunflower seed	NEU	Outdoor	<0.017 (12)	<u>≤0.025</u> (12)	0.025	0.025	n/a
Sunflower seed	SEU	Outdoor	<0.017 (11)	<u>≤0.025</u> (11)	0.025	0.025	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A sufficient number of acceptable trials for NEU and SEU was provided by the applicant.

Sugar beet

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at pre-emergence stage up to BBCH 09. The PHI is covered by the growing period between application and harvest.

Table 2.7-4: Overview of the selected supervised residue trials for dimethenamid-P in beet

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Beet leaf	NEU	Outdoor	<0.017 (8)	<u>≤0.025</u> (8)	0.025	0.025	n/a
Beet root	NEU	Outdoor	<0.017 (8)	<u>≤0.025</u> (8)	0.025	0.025	n/a
Beet leaf	SEU	Outdoor	<0.017 (4)	<u>≤0.025</u> (4)	0.025	0.025	n/a
Beet root	SEU	Outdoor	<0.017 (4)	<u>≤0.025</u> (4)	0.025	0.025	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A sufficient number of acceptable trials for NEU and SEU was provided by the applicant. These trials are also considered acceptable for fodder beet and red beet. It should be noted however, that sample storage time of metabolite M26 in high water content commodities (beet leaf) was not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR.

Oilseed rape

The cGAP in N+SEU is 1 x 0.500 kg as/ha spray application at post-emergence stage up to BBCH 18. The PHI is covered by the growing period between application and harvest.

Table 2.7-5: Overview of the selected supervised residue trials for dimethenamid-P in oilseed rape

Commodity	Region[a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[b]	HR (mg/kg)[c]	Median CF[d]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Oilseed rape seeds	NEU	Outdoor	<0.017 (8)	<u>≤0.025</u> (8)	0.025	0.025	n/a
Oilseed rape plant	NEU	Outdoor	<0.017 (2), 0.017, 0.021, 0.022, 0.043, 0.054, 0.073	<0.025 (2), 0.025, <u>0.029</u> (2), 0.051, 0.062, 0.081	0.029	0.081	1.1, <u>1.2</u> (2), <u>1.3</u>, 1.4, 1.5
Oilseed rape seeds	SEU	Outdoor	<0.017 (3)	<u>≤0.025</u> (3)	0.025	0.025	n/a
Oilseed rape plant	SEU	Outdoor	<0.017 (3)	<u>≤0.025</u> (3)	0.025	0.025	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A sufficient number of acceptable trials for NEU and SEU was provided by the applicant. It should be noted however, that sample storage time of metabolite M26 in high water content commodities (plant) was not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR.

2.7.5 MRL Application

Tree nuts, pome fruit and stone fruit

No trials were provided by the applicant. As dimethenamid-P is applied to soil surface under the trees, infiltration in deeper soil layers and uptake by the roots followed by translocation into the fruits might be possible in principle. However, significant residues of dimethenamid-P metabolites in rotational crop studies (at 1.2N) were only found at a PBI of 30 days. Given that dimethenamid-P is not applied to tree nuts after BBCH 55 and to pome fruit and stone fruit not between BBCH 76 (Fruit about 60 % final size) and harvest, it is assumed that no residues occur from the intended uses. Consequently no trials are required.

Carrot

No trials were provided. The applicant should provide at least 8 trials with carrots (4 trials if residues < 0.01 mg/kg per analyte) for N+SEU each. **This is considered a data gap.**

Swedes, turnips and horseradish

No trials were provided. However, as the GAP for swedes, turnips and horseradish is less critical than the one for sugar beets and a no-residue situation was seen in sugar beet roots, extrapolation from sugar beets is possible in agreement with SANCO 7525/VI/95 - rev.10.1 (EC, 2015).

Welsh/spring onions

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at post-emergence stage up to BBCH 14. PHI is covered by the growing period between application and harvest.

Table 2.7-6: Overview of the selected supervised residue trials for dimethenamid-P in Welsh/spring onions

Commodity	Region[a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[b]	HR (mg/kg)[c]	Median CF[d]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Welsh/spring onions	NEU	Outdoor	<0.02 (2), 0.02, 0.04	<u><0.03 (2), 0.03</u>, 0.04	0.03	0.04	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

As spring onions are considered a minor crop, 4 trials are considered sufficient for NEU. According to the GAP, uses in SEU Member States are intended as well, but no trials were provided. However, since 4 trials for leeks in SEU were provided, extrapolation is possible in agreement with SANCO 7525/VI/95 - rev.10.1 (EC, 2015). It should also be noted that sample storage time for metabolite M26 is not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR.

Leek

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at post-emergence stage up to BBCH 18. PHI is covered by the growing period between application and harvest.

Table 2.7-7: Overview of the selected supervised residue trials for dimethenamid-P in leek

Commodity	Region[a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[b]	HR (mg/kg)[c]	Median CF[d]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Leek	SEU	Outdoor	<0.02 (4)	<u><0.03 (4)</u>	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 4 supervised residue trials (all SEU) were provided by the applicant. All trials are considered acceptable and residues in the commodity at harvest were consistently < 0.01 mg/kg per analyte. Consequently 4 trials are considered sufficient. However, sample storage time for metabolite M26 is not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR. According to the GAP, uses in NEU Member States are intended as well, but no trials were provided for that region. However, since 4 trials for green onions in NEU were provided, extrapolation is possible in agreement with SANCO 7525/VI/95 - rev.10.1 (EC, 2015).

Cucumber, zucchini and patisson

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at post-emergence stage up to BBCH 16. PHI is covered by the growing period between application and harvest.

Table 2.7-8: Overview of the selected supervised residue trials for dimethenamid-P in cucumber

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Cucumber	NEU	Outdoor	<0.02 (4)	<0.03 (4)	0.03	0.03	n/a

Table 2.7-9: Overview of the selected supervised residue trials for dimethenamid-P in zucchini

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Zucchini	NEU	Outdoor	<0.02 (4)	<0.03 (4)	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 8 supervised residue trials were performed in NEU on cucumbers and zucchini, respectively, with 4 trials each. All residues were < LOQ. Hence, the dataset may be used for the entire group of cucurbits with edible peel. However, sample storage time for metabolite M26 is not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR. According to the GAP, uses in S-EU Member States (FR) are intended as well, but no trials were provided.

Melon, pumpkin and oil pumpkin

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at post-emergence stage up to BBCH 16. PHI is covered by the growing period between application and harvest.

Table 2.7-10: Overview of the selected supervised residue trials for dimethenamid-P in melon

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Melon	NEU	Outdoor	<0.02 (4)	<0.03 (4)	0.03	0.03	n/a

Table 2.7-11: Overview of the selected supervised residue trials for dimethenamid-P in pumpkin

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Pumpkin	NEU	Outdoor	<0.02 (4)	<0.03 (4)	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 8 supervised residue trials were performed in NEU on melon and pumpkin, with 4 trials each. All residues were < LOQ. Hence, the dataset may be used for the entire group of cucurbits with inedible peel. For oil pumpkin, even though residues refer to the total fruit the number of trials is nevertheless considered sufficient to conclude that residues in seeds will not be in excess of the limit of analytical quantification. It should be noted that sample storage time for metabolite M26 is not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR. According to the GAP, uses in SEU Member States (FR) are intended as well, but no trials were provided.

Sweet corn

The cGAP in N+SEU is 1 x 0.864 kg as/ha spray application at post-emergence stage up to BBCH 16. PHI is covered by the growing period between application and harvest. According to Commission Regulation (EU) No 752/2014, kernels with cob and without husks should be used for MRLs on sweet corn. In the trials however, residues were reported for maize cob with husks at silage stage. This is considered more conservative since the husks were included.

Table 2.7-12: Overview of the selected supervised residue trials for dimethenamid-P in sweet corn

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Maize cob with husks, silage stage	NEU	Outdoor	<0.02 (4)	<u><0.03 (4)</u>	0.03	0.03	n/a
Maize cob with husks, silage stage	SEU	Outdoor	<0.02 (4)	<u><0.03 (4)</u>	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 8 trials (4 x SEU and 4 x NEU) were provided. This is considered to be sufficient as all residues were < LOQ.

Flowering brassicas

The cGAP in N+SEU is 1 x 0.720 kg as/ha spray application at post-emergence stage up to BBCH 16. The proposed PHI is set to 35 days.

Table 2.7-13: Overview of the selected supervised residue trials for dimethenamid-P in cauliflower

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Cauliflower	NEU	Outdoor	<0.02 (2)	<u><0.03 (2)</u>	0.03	0.03	n/a
Cauliflower	SEU	Outdoor	<0.02 (4)	<u><0.03 (4)</u>	0.03	0.03	n/a

Table 2.7-14: Overview of the selected supervised residue trials for dimethenamid-P in broccoli

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Broccoli	NEU	Outdoor	<0.02 (2)	<u><0.03 (2)</u>	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 6 trials performed with cauliflower (4 SEU and 2 NEU) and 2 trials performed with broccoli (NEU) were provided by the applicant covering application rates between 460 and 530 g a.s/ha. With the application rate according to the cGAP being 720 g/ha, all trials have to be considered underdosed, even if the 25 % rule is applied. However, the data may be used in support of a fall-back GAP with an application rate of 500 g/ha. As the treatment is made at an early growth stage (up to BBCH 18) and no residues were detected in flowers at commercial harvest in any of the trials, all data on cauliflower and broccoli across the EU can be combined. It should be noted that the sample storage period for metabolite M26 is not covered by the storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR.

Brussels sprouts

The cGAP in N+SEU is 1 x 0.720 kg as/ha spray application at post-emergence stage up to BBCH 16. The proposed PHI is set to 90 days.

Table 2.7-15: Overview of the selected supervised residue trials for dimethenamid-P in Brussels sprouts

Commodity	Region[a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[b]	HR (mg/kg)[c]	Median CF[d]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Brussels sprouts	NEU	Outdoor	<0.02 (4)	<u><0.03 (4)</u>	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 4 supervised residue trials (all NEU) were provided by the applicant. Residues in all samples were < 0.01 mg/kg per analyte. Consequently, the number of trials is considered sufficient. However, sample storage time for metabolite M26 is not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR. According to the GAP, uses in SEU Member States (FR) are intended as well, but no trials were provided.

Head cabbage

The cGAP in N+SEU is 1 x 0.720 kg as/ha spray application at post-emergence stage up to BBCH 16. PHI is covered by the growing period between application and harvest.

Table 2.7-16: Overview of the selected supervised residue trials for dimethenamid-P in head cabbage

Commodity	Region[a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[b]	HR (mg/kg)[c]	Median CF[d]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Head cabbage	NEU	Outdoor	<0.02 (2)	<u><0.03 (2)</u>	0.03	0.03	n/a
Head cabbage	SEU	Outdoor	<0.02 (3)	<u><0.03 (3)</u>	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.

(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 7 supervised residue trials (4 SEU and 3 NEU) performed with white cabbage were provided by the applicant. Two trials were not considered acceptable as their application rate was not within the 25 % rule of the cGAP. As the residue in all samples was < 0.01 mg/kg per analyte, the number of trials remaining is considered sufficient. However, sample storage time for metabolite M26 is not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR.

Leafy brassica

The cGAP in N+SEU is 1 x 0.720 kg as/ha spray application at post-emergence stage up to BBCH 16. The proposed PHI is set to 60 days.

Table 2.7-17: Overview of the selected supervised residue trials for dimethenamid-P in Chinese cabbage

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Chinese cabbage	SEU	Outdoor	<0.02, 0.03 (2), 0.06	<0.03, 0.03, 0.04, 0.06	0.04	0.06	n/a

Table 2.7-18: Overview of the selected supervised residue trials for dimethenamid-P in curly kale

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Curly kale	NEU	Outdoor	<0.02 (3), 0.02	<0.03 (3), 0.03	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 4 trials performed with 490 to 530 g as/ha on Chinese cabbage (SEU) and 4 trials performed with 480 to 510 g as/ha on kale (NEU) were provided by the applicant. With the application rate according to the cGAP being 720 g/ha, all trials have to be considered underdosed, even if the 25 % rule is applied. However, the data may be used in support of a fall-back GAP with an application rate of 500 g/ha. As the treatment is made at an early growth stage (up to BBCH 18) and no residues were detected, the trials for Chinese cabbage and kale were combined. Sample storage time for metabolite M26 is not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR.

Green bean, climbing bean (fresh)

The cGAP in N+SEU is 1 x 0.850 kg as/ha spray application at post-emergence stage up to BBCH 14. PHI is covered by the growing period between application and harvest.

Table 2.7-19: Overview of the selected supervised residue trials for dimethenamid-P in green beans

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Green beans	NEU	Outdoor	<0.02 (8)	<u><0.03 (8)</u>	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

A total of 8 supervised residue trials (all NEU) were provided by the applicant. All trials are considered acceptable and residues were consistently < 0.01 mg/kg per analyte both in pods with seeds, fresh and seeds without pods, fresh. However, sample storage time for metabolite M26 is not covered by storage stability studies evaluated in Vol. 3, section B.7.1.1 of the RAR. According to the GAP, uses in SEU member states are intended as well, but no trials were provided.

Vicia bean (dry)

The cGAP in N+SEU is 1 x 0.850 kg as/ha spray application at post-emergence stage up to BBCH 14. PHI is covered by the growing period between application and harvest.

Table 2.7-20: Overview of the selected supervised residue trials for dimethenamid-P in vicia bean (dry)

Commodity	Region[(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg)[(b)]	HR (mg/kg)[(c)]	Median CF[(d)]
			Monitoring (Sum of dimethenamid-P + metabolite M30, expressed as dimethenamid-P)	Risk assessment (Sum of dimethenamid-P + metabolite M26 and M30, expressed as dimethenamid-P)			
Beans (dry)	NEU	Outdoor	<0.02 (8)	<u><0.03 (8)</u>	0.03	0.03	n/a

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial

The trials performed with garden bean were used for dry vicia bean, since the dried seed was analysed for residues of dimethenamid-P and metabolites as well. A total of 8 supervised residue trials (all NEU) were provided by the applicant. All trials are considered acceptable and residues were consistently < 0.01 mg/kg per analyte. According to the GAP, uses in S-EU Member States are intended as well, but no trials were provided.

Lupin

No trials were provided. However, as the GAP for lupins is identical to that on dry beans extrapolation from dry beans is possible in agreement with SANCO 7525/VI/95 rev.10.1 (EC, 2015).

Millet and sorghum

Residue trials were provided neither on millet nor on sorghum. However, as the GAP for millet and

sorghum is identical to the cGAP of maize, extrapolation from maize is possible in agreement with SANCO 7525/VI/95 rev.10.1 (EC, 2015).

Witloof/Belgian endive, chicory roots

No trials were provided. However, since the treatment in the field occurs at an early growth stage of the crop (up to BBCH 18) and taking into account that sprouts are forced from roots indoors, quantifiable residues are not anticipated to occur in witloof. Likewise, with a view to the results seen in the trials on sugar beet, residues in chicory roots are also not expected above the LOQ (table 3 of SANCO 7525/VI/95 - rev.10.1 (EC, 2015)). Hence, no trials are required.

2.7.6 Summary of feeding studies in poultry, ruminants, pigs and fish

For the calculation of the livestock dietary burden only metabolite M30 was taken into consideration. The reasons for doing so were i) no parent dimethenamid was detected in primary or rotational crop metabolism studies, as well as in animal feed commodities from field trials, ii) M30 occurred as the main metabolite in animal feed commodities during primary plant metabolism studies. The input values from the representative uses and MRL application uses are shown in Table 2.7-21.The livestock dietary burden was calculated using the *OECD Animal Intake and Feeding* calculator (OECD, 2013).

Table 2.7-21: Input values for the dietary burden calculation for metabolite M30

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Sugar beet tops	0.01*	STMR	0.01*	HR
Maize forage	0.02	STMR	1.1	HR
Rape forage	0.02	STMR	0.09	HR
Soybean forage	0.01*	STMR	0.01*	HR
Maize grain	0.01*	STMR	0.01*	STMR
Soybean seed	0.01*	STMR	0.01*	STMR
Canola (meal)	0.01*	STMR	0.01*	STMR
Sunflower (meal)	0.01*	STMR	0.01*	STMR
MRL application				
Bean vines	0.01*	STMR	0.01*	HR
Cabbage	0.01*	STMR	0.01*	HR
Kale leaves	0.01*	STMR	0.013	HR
Turnip tops	0.01*	STMR, extrapolated from sugar beet tops	0.01*	HR, extrapolated from sugar beet tops
Turnip roots	0.01*	STMR, extrapolated from sugar beet root	0.01*	HR, extrapolated from sugar beet root
Swede roots	0.01*	STMR, extrapolated from beet root	0.01*	HR, extrapolated from beet root
Bean seed	0.01*	STMR	N/A	
Lupin seed	0.01*	STMR, extrapolated from dry beans	N/A	
Millet grain	0.01*	STMR, extrapolated from maize grain	N/A	
Sorghum grain	0.01*	STMR, extrapolated from maize grain	N/A	

Forages of millet and sorghum were not considered in the dietary burden calculation, as their use as animal feed is rather unusual and extrapolation from maize forage would result in exaggerated intake rates.

Table 2.7-22: Maximum dietary burden estimation of metabolite M30 in cattle, sheep and swine

	Cattle						Sheep						Swine					
	Beef			Dairy			Ram/Ewe			Lamb			Breeding			Finishing		
Body weight (kg)	500			650			75			40			260			100		
Daily intake (DM in kg)	12			25			2.5			1.7			6			3		
Contributor 1	Corn, field	forage/silage	80 %	Corn, field	forage/silage	60 %	Rape	forage	40 %	Rape	forage	40 %	Corn, field	forage/silage	20 %	Swede	roots	40 %
Contributor 2	Swede	roots	20 %	Swede	roots	20 %	Swede	roots	30 %	Swede	roots	30 %	Swede	roots	40 %	Sorghum	grain	60 %
Contributor 3				Sorghum	grain	20 %	Sorghum	grain	30 %	Sorghum	grain	30 %	Sorghum	grain	40 %			
Median intake (mg/kg bw/d)	0.002			0.002			0.002			0.002			0.001			0.001		
Maximum Intake (mg/kg bw/d)	**0.053**			**0.064**			**0.005**			**0.006**			**0.014**			0.001		

Table 2.7-23: Maximum dietary burden estimation of metabolite M30 in poultry

	Poultry								
	Broiler			Layer			Turkey		
Body weight (kg)	1.7			1.9			7		
Daily intake (DM in kg)	0.12			0.13			0.5		
Contributor 1	Swede	roots	10 %	Corn, field	forage/silage	10 %	Swede	roots	10 %
Contributor 2	Sorghum	grain	70%	Swede	roots	10%	Sorghum	grain	50%
Contributor 3	Canola	meal	18%	Sorghum	grain	70%	Canola	meal	20%
Contributor 4				Canola	meal	10%			
Median intake (mg/kg bw/d)	0.001			0.002			0.001		
Maximum Intake (mg/kg bw/d)	0.001			**0.020**			0.001		

The results of the dietary burden calculation are shown in Table 2.7-22 and Table 2.7-23. The trigger value of 0.004 mg/kg bw for the requirement of a feeding study was exceeded for cattle, sheep and breeding swine, as well as for layer poultry (see B.7.4). The exceedance of the trigger was mostly due to residues of metabolite M30 found in maize forage.

In a metabolism study performed with metabolite M30 in a lactating goat dosed at 0.566 mg/kg bw/day (9N), residues of M30 were detected up to 0.048 and 0.027 mg eq/kg in kidney and liver, respectively (see B.7.2.3). Extrapolation of these residues to the calculated dietary burden resulted in theoretical residues of 0.005 mg/kg in kidney and 0.003 mg/kg in liver. Therefore, a feeding study in ruminants is considered not necessary at this point in time.

In a metabolism study performed with racemic dimethenamid in laying hens, M30 was detected in excreta at 3.5 % TRR and is therefore assumed to be bioavailable. If only this fraction of the total dose of 10 mg/kg bw day is considered and compared to the estimated maximum dietary burden of 0.019 mg/kg bw/day, the metabolism study is overdosed by a factor of 18. Additionally, no residues of M30 were detected in edible tissues and eggs. Consequently, a feeding study in poultry is considered not necessary either.

2.7.7 Summary of effects of processing

As the parent dimethenamid-P was not detected in food or feed from controlled field trials, no processing study is formally necessary. On the other hand, metabolite M30 is the predominant residue at relevant harvest intervals in edible commodities and animal feed items. The effects of processing were therefore demonstrated with metabolite M30 which did not hydrolyse at pH 4, pH 5 and pH 6 after 20 min, 60 min and 20 min of incubation of the samples at 90 ± 5, 100 ± 5, and 120 ± 5 °C. Consequently it is assumed that metabolite M30 is not expected to hydrolyse during the pasteurisation (90 °C), baking/brewing/boiling (100 °C), and sterilisation (120 °C).

2.7.8 Summary of residues in rotational crops

During the initial EU review of the active substance, dimethenamid-P residues in rotational crops were investigated using [3-^{14}C-thienyl]-labelled dimethenamid (DAR, 2000, ASB2010-10566). After Annex I inclusion, one additional rotational crop study using ^{14}C-labelled dimethenamid-P was evaluated by France in 2013. Both studies were also reviewed by EFSA under Article 12 (EFSA 2013, ASB2013-6081).
Only moderate translocation of radioactive residues was observed, even further declining during later plant back intervals. Therefore accumulation into rotational crops can be excluded. Dimethenamid-P was extensively metabolised in rotational crop matrices after application to soil and translocation into the plants. This is also indicated by the large fraction of polar metabolites. Individually identified metabolites were M23, M27, M30 (all below 0.01 mg/kg), M51 (up to 0.021 mg/kg, PBI 30 days) and M81 (up to 0.1 mg/kg, PBI 30 days). Based on the identified metabolites in both studies the proposed metabolic pathway can be considered as similar compared to the metabolic pathway identified in the maize, sugar beet, hen, goat and rat metabolism studies.

2.7.9 Summary of other studies

No other studies were submitted.

2.7.10 Estimation of the potential and actual exposure through diet and other sources

The consumer intake and risk assessment for the representative uses alone and in combination with the MRL application uses has been performed with EFSA's PRIMo and nationally with NVS II. The appropriate input values for the intended uses are given in Table 2.7-24. The ADI is proposed equal to **0.04 mg/kg bw/d** on the basis of an overall 90 day and 1 year dog NOAEL (4 mg/kg bw/d) and an uncertainty factor of 100. The ARfD is proposed equal to **0.25 mg/kg bw** on the basis of a 4 day mechanistic rat study NOAEL (25 mg/kg bw/d) and an uncertainty factor of 100.

Table 2.7-24: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Representative uses				
Maize grain	0,03*	STMR	0,03*	STMR
Soya bean seed	0,03*	STMR	0,03*	STMR
Sunflower seed	0,03*	STMR	0,03*	STMR
Sugar beet root	0,03*	STMR	0,03*	HR
Oilseed rape seed	0,03*	STMR	0,03*	STMR
MRL application				
Tree nuts	0.03*	LOQ	0.03*	LOQ
Pome fruit	0.03*	LOQ	0.03*	LOQ
Stone fruit	0.03*	LOQ	0.03*	LOQ
Beet root	0.03*	Extrapolation from sugar beet root	0.03*	Extrapolation from sugar beet root
Swedes	0.03*	Extrapolation from sugar beet root	0.03*	Extrapolation from sugar beet root
Turnips	0.03*	Extrapolation from sugar beet root	0.03*	Extrapolation from sugar beet root
Spring onions/green onions and Welsh onions	0.03*	STMR	0.04	HR
Pumpkin	0.03*	STMR	0.03*	HR
Cucumber	0.03*	STMR	0.03*	HR
Zucchini	0.03*	STMR	0.03*	HR
Melon	0.03*	STMR	0.03*	HR
Sweet corn	0.03*	STMR	0.03*	HR
Flowering brassica	0.03*	STMR	0.03*	HR
Head brassica	0.03*	STMR	0.03*	HR
Leafy brassica	0.03	STMR	0.06	HR
Beans with pods (fresh)	0.03*	STMR	0.03*	HR
Leek	0.03*	STMR	0.03*	HR
Beans (dry)	0.03*	STMR	0.03*	HR
Lupins	0.03*	Extrapolation from dry beans	0.03*	Extrapolation from dry beans
Millet	0.03*	Extrapolation from maize	0.03*	Extrapolation from maize
Sorghum	0.03*	Extrapolation from maize	0.03*	Extrapolation from maize
Chicory root	0.03*	LOQ	0.03*	LOQ
other commodities	variable	MRL	-	not necessary

2.7.10.1 Representative uses

Using EFSA PRIMo, the resulting TMDI (% ADI) is determined equal to 1.4 %, based on UK toddlers. The IESTI (% ARfD) is determined <1 %, based on UK children, 4 - 6 years with sugar beet as the highest contributor.
Using Germany's NVS II, the resulting NTMDI (% ADI) is determined < 1 %, DE general population, 14 - 80 years old. The NESTI (% ARfD) is determined <1 %, based on DE children, 2 - 4 years with sugar beet as the highest contributor.

In conclusion for the representative uses, neither a long-term nor a short-term risk was identified for consumers with dietary exposure to residues of dimethenamid-P and/or metabolites.

2.7.10.2 Representative uses + MRL Application

Using EFSA PRIMo, the resulting TMDI (% ADI) is determined equal to 2.0 %, based on UK toddlers. The IESTI (% ARfD) is determined 1.8 %, based on BE children with melon as the highest contributor.

Using Germany's NVS II, the resulting NTMDI (% ADI) is determined 1.2 %, based on DE children, 2 - 4 years old. The NESTI (% ARfD) is determined 1.1 %, based on DE children 2 - 4 years old, with each, apples and pears as the highest contributors.

In conclusion for the representative uses + MRL application uses, neither a long-term nor a short-term risk was identified for consumers with dietary exposure to residues of dimethenamid-P and/or metabolites.

2.7.10.3 All intended uses + MRLs according to Regulation (EC) No 396/2005

Using EFSA PRIMo, the resulting TMDI (% ADI) is determined equal to 2.9 %, based on UK toddlers. The IESTI (% ARfD) is determined 1.8 %, based on BE children with melon as the highest contributor.

Using Germany's NVS II, the resulting NTMDI (% ADI) is determined 2.4 %, based on DE children, 2 - 4 years old. The NESTI (% ARfD) is determined 1.1 %, based on DE children 2 - 4 years old, with each, apples and pears as the highest contributors.

In conclusion for all intended used + MRLs according to Regulation (EC) No 396/2005, neither a long-term nor a short-term risk was identified for consumers with dietary exposure to residues of dimethenamid-P and/or metabolites.

2.7.11 Proposed MRLs and compliance with existing MRLs

For the representative uses and MRL application uses, the existing EU MRLs, implemented with Regulation (EU) 2015/552 following EFSA's MRL review under Article 12 (EFSA 2013, ASB2013-6081), as well as the MRLs proposed are shown in Table 2.7-25. For animal matrices no MRLs have been proposed at this point, since no residues are expected to occur from the uses assessed so far. This however might change in the future if additional uses are requested for authorisation.

Table 2.7-25: EU MRLs, tentative MRLs under Article 12 and MRLs proposed by the RMS

Code Number	Commodity	Existing EU MRL (mg/kg)	MRL Proposed by RMS (mg/kg)	Comments
Plant matrices				
Existing enforcement residue definition: dimethenamid-P (dimethenamid-P including other mixtures of constituent isomers (sum of isomers)) **Proposed enforcement residue definition:** Sum of stereoisomers of dimethenamid + metabolite M30, expressed as dimethenamid-P				
Representative uses				
401050	Sunflower	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT
401060	Oilseed rape	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT
401070	Soya bean	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT
500030	Maize	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT
900010	Sugar beet	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT
MRL application				
0100000	Tree nuts	0.01*	0.02*	N+SEU. Based on the intended use, residues exceeding the LOQ are not expected
0130000	Pome fruits	0.01*	0.02*	N+SEU. Based on the intended use, residues exceeding the LOQ are not expected
0140000	Stone fruits	0.01*	0.02*	N+SEU. Based on the intended use, residues exceeding the LOQ are not expected
0213010	Beet root	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT extrapolated from sugar beet
0213020	Carrots	0.01*	-	**No trials were provided by the applicant.** **8 trials required for NEU and SEU each.**
0213040	Horseradish	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT extrapolated from sugar beet
0213100	Swedes	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT extrapolated from sugar beet
0213110	Turnips	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT extrapolated from sugar beet
0220040	Spring onions/green onions and Welsh onions	0.01*	0.07	The cGAP of NEU is supported by a sufficient number of CFT. The GAP of SEU is covered by extrapolation from leeks.

Code Number	Commodity	Existing EU MRL (mg/kg)	MRL Proposed by RMS (mg/kg)	Comments
0232000	Cucurbits with edible peel	0.01*	0.02*	The cGAP of NEU is supported by a sufficient number of CFT. No trials were available for SEU.
0233000	Cucurbits with inedible peel	0.01*	0.02*	The cGAP of NEU is supported by a sufficient number of CFT. No trials were available for SEU.
0234000	Sweet corn	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT
0241000	Flowering brassica	0.01*	0.02*	**Trials are underdosed**. Only the fall-back GAP of both NEU and SEU is supported by a sufficient number of CFT
0242000	Head brassica	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT for head cabbage, while for Brussels sprouts no SEU trials are available.
0243000	Leafy brassica	0.01*	0.09	**Trials are underdosed**. Only the fall-back GAP of both NEU and SEU is supported by a sufficient number of CFT.
0255000	Witloof	0.01*	0.02*	Based on the intended use, residues exceeding the LOQ are not expected
0260010	Beans (with pods)	0.01*	0.02*	The cGAP of NEU is supported by a sufficient number of CFT. No trials were available for SEU.
0270060	Leeks	0.01*	0.07	The cGAP of SEU is supported by a sufficient number of CFT, for NEU extrapolation from spring onions is made
0300010	Beans	0.01*	0.02*	The cGAP of NEU is supported by a sufficient number of CFT. No trials were available for SEU.
0300040	Lupins	0.01*	0.02*	The cGAP of NEU is supported by a sufficient number of CFT, extrapolated from dry beans. No trials were available for SEU.
0500040	Millet	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT, extrapolated from maize
0500080	Sorghum	0.01*	0.02*	The cGAP of both NEU and SEU are supported by a sufficient number of CFT, extrapolated from maize
0900030	Chicory root	0.01*	0.02*	Based on the intended use, residues exceeding the LOQ are not expected
Animal matrices				
Existing enforcement residue definition: Sum of metabolites M26 and M30, expressed as dimethenamid-P (provisional) **Proposed enforcement residue definition:** Sum of stereoisomers of metabolite M30, expressed as dimethenamid-P (provisional)				
no MRLs proposed for the time being				

* indicates the lower limit of analytical determination

2.7.12 Proposed import tolerances and compliance with existing import tolerances

None proposed.

2.8 Fate and behaviour in the environment

2.8.1 Summary of fate and behaviour in soil

2.8.1.1 Route of degradation in soil

2.8.1.1.1 Laboratory studies, aerobic

The degradation route of dimethenamid-P was investigated under aerobic conditions in six acceptable soil studies with 6 different soils in total. A brief summary of the study conditions of the soil studies is given in Table 2.8-1. An overview over the radioactive distribution in the investigated soils is given in

Table 2.8-2.

Table 2.8-1: Study conditions of all acceptable route studies in soil under aerobic conditions with dimethenamid (=DMTA) and/or dimethenamid-P (DMTA-P)

Reference	soil	Soil type	pH	oc (%)	T (°C)	Moisture	Durat-ion (d)	Investigated Compound
Koenig, 1995	BBA 2.2	Loamy sand	5.8 ($CaCl_2$)	2.29	20	40 % MWHC	119	DMTA
	BBA 2.3	Sandy loam	6.6 ($CaCl_2$)	1.34				
Koenig, 1996	Flaach	Sandy clay loam	7.95 (n.a.)	1.34	20	40 % MWHC	120	DMTA
Wendt, 1997	Elliot	Clay Loam	6.9 (n.a.)	2.4	23	75 % of FC	120	DMTA & DMTA-P
Staudenmaier, 2013	Borstel	Sand	5.9 ($CaCl_2$)	0.75	20	40 % MWHC	119	R-enantiomer & S-enantiomer of DMTA-P
Staudenmaier, 2009 & 2014	Borstel	Sand	5.9 ($CaCl_2$)	0.75	20	50 % MWHC	119	DMTA-P
Unsworth, 2014	Calke	Sandy loam	4.6 ($CaCl_2$)	3.9	20	pF2	120	DMTA-P

n.a. information on buffer solution not available

Table 2.8-2 Radioactive distribution in all investigated soils under aerobic conditions with dimethenamid (=DMTA) or/and dimethenamid-P (DMTA-P)

Reference	soil	Soil type	CO_2 (%)	Bound residues (%)	Metabolites
Koenig, 1995	BBA 2.2	Loamy sand	Not measured	42.32	M656H023: 9.1 % on day 28 M656H027: 10.89 % on day 42 M656H031: 7.11 % on day 42
	BBA 2.3	Sandy loam		43.45	M656H023: 3.56 % on day 28 M656H027: 13.32 % on day 42 M656H031: 10.34 % on day 28
Koenig, 1996	Flaach	Sandy Clay loam	35.8	41.4	M656H023: 8.4 % on day 21 M656H027: 9.3 % on day 21 M656H031: 4 % on day 28
Wendt, 1997	Elliot	Clay Loam	DMTA: 29.5 DMTA-P: 28.5	DMTA: 39.5 DMTA-P: 39.9	DMTA: M656H023: 7.8 % after 28 d M656H027: 8.7 % after 14 d M656PH031: 10.3 % after 56 d DMTA-P: M656PH023: 8.2 % on d 14 M656PH027: 9.0 % on d 42 M656PH031: 9.7 % on d 28
Staudenmaier, 2013	Borstel	Sand	n.d.	n.d.	n.d.
Staudenmaier, 2009 & 2014	Borstel	Sand	17.5	41.5	M656PH023: 12.2 % on d 58 M656PH027: 5.4 % on d 89 & 99 M656PH031: 5 % on d 89
Unsworth, 2014	Calke	Sandy loam	23.1	43.0	M656PH023: 6.0 % on d 69 M656PH027: 3.8 % on d 120 M656PH031: 2.2 % on d 59

n.d.: not determined

After aerobic degradation of dimethenamid and dimethenamid-P, mineralisation amounted to 29.5 – 35.8 % after 120 d and to 17.5 – 28.5 % after 119 - 120 d, respectively. 39.5 – 43.5 % non-extractable residues were formed from dimethenamid and 39.9 – 43.0 % non-extractable residues were formed from dimethenamid-P after 119 - 120 d. Three metabolites were formed in the soil in significant concentrations. The metabolite M656H023 or M656PH023 was formed with maximum concentrations between 3.56 – 12.2 % AR after 14 – 69 d, the maximum of 12.2 % was found after 28 d. The metabolite M656H027 or M656PH027 was formed with maximum concentrations between 3.8 – 13.32 % at 14 – 120 d, the maximum of 13.32 % was found after 32 d. The metabolite M656H031 or M656PH031 was formed with maximum concentrations between 2.2 – 10.34 % at 28 – 89 d, the maximum of 10.34 % was found after 28 d. There was no major difference in the degradation pattern of dimethenamid and dimethenamid-P, thus the studies were considered together for environmental fate assessment of dimethenamid-P.

During aerobic degradation in soil, the ratio between the S-enantiomer (~97 %) and the R-enantiomer (~3 %) of dimethenamid-P remained constant (Staudenmaier, 2013 & Unsworth, 2014). The S-enantiomer further seperated into isomer 1 and 2 (~35 % to ~ 63 %) The ratio of these isomers also remained constant during aerobic incubation. Further isomeric separation of the R-entantiomer could not be determined.

2.8.1.1.2 Laboratory studies, anaerobic

No acceptable soil study with dimethenamid-P under anaerobic conditions was available. However, dimethenamid-P is not expected to degrade under anaerobic conditions over prolonged periods of time in the representative uses.

2.8.1.1.3 Soil photolysis study

The soil photolysis of dimethenamid-P was investigated in two studies. A brief summary of the study conditions of the soil photolysis studies is given in Table 2.8-3. An overview over the radioactive distribution in the investigated soils is given in Table 2.8-4.

Table 2.8-3: Study conditions of all acceptable soil photolysis studies with dimethenamid (=DMTA) and/or dimethenamid-P (DMTA-P)

Reference	soil	Soil type	pH	oc (%)	T (°C)	Light intensity (W/m^2)	Duration (d)	Investigated Compound
Sabat & Yu, 1992	Kenyon	loam	7.4	1.9	25	8.55×10^2	9	DMTA
Nietschmann & Yu, 1997	Elliot	Clay loam	6.4	2.4	22	7.83×10^2	23	DMTA & DMTA-P

Table 2.8-4: Radioactive distribution and DT_{50}/DT_{90} values of dimethenamid (=DMTA) or/and dimethenamid-P (DMTA-P) in the soil photolysis studies

Reference	soil	Soil type	conditions	CO_2 (%)	Bound residues (%)	Kinetic	Metabolites
Sabat & Yu, 1992	Kenyon	loam	Light	5.8	27.3	-2)	M656H009: 5.8 % after 6 d * M656H011: 6.1 % after 6 d * M656H007: 2.1 % after 9 d *
			Dark control	-	6.6	-3)	All < 1 %
Nietsch-mann & Yu, 1997	Elliot	Clay loam	Light	DMTA-P: 10.1 DMTA: 12.3	DMTA-P: 9.3 DMTA: 8.4	SFO	DMTA-P: Unknown (region 5): 5.5 % after 23 d * DMTA: All < 5 %
			Dark control	DMTA-P: 0.4 DMTA: 0.3	DMTA-P: 2.3 DMTA: 2.7	-3)	All < 2 %

* 2 x >5 % in consecutive samples
2) not enough sample points for determination, DMP declined to 27 % AR
3) concentration of active substance remained >90 % until end of study

After soil photolysis of dimethenamid and dimethenamid-P, mineralisation amounted to 5.8 and 12.3 % after 9 and 23 d and to 10.1 % after 23 d, respectively. 8.4 and 43.5 % non-extractable residues were formed from dimethenamid after 9 and 23 d and 9.3 % non-extractable residues were formed from dimethenamid-P after 23 d. Three metabolites were formed in the soil in significant concentrations. The metabolite M656H009 was formed with maximum concentrations between 5.8 % AR after 6 d. The metabolite M656H011 (region 5) was formed with maximum concentrations between 6.11 % at 6 d and one unknown metabolite was formed with maximum concentrations of 5.5 % at 23 d.

2.8.1.1.4 Field studies

The soil metabolites of dimethenamid and dimethenamid-P were also investigated in three field dissipation studies with nine field trials in total performed with dimethenamid and in two field degradation studies with six trials in total performed with dimethenamid-P according to the study

design described by EFSA (2014). In the field dissipation studies, the metabolites M656H023 and M656H027 were measured. In the field degradation studies, the metabolites M656PH023, M656PH031 and M656PH027 were measured. A brief summary of the study conditions of the field dissipation studies is given in Table 2.8-5. An overview over the measured metabolites in the field dissipation trials is given in Table 2.8-7. A brief summary of the study conditions of the field degradation studies is given in Table 2.8-6. An overview over the measured metabolites in the field degradation trials is given in Table 2.8-8.

Table 2.8-5: Study conditions of all acceptable field dissipation studies with dimethenamid (=DMTA) and/or dimethenamid-P (DMTA-P)

Field dissipation studies							
Reference	**Trial no**	**Location**	**Duration (d)**	**Investigated Compound**	**Soil type**	**pH (n.a.)**	**oc (%)**
Fricker & Hertl, 1995a	R10283	Niederaula, Germany	303	DMTA	Loamy sand	6.5	0.9
	R10284	Goslar, Germany	303	DMTA	Silty loam	7.6	1.2
Fricker & Hertl, 1995b	R10242	Brevelay, France	181	DMTA	Sandy silty loam	5.9	1.5
	R10243	Degre, France	183	DMTA	Loam	6.0	1.1
Carrier & Blanz, 1997	R10244	Vergoignan, France	184	DMTA	Sand	0.5	6.1
	R10245	Cestas, France	184	DMTA	Sandy loam	1.2	4.9
Carrier, 1997	R10246	Budrio, Italy	196	DMTA	Sandy loam	0.7	7.4
	R10247	Mezzolara, Italy	122	DMTA	Sandy loam	0.4	7.4
	R10248	Argenta, Italy	245	DMTA	Loam	0.9	7.4

Table 2.8-6: Study conditions of all acceptable field degradation studies with dimethenamid (=DMTA) and/or dimethenamid-P (DMTA-P)

Field degradation studies							
Reference	**Trial no**	**Location**	**Duration (d)**	**Investigated Compound**	**Soil type**	**pH ($CaCl_2$)**	**oc (%)**
Bayer & Marvick, 2014a	L110061	Goch-Nierswalde, Germany	710	DMTA-P	Silt loam	5.85	1.75
	L110062	Stotzheim, France (North)	721	DMTA-P	Silt loam	7.11	1.7
	L110063	Meauzac, France (South)	725	DMTA-P	Sandy loam	6.93	1.3
	L110064	Utrera, Spain	725	DMTA-P	Sand	7.55	0.48
Bayer & Marvick, 2014c	L110481	Wilson, United Kingdom	548	DMTA-P	Silt loam	6.84	2.48
	L110482	Lentzke, Germany	545	DMTA-P	Sandy loam	5.73	0.62

Table 2.8-7: Distribution of investigated metabolites for all acceptable field dissipation studies with dimethenamid

Field dissipation studies			
Reference	**Trial no**	**Location**	**Metabolites**
Fricker & Hertl, 1995a	R10283	Niederaula, Germany	M656H023: 6.92 % on d 14 M656H027: 3.39 % on d 21 M656PH031: not determined
	R10284	Goslar, Germany	M656H023: 8.66 % on d 7 M656H027: 7.99 % on d 7 M656PH031: not determined
Fricker & Hertl, 1995b	R10242	Brevelay, France	M656H023: 13.44 %on d 28 M656H027: 1.52 % on d15 M656PH031: not determined
	R10243	Degre, France	M656H023: 9.20 % on d 59 M656H027: 7.64 % on d 59 M656PH031: not determined
Carrier & Blanz, 1997	R10244	Vergoignan, France	M656H023: 3.70 % on d 0 M656H027: 4.50 % ug/g on d 14 M656PH031: not determined
	R10245	Cestas, France	M656H023: < 1.25 % M656H027: < 1.25 % M656PH031: not determined
Carrier, 1997	R10246	Budrio, Italy	M656H023: 3.94 % on d 21 M656H027: 3.56 % on d 30 M656PH031: not determined
	R10247	Mezzolara, Italy	M656H023: 1.91 % on d 21 & 30 M656H027: 5.73 % on d 30 M656PH031: not determined
	R10248	Argenta, Italy	M656H023: 5.41 % on d 122 M656H027: 7.16 % on d 60 & 93 M656PH031: not determined

Table 2.8-8: Distribution of investigated metabolites for all acceptable field degradation studies with dimethenamid-P

Field degradation studies			
Reference	**Trial no**	**Location**	**Metabolites**
Bayer & Marvick, 2014a	L110061	Goch-Nierswalde, Germany	M656PH023: 3.81 % on 28 M656PH027: 4.79 % on d 58-59 M656PH031: 2.25 % on d 28
	L110062	Stotzheim, France (North)	M656PH023: 2.37 % on d 16 M656PH027: 5.37 % on d 28 M656PH031: 8.56 % on d 28
	L110063	Meauzac, France (South)	M656PH023: 4.11 % on d 28-31 M656PH027:6.16 % on day 28-31 M656PH031: 3.68 % on d 28-31
	L110064	Utrera, Spain	M656PH023: 4.20 % on day 28-31 M656PH027: 5.04 % on d 28-31 M656PH031: 6.05 % on d 28-31
Bayer & Marvick, 2014c	L110481	Wilson, United Kingdom	M656PH023: 3.17 % on d 59-62 M656PH027: 7.37 % on d 182-185 M656PH031: 2.14 % on d 17
	L110482	Lentzke, Germany	M656PH023: < LOQ M656PH027: < LOQ M656PH031: < LOQ

In the field dissipation studies with dimethenamid, the metabolite M656H023 was formed with maximum concentrations between <1.25 % – 13.44 % AR after 0 – 59 d, the maximum of 13.44 % was found after 28 d. The metabolite M656H027 was formed with maximum concentrations between

<1.25 %– 7.64 % at 7 – 59 d, the maximum of 7.64 % was found after 59 d. The metabolite M656H031 was not measured in the studies.
In the field degradation studies with dimethenamid-P, the metabolite M656PH023 was formed with maximum concentrations between <LOQ % – 4.20 % AR after 16 – 62 d, the maximum of 4.20 % was found after 28 - 31 d. The metabolite M656PH027 was formed with maximum concentrations between <LOQ % – 7.37 % at 28 – 185 d, the maximum of 7.37 % was found after 182 - 185 d. The metabolite M656PH031 was formed with maximum concentrations between <LOQ % – 8.56 % at 17 – 31 d, the maximum of 8.56 % was found after 28 d.

2.8.1.2 Rate of degradation in soil

2.8.1.2.1 Laboratory studies, aerob

The degradation rate of dimethenamid-P and its soil metabolites M656PH023, M656PH027 and M656PH031 under aerobic conditions was investigated in six acceptable route studies with 6 different soils in total. The degradation rates of dimethenamid-P are presented in Table 2.8-10. The degradation rates of M656PH023, M656PH027 and M656PH031 are presented in Table 2.8-11, Table 2.8-13 and Table 2.8-12, respectively.
Additionally, one rate study under aerobic conditions in three soils was performed for M656PH054, M656PH047 and M656PH043 that were identified in the unknown lysimeter fractions in order to derive trigger endpoints. A brief summary of the study condition of this additional rate soil studies is given in Table 2.8-9. The resulting degradation rates for M656PH054, M656PH047 and M656PH043 are summarised in Table 2.8-14, Table 2.8-15 and Table 2.8-16, respectively.

Table 2.8-9: Study conditions of the acceptable rate soil study under aerobic conditions with the metabolites M656PH054, M656PH047 and M656PH043

Reference	soil	Soil type	pH	oc (%)	T (°C)	Moisture	Duration (d)
Class & Heinz, 2014	Li10	Loamy sand	6.9 (H_2O)	0.84	20	40 % MWHC	118
	LUFA 2.2	Sandy loam	5.9 (H_2O)	1.47			
	LUFA 5M	Loamy sand	7.9 (H_2O)	2.03			

Table 2.8-10: Degradation rates of dimethenamid (=DMTA) or/and dimethenamid-P (DMTA-P) in all investigated soils under aerobic conditions (persistence and modelling endpoints)

Soil	Soil type	pH	T. (°C)	Moisture	Com-pound	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2	Kinetic model	Ref.
BBA 2.2	Loamy Sand	5.8 ($CaCl_2$)	20	40 % MWHC	DMTA	12.8	42.55	9.8	SFO	Koenig, 1995/ Platz, 2008
BBA 2.3	Sandy Loam	6.6 ($CaCl_2$)	20	40 % MWHC	DMTA	13.3	44.1	9.0	SFO	
Flaach	Sandy Clay loam	7.95 (n.a.)	20	40 % MWHC	DMTA	7.69	25.56	4.8	SFO	Koenig, 1996/ Platz, 2008
Elliot	Clay loam	6.9 (n.a.)	23	75 % of FC	DMTA-P	9.32	30.97	11.4	SFO	Wendt (1997)/ Bronner (2010)
					DMTA	9.4	31.23	(11.4)	SFO	
Borstel	Sand	5.9 ($CaCl_2$)	20	50 % MWHC	DMTA-P	31.49	104.6	30.6	SFO	Stauden-maier, 2009 & 2014
			20	40 % MWHC	S-enant.	31.6	104.9	-	SFO	Stauden-maier, 2013
					R.-enant.	30.9	102.8	-	SFO	
Calke	Sandy loam	4.6 ($CaCl_2$)	20	pF2	DMTA-P	21.93	72.84	21.93	SFO	Unsworth, 2014
Geometric mean (n = 6)								12.2		
pH dependent					No					

n.a. information on buffer solution not available
(…) not included in geometric mean
S-enant. : S-enantiomer of dimethenamid-P
R-enant.: S-enantiomer of dimethenamid-P

Table 2.8-11: Degradation rates of M656PH023 or M656H023 in all investigated soils under aerobic conditions (persistence and modelling endpoints)

Soil	Soil type	pH	T. (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	f.f.+	DT_{50} (d) 20 °C pF2	Kinetic	Ref.
BBA 2.2	Loamy Sand	5.8 ($CaCl_2$)	20	40 % MWHC	41	136	0.1435	31.5	SFO	Koenig, 1995/ Platz, 2008
BBA 2.3	Sandy Loam	6.6 ($CaCl_2$)	20	40 % MWHC	23.8	79.1	0.1891	16.0	SFO	
Flaach	Sandy Clay loam	7.95 (n.a.)	20	40 % MWHC	24.1	80.18	0.1282	15.0	SFO	Koenig, 1996/ Platz, 2008
Elliot	Clay loam	6.9 (n.a.)	23	75 % of FC	26.24§	87.17§	0.117§	37.0	SFO	Wendt (1997)/ Bronner (2010)
					30.07*	99.89*	(0.131)*	(32.2)*	SFO	
Calke	Sandy loam	4.6 ($CaCl_2$)	20	pF2	63.94	212.4	0.1121	63.94	SFO	Unsworth, 2014
DT_{50} values				Geometric mean (n= 5)				35.4		
pH dependent				No						
Formation fraction from active substance to metabolite				Arithmetic mean (n = 5)			0.1380+			

n.a. information on buffer solution not available
\+ formation fraction from active substance to metabolite
(…) not included in geometric mean and arithmetic mean
§ soil incubation with DMTA-P
* soil incubation with DMTA

Table 2.8-12: Degradation rates of M656PH031 or M656H031 in all investigated soils under aerobic conditions (persistence and modelling endpoints)

Soil	Soil type	pH	T. (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	f.f.+	DT_{50} (d) 20 °C pF2	Kinetic	Ref.
BBA 2.2	Loamy Sand	5.8 ($CaCl_2$)	20	40 % MWHC	61.3	203.5	0.1007	47.1	SFO	Koenig, 1995/ Platz, 2008
BBA 2.3	Sandy Loam	6.6 ($CaCl_2$)	20	40 % MWHC	39.4	130.8	0.0572	23.5	SFO	
Flaach	Sandy Clay loam	7.95 (n.a.)	20	40 % MWHC	37.7	125.1	0.0425	78.1	SFO	Koenig, 1996/ Platz, 2008
Elliot	Clay loam	6.9 (n.a.)	23	75 % of FC	55.9§	185.8§	0.120§	82.7§	SFO	Wendt (1997)/ Bronner (2010)
					63.63*	211.4*	(0.100)*	(68.6)*	SFO	
Borstel	Sand	5.9 ($CaCl_2$)	20	50 % MWHC	85.2	283	0.0918	78.1	SFO	Staudenmaier (2009 & 2014)
Calke	Sandy loam	4.6 ($CaCl_2$)	20	pF2	103.3	343.1	0.0385	103.3	SFO	Unsworth, 2014
DT_{50} values				Geometric mean (n= 6)				51.9		
pH dependent				No						
Formation fraction from active substance to metabolite				Arithmetic mean (n = 6)			0.0751+			

n.a. information on buffer solution not available
\+ formation fraction from active substance to metabolite
(…) not included in geometric mean and arithmetic mean
§ soil incubation with DMTA-P
* soil incubation with DMTA

Table 2.8-13: Degradation rates of M656PH027 or M656H027 in all investigated soils under aerobic conditions (persistence and modelling endpoints)

Soil	Soil type	pH	T. (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	f.f.+	DT_{50} (d) 20 °C pF2	Kinetic	Ref.
BBA 2.2	Loamy Sand	5.8 ($CaCl_2$)	20	40 % MWHC	60.6	201.3	0.1251	46.3	SFO	Koenig, 1995/ Platz, 2008
BBA 2.3	Sandy Loam	6.6 ($CaCl_2$)	20	40 % MWHC	43.5	144.4	0.1710	29.3	SFO	
Flaach	Sandy Clay loam	7.95 (n.a.)	20	40 % MWHC	33.1	109.9	0.1331	20.6	SFO	Koenig, 1996/ Platz, 2008
Elliot	Clay loam	6.9 (n.a.)	23	75 % of FC	45.6§	151.4§	0.110§	60.7§	SFO	Wendt (1997)/ Bronner (2010)
					49.35	164.0	(0.109)*	(68.6)*	SFO	
Borstel	Sand	5.9 ($CaCl_2$)	20	50 % MWHC	87.2	289.6	0.0588	84.7	SFO	Stauden-maier (2009 & 2014)
Calke	Sandy loam	4.6 ($CaCl_2$)	20	pF2	149.2	495.6	0.0390	149.2	SFO	Unsworth, 2014
DT_{50} values				Geometric mean (n= 6)				60.7		
pH dependent				No						
Formation fraction from active substance to M656H027				Arithmetic mean (n = 6)			0.1062			
Formation fraction from M656H031 to M656H027				Default			1.0			

n.a. information on buffer solution not available
\+ formation fraction from active substance to metabolite
(…) not included in geometric mean and arithmetic mean
§ soil incubation with DMTA-P
* soil incubation with DMTA

Table 2.8-14: Degradation rates of M656PH054 in all investigated soils under aerobic conditions (persistence endpoints)

Soil	Soil type	pH	T. (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	f.f.+	DT_{50} (d) 20 °C pF2	Kinetic	Ref.
Li10	Loamy Sand	6.9 (H_2O)	20	40 % MWHC	37	122	-	-	SFO	Class & Heinz, 2014
LUFA 5M	Loamy Sand	7.9 (H_2O)	20	40 % MWHC	22	73	-	-	SFO	
LUFA 2.2	Loamy Sand	5.9 (H_2O)	20	40 % MWHC	40	334	-	-	FOMC	

\+ formation fraction from active substance to metabolite

Table 2.8-15: Degradation rates of M656PH047 in all investigated soils under aerobic conditions (persistence endpoints)

Soil	Soil type	pH	T. (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	f.f.+	DT_{50} (d) 20 °C pF2	Kinetic	Ref.
Li10	Loamy Sand	6.9 (H_2O)	20	40 % MWHC	95	314	-	-	SFO	Class & Heinz, 2014
LUFA 5M	Loamy Sand	7.9 (H_2O)	20	40 % MWHC	43	142	-	-	SFO	
LUFA 2.2	Loamy Sand	5.9 (H_2O)	20	40 % MWHC	87	289	-	-	SFO	

+ formation fraction from active substance to metabolite

Table 2.8-16: Degradation rates of M656PH043 in all investigated soils under aerobic conditions (persistence endpoints)

Soil	Soil type	pH	T. (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	f.f.+	DT_{50} (d) 20 °C pF2	Kinetic	Ref.
Li10	Loamy Sand	6.9 (H_2O)	20	40 % MWHC	21	154	-	-	DFOP	Class & Heinz, 2014
LUFA 5M	Loamy Sand	7.9 (H_2O)	20	40 % MWHC	10	34	-	-	SFO	
LUFA 2.2	Loamy Sand	5.9 (H_2O)	20	40 % MWHC	30	364	-	-	FOMC	

+ formation fraction from active substance to metabolite

Dimethenamid-P degrades in laboratory soil studies under aerobic conditions following SFO kinetics with DT_{50} values between 9.32 and 31.5 d and DT_{90} values between 25.6 and 105 d. The geometric mean of the DT_{50} values normalised to reference conditions of 20 °C and pF2 is 12.2 d. The degradation of dimethenamid-P showed no pH dependency. There is no difference in the degradation rates of racemic dimethenamid and dimethenamid-P or between the S- and R-enantiomer of dimethenamid-P.

The metabolite M656PH023 or M656H023 degrades in laboratory soil studies under aerobic conditions following SFO kinetics with DT_{50} values between 23.8 and 63.9 d and DT_{90} values between 79.1 and 212.4 d. Formation fraction from its parent dimethenamid-P ranged from 0.117 and 0.1435. The geometric mean of the DT_{50} values normalised to reference conditions of 20 °C and pF2 is 35.4 d. The arithmetic mean of the formation fractions is 0.1380. The formation and degradation of M656PH023 or M656H023 showed no pH dependency. There is no difference in the degradation rates of the metabolite M656H023 of the racemic dimethenamid and the metabolite M656PH023 of dimethenamid-P.

The metabolite M656PH031 or M656H031 degrades in laboratory soil studies under aerobic conditions following SFO kinetics with DT_{50} values between 37.7 and 103 d and DT_{90} values between 125 and 343 d. Formation fraction from its parent dimethenamid-P ranged from 0.0385 and 0.1007. The geometric mean of the DT_{50} values normalised to reference conditions of 20 °C and pF2 is 51.9 d. The arithmetic mean of the formation fractions is 0.0751. The formation and degradation of M656PH031 or M656H031 showed no pH dependency. There is no difference in the degradation rates of the metabolite M656H031 of the racemic dimethenamid and the metabolite M656PH031 of dimethenamid-P.

The metabolite M656PH027 or M656H027 degrades in laboratory soil studies under aerobic conditions following SFO kinetics with DT_{50} values between 33.1 and 149 d and DT_{90} values between 110 and 497 d. Formation fraction from its parent dimethenamid-P ranged from 0.0390 and 0.1710. The

geometric mean of the DT_{50} values normalised to reference conditions of 20 °C and pF2 is 60.7 d. The arithmetic mean of the formation fractions from dimethenamid-P to M656H027 is 0.1062. Formation fraction from M656H031 to M656H027 is set to 1.0. The formation and degradation of M656PH027 or M656H027 showed no pH dependency. There is no difference in the degradation rates of the metabolite M656H027 of the racemic dimethenamid and the metabolite M656PH027 of dimethenamid-P.

The metabolite M656H054 degrades in laboratory soil studies under aerobic conditions following SFO and FOMC kinetics with DT_{50} values between 22 and 40 d and DT_{90} values between 73 and 334 d. The metabolite M656H047 degrades in laboratory soil studies under aerobic conditions following SFO kinetics with DT_{50} values between 43 and 95 d and DT_{90} values between 142 and 314 d. The metabolite M656H043 degrades in laboratory soil studies under aerobic conditions following SFO, DFOP and FOMC kinetics with DT_{50} values between 10 and 30 d and DT_{90} values between 34 and 364 d. The degradation of all three metabolites showed no pH dependency.

2.8.1.2.2 Laboratory studies, anaerobic

No acceptable soil study with dimethenamid-P under anaerobic conditions was available. However, dimethenamid-P is not expected to degrade under anaerobic conditions over prolonged periods of time in the representative uses.

2.8.1.2.3 Soil photolysis study:

The soil photolysis rate of dimethenamid and dimethenamid-P was investigated in one study. The resulting DT_{50} and DT_{90} values are given in Table 2.8-17.

Table 2.8-17: DT_{50} and DT_{90} values of dimethenamid (=DMTA) or/and dimethenamid-P (DMTA-P) in the soil photolysis study

Reference	soil	Soil type	conditions	DT_{50} (d)	Kinetic
Nietschmann & Yu, 1997	Elliot	Clay loam	Light	DMTA-P: 34.84 DMTA: 27.21	SFO
			Dark control	-[3)]	-[3)]

3) concentration of active substance remained >90 % until end of study

The experimental DT_{50} value of dimethenamid was 34.84 d. The DT_{50} value of dimethenamid-P was 27.21 d following SFO kinetics. There was no degradation of dimethenamid and dimethenamid-P in the dark controls.

2.8.1.2.4 Field studies

The dissipation rate of dimethenamid was investigated in the 9 field trials. The field degradation rate of dimethenamid-P according to EFSA (2014) guidance was determined in 6 trials throughout Europe. Additionally, four field degradation trials with M656PH027 were performed according to EFSA (2014) guidance. A brief summary of the study conditions of the field degradation studies with M656PH027 is given in Table 2.8-18. The not-normalised dissipation rates of dimethenamid are summarised in Table 2.8-19. The not-normalised degradations rates of dimethenamid-P are summarised in Table 2.8-20. The not-normalised degradations rates of M656PH027 are summarised in Table 2.8-21. The temperature and moisture normalised degradation rates of dimethenamid-P and M656PH027 to be used for modelling are summarised in Table 2.8-22 and Table 2.8-23.

Table 2.8-18: Study conditions of all acceptable field degradation studies with M656PH027

Field degradation studies						
Reference	**Trial no**	**Location**	**Duration (d)**	**Soil type**	**pH ($CaCl_2$)**	**oc (%)**
Bayer & Marvick, 2014b	L110330	Goch-Nierswalde, Germany	710	Silt loam	6.36	1.65
	L110331	Stotzheim, France (North)	721	Silt loam	5.47	0.83
	L110332	Meauzac, France (South)	725	Sandy loam	7.49	1.38
	L110333	Utrera, Spain	725	Sand	6.66	0.38

Table 2.8-19: Not-normalised dissipation rates of dimethenamid from the field dissipation studies (persistence endpoints)

Trial no	**Location**	**Soil type**	**pH (n.a.)**	**Depth (cm)**	**DT_{50} not.norm. (d)**	**DT_{90} not.norm. (d)**	**Kinetic**	**Ref.**
R10283	Niederaula, Germany	Loamy sand	6.5	40	2.9	9.6	SFO	Fricker & Hertl, 1995a
R10284	Goslar, Germany	Silty loam	7.6	40	- 1)	- 1)	- 1)	
R10242	Brevelay, France	Sandy silty loam	5.9	50	1.93	21.80	SFO	Fricker & Hertl, 1995b
R10243	Degre, France	Loam	6.0	50	35.12	116.69	SFO	
R10244	Vergoignan, France	Sand	0.5	30	16.47	54.72	SFO	Carrier & Blanz, 1997
R10245	Cestas, France	Sandy loam	1.2	30	16.22*	53.87*	SFO	
R10246	Budrio, Italy	Sandy loam	0.7	50	10.08	33.50	SFO	Carrier, 1997
R10247	Mezzolara, Italy	Sandy loam	0.4	50	9.06	30.08	SFO	
R10248	Argenta, Italy	Loam	0.9	50	15.31	50.84	SFO	

n.a.: not available
* residue value at day 2 removed as outlier
1) no statistically reliable fit could be obtained

Table 2.8-20: Not-normalised degradation rates of dimethenamid-P in the field degradation studies (persistence endpoints)

Trial no	**Location**	**Soil type**	**pH ($CaCl_2$)**	**Depth (cm)**	**DT_{50} not.norm. (d)**	**DT_{90} not.norm. (d)**	**Kinetic; para-meter**	**Ref.**
L110061	Goch-Nierswalde, Germany	Silt loam	5.85	90	20.4	67.7	SFO	Bayer & Marwitz (2014a)/ Wiede-mann (2014a)
L110062	Stotzheim, France (North)	Silt loam	7.11	90	17.6	58.6	SFO	
L110063	Meauzac, France (South)	Sandy loam	6.93	90	14.5	48.1	SFO	
L110064	Utrera, Spain	Sand	7.55	90	16.5	54.7	SFO	
L110481	Wilson, United Kingdom	Silt loam	6.84	90	17.6	167	FOMC α: 0.955 β: 16.5	Bayer & Marwitz (2014c) / Wiede-mann (2014b)
L110482	Lentzke, Germany	Sandy loam	5.73	90	10.2	68.2	FOMC, α: 1.36 β: 15.4	

Table 2.8-21: Not-normalised degradation rates of the metabolite M656PH027 from the field degradation studies (persistence endpoints)

Trial no	Location	Soil type	pH ($CaCl_2$)	Depth (cm)	DT_{50} not.norm. (d)	DT_{90} not.norm. (d)	Kinetic; para-meter	Ref.
L110330	Goch-Nierswalde, Germany	Silt loam	6.36	90	31.4	104	SFO	Bayer & Marwitz (2014b)/ Wiede-mann (2014a)
L110331	Stotzheim, France (North)	Silt loam	5.47	90	12	40	SFO	
L110332	Meauzac, France (South)	Sandy loam	7.49	90	19.4	64.3	SFO	
L110333	Utrera, Spain	Sand	6.66	90	23.7	78.6	SFO	

Table 2.8-22: Temperature and moisture normalised degradation rates of dimethenamid-P from the field degradation studies (modelling endpoints)

Trial no	Location	Soil type	pH ($CaCl_2$)	Depth (cm)	DT_{50} 20 °C, pF2 (d)	Kinetic 20 °C, pF2	Ref.
L110061	Goch-Nierswalde, Germany	Silt loam	5.85	90	12.6	SFO	Bayer & Marwitz (2014a)/ Wiede-mann (2014b)
L110062	Stotzheim, France (North)	Silt loam	7.11	90	10.4	SFO	
L110063	Meauzac, France (South)	Sandy loam	6.93	90	10.9	SFO	
L110064	Utrera, Spain	Sand	7.55	90	9.7	SFO	
L110481	Wilson, United Kingdom	Silt loam	6.84	90	13.8	SFO	Bayer & Marwitz (2014c) / Wiede-mann (2014b)
L110482	Lentzke, Germany	Sandy loam	5.73	90	6.9	SFO	
Geometric mean (n = 6)					10.5		
pH dependent			No				

Table 2.8-23: Temperature and moisture normalised degradation rates of M656PH027 from the field degradation studies (modelling endpoints)

Trial no	Location	Soil type	pH ($CaCl_2$)	Depth (cm)	DT_{50} 20 °C, pF2 (d)	Kinetic 20 °C, pF2	Ref.
L110330	Goch-Nierswalde, Germany	Silt loam	6.36	90	14.6	SFO	Bayer & Marwitz (2014b)/ Wiede-mann (2014b)
L110331	Stotzheim, France (North)	Silt loam	5.47	90	8.8	SFO	
L110332	Meauzac, France (South)	Sandy loam	7.49	90	12.7	SFO	
L110333	Utrera, Spain	Sand	6.66	90	25.9	SFO	
Geometric mean (n = 4)					14.3		
pH dependent			No				

In the field dissipation studies, not-normalised DT_{50} values of dimethenamid ranged from 1.93 – 16.22 d with DT_{90} values from 9.6 – 53.87 d following SFO kinetics. In the field degradation studies where volatilisation and photolysis of dimethenamid was excluded, not-normalised DT_{50} values of dimethenamid-P were significantly longer and ranged from 10.2 – 20.4 d with DT_{90} values from 48.1 – 167 d following SFO or FOMC kinetics. Not-normalised DT_{50} values of the metabolite M656PH027

from the field degradation studies ranged from 12 – 31.4 d with DT_{90} values from 40 – 104 d.
The geometric mean of the temperature and moisture normalised DT_{50} values of dimethenamid-P from the field degradation studies is 10.5 d. The geometric mean of the temperature and moisture normalised DT_{50} values of the metabolite M656PH027 from the field degradation studies is 14.3 d. The degradation of dimethenamid-P and M656PH027 under field condition does not show a pH dependency.

To determine, whether the temperature and moisture normalised laboratory and field degradation rates of dimethenamid-P are statistically different or from the same population applying the Student's t-test with a significsance level of 25 %.
The same procedure was also performed for the temperature and moisture normalised laboratory and field degradation rates of the metabolite M656PH027.

For dimethenamid-P, the temperature and moisture normalised laboratory and field degradation rates were not significantly different and should therefore be combined for modelling.
For M656H027, temperature and moisture normalised field degradation rates were significantly shorter than the temperature and moisture normalised laboratory degradation rates and should therefore be used separately for modelling.
The resulting DT_{50} values and formation fractions for dimethenamid-P and the metabolite M656PH027 to be used for modelling are summarised in Table 2.8-24.

Table 2.8-24: Degradation endpoints of dimethenamid-P and its metabolite M656PH027 to be used for modelling

Dimethenamid-P		
Endpoints for modelling		
DT_{50} (d)	11.5	Geometric mean, n=12, laboratory and field data
Metabolite M656H027		
Endpoints for modelling		
DT_{50} (d)	14.3	Geometric mean, n = 4, field data
Formation fraction (as → M656H027)	1	default
Formation fraction (M656H031→ M656H027)	-*	-*

* not found in field degradation studies with M656H027

The combined geometric mean of the temperature and moisture normalised DT_{50} values of dimethenamid-P from laboratory and field studies is 11.5 d.

2.8.1.3 Adsorption and desorption in soil

The adsorption and desorption of dimethenamid-P was investigated in one acceptable study with 10 different soils in total. The adsorption and desorption of the metabolite M656PH023 was investigated in one acceptable study with 5 soils in total. The adsorption and desorption of the metabolite M656PH027 was investigated in two acceptable studies with 9 soils in total. The adsorption and desorption of the metabolite M656H031 was investigated in two acceptable studies with 10 soils in total. The resulting adsorption properties of dimethenamid-P, M656PH023, M656PH027 and M656PH031 are given in Table 2.8-25, Table 2.8-26, Table 2.8-27 and Table 2.8-28.

Additionally, the adsorption and desorption properties of the metabolites M656PH043, M656PH047 and M656PH054, that were identified in the unknown lysimeter fractions, were determined in one study and for different 4 soils each. The resulting adsorption properties of dimethenamid-P, M656PH054, M656PH047 and M656PH043 are given in Table 2.8-29, Table 2.8-30 and Table 2.8-31.

Table 2.8-25: Freundlich adsorption coefficients and exponents of dimethenamid-P

Soil	Soil Type	OC %	Soil pH ($CaCl_2$)	K_F (mL/g)	K_{Foc} (mL/g)	1/n	Ref.
Eu-1	Sandy clay loam	1.4	5.6	6.61	474	0.92	Tong & Su, 1997 & Addendum Paulick, 2007
Eu-2	Clay loam	2.03	8.0	2.51	123	0.96	
Eu-3	Sandy loam	2.38	5.5	2.14	90	1.00	
Eu-4	Silt loam	1.22	6.6	1.23	101	1.07	
Eu-5	Sand	3.43	3.9	13.49	393	0.94	
US-1	Clay	0.99	8.0	2.09	211	1.05	
US-2	Clay loam	2.3	6.4	2.51	105	0.97	
US-3	Loam	1.22	7.3	3.02	247	1.03	
US-4	Sandy loam	0.35	7.0	0.72	205.71	1.04	
US-5	Silt loam	1.51	6.7	1.95	129	0.96	
Geometric mean (n= 10)				2.58	177		
Median (n=10)					167.4		
Arithmetic mean (n=10)					207.9	0.994	
pH dependence				No			

Table 2.8-26: Freundlich adsorption coefficients and exponents of the metabolite M656PH023

Soil	Soil Type	OC %	Soil pH ($CaCl_2$)	K_F (mL/g)	K_{Foc} (mL/g)	1/n	Ref.
Nierswalder Wildacker	Silt Loam	1.85	5.7	0.14	7.62	0.68	Sacchi, 2013
Li10	Loamy Sand	0.93	6.0	0.10	10.53	0.76	
LUFA 2.1	Sand	0.60	5.6	0.13	22.39	0.87	
LUFA 2.3	Sandy Loam	0.99	6.7	0.12	12.46	0.70	
LUFA 5M	Sandy Loam	1.07	7.4	0.07	6.29	0.60	
Geometric mean (n= 5)				0.109	10.71		
Arithmetic mean (n=5)					11.9	0.722	
pH dependence				No			

Table 2.8-27: Freundlich adsorption coefficients and exponents of the metabolite M656PH027

Soil	Soil Type	OC %	Soil pH ($CaCl_2$)	K_F (mL/g)	K_{Foc} (mL/g)	1/n	Ref.
Nierswalder Wildacker	Silt Loam	1.85	5.7	0.16	8.55	1.14	Sacchi, 2013
Li10	Loamy Sand	0.93	6.0	0.09	9.89	0.97	
LUFA 2.1	Sand	0.60	5.6	0.05	7.73	1.00	
LUFA 2.3	Sandy Loam	0.99	6.7	0.11	10.96	0.98	
LUFA 5M	Sandy Loam	1.07	7.4	0.14	13.54	0.94	
Sora	Silt loam	1.9	6.4	0.076	4.0	0.992	Class & Dorn, 2004
LUFA 3A	Loam	2.44	7.2	0.12	4.92	0.940	
Birnbaum	Loamy sand	2.72	7.3	0.036	1.32	0.937	
Bruch West	Sandy loam	0.8	6.1	0.030	3.75	0.910	
Geometric mean (n= 9)				0.078	5.96		
Arithmetic mean (n=9)					7.0	0.979	
pH dependence				No			

Table 2.8-28: Freundlich adsorption coefficients and exponents of the metabolite M656PH031

Soil	Soil Type	OC %	Soil pH ($CaCl_2$)	K_F (mL/g)	K_{Foc} (mL/g)	1/n	Ref.
Nierswalder Wildacker	Silt Loam	1.85	5.7	< 0.1*	< 5	-*	Sacchi, 2013
Li10	Loamy Sand	0.93	6.0	< 0.1*	< 11	-*	
LUFA 2.1	Sand	0.60	5.6	< 0.1*	< 17	-*	
LUFA 2.3	Sandy Loam	0.99	6.7	< 0.1*	< 10	-*	
LUFA 5M	Sandy Loam	1.07	7.4	< 0.1*	< 9	-*	
LUFA 2.1	sand	0.52	5.2	< 0.1*	< 19	-*	Class, 2011
Li 10	Loamy sand	0.88	5.9	< 0.1*	< 11	-*	
Nierswalder Wildacker	Silt loam	1.63	6.5	< 0.1*	< 6	-*	
LUFA 2.3	Sandy loam	1.09	6.9	< 0.1*	< 9	-*	
La Gironda	Silty clay loam	3.84	7.5	< 0.1*	< 3	-*	

* adsorption too poor to determine reliable Freundlich coefficients or exponents

Table 2.8-29: Freundlich adsorption coefficients and exponents of the metabolite M656PH043

Soil	Soil Type	OC %	Soil pH ($CaCl_2$)	K_d (mL/g)	K_{oc} (mL/g)	1/n	Ref.
Schifferstadt	Sand	0.75	4.1	0.229	30.5	-*	Class & Walter, 2014a
LUFA 5M	Loamy sand	2.03	7.2	< 0.1*	< 5	-*	
LUFA 2.2	Sandy Loam	1.47	5.4	< 0.1*	< 7	-*	
Li 10	Loamy sand	0.84	6.4	< 0.1*	< 12	-*	
La Gironda (Arahal)	Sandy clay loam	1.22	7.4	< 0.1*	< 8	-*	

* adsorption too poor to determine reliable Freundlich coefficients or exponents

Table 2.8-30: Freundlich adsorption coefficients and exponents of the metabolite M656PH047

Soil	Soil Type	OC %	Soil pH ($CaCl_2$)	K_d (mL/g)	K_{oc} (mL/g)	1/n	Ref.
Schifferstadt	Sand	0.75	4.1	< 0.1*	< 13	-*	Class & Walter, 2014b
LUFA 5M	Loamy sand	2.03	7.2	< 0.1*	< 5	-*	
LUFA 2.2	Sandy Loam	1.47	5.4	< 0.1*	< 7	-*	
Li 10	Loamy sand	0.84	6.4	< 0.1*	< 12	-*	
La Gironda (Arahal)	Sandy clay loam	1.22	7.4	< 0.1*	< 8	-*	

* adsorption too poor to determine reliable Freundlich coefficients or exponents

Table 2.8-31: Freundlich adsorption coefficients and exponents of the metabolite M656PH054

Soil	Soil Type	OC %	Soil pH ($CaCl_2$)	K_d (mL/g)	K_{oc} (mL/g)	1/n	Ref.
Schifferstadt	Sand	0.75	4.1	0.217	28.9	-*	Class & Walter, 2014c
LUFA 5M	Loamy sand	2.03	7.2	< 0.1*	< 5	-*	
LUFA 2.2	Sandy Loam	1.47	5.4	< 0.1*	< 7	-*	
Li 10	Loamy sand	0.84	6.4	< 0.1*	< 12	-*	
La Gironda (Arahal)	Sandy clay loam	1.22	7.4	< 0.1*	< 8	-*	

* adsorption too poor to determine reliable Freundlich coefficients or exponents

Dimethenamid-P shows only weak adsorption to soil with K_{foc} values ranging from 90 to 474 mL/g with a median of 167.4 mL/g to be used for modelling. Freundlich exponents range from 0.94 – 1.05 with an arithmetic mean of 0.994 and indicate almost no dependency of the adsorption on concentration levels of dimethenamid-P. The adsorption of dimethenamid-P to soil is not pH dependent.
Also the adsorption of the main soil metabolites M656PH023, M656PH027 and M656PH031 to soil is weak and less strong than the adsorption of dimethenamid-P. The K_{foc} values of M656PH023 range from 6.29 – 22.39 mL/g with an arithmetic mean of 11.9 mL/g to be used for modelling. Freundlich exponents range from 0.60 – 0.87 with an arithmetic mean of 0.722 thus indicating a dependency of the adsorption on concentration levels of M656PH023. The K_{foc} values of M656PH027 range from 1.32 – 13.54 mL/g with an arithmetic mean of 7.0 mL/g to be used for modelling. Freundlich exponents range from 0.94 – 1.00 with an arithmetic mean of 0.979, thus also indicating almost no dependency of the adsorption on concentration levels of of M656PH027. The adsorption of M656PH031 was too poor to allow a quantitative determination of adsorption coefficients. Adsorption coefficients were < 0.1 mL/g in all investigated soils. The respective K_{OC} values for M656PH031 thus remained < 6 - < 17 mL/g.
Also the metabolites M656PH043, M656PH047 and M656PH054, identified in the unknown lysimeter fractions, show very poor adsorption properties. One reliable K_D value of 0.229 mL/g resulting in a Koc value of 30.5 mL/g could only be obtained for M656PH043. Adsorption coefficients in the remaining four soils were < 0.1 mL/g with Koc values from < 5 - < 12 mL/g. For M656PH047, all adsorption coefficients in the five investigated soils remained < 0.1 mL/g with Koc values from < 5 - < 13 mL/g. For M656PH054, One reliable K_D value of 0.217 mL/g resulting in a Koc value of 28.9 mL/g could only be obtained. Adsorption coefficients in the remaining four soils were < 0.1 mL/g with Koc values from < 5 - < 12 mL/g.

2.8.1.4 Mobility in soil:

2.8.1.4.1 Column leaching studies

The mobility of dimethenamid in the soil column was investigated in three acceptable column leaching studies. A brief summary of the study conditions of the column leaching studies is given in Table 2.8-32. An overview over the radioactive distribution in the investigated soil columns is given in Table 2.8-33.

Table 2.8-32: Study conditions of all acceptable column leaching studies with dimethenamid

Reference	soil	Soil type	oc (%)	pH	Aging of as	Preciptiation (mm)
Koenig, 1995a	BBA 2.1	Sand	0.2	7.6	no	200 mm deionised water over two days
	BBA 2.2	Sandy loam	1.5	7.0		
	BBA 2.3	Loamy sand	0.7	7.9		
	Möhlin	Silt loam	0.9	7.0		
	Flaach	Sandy clay loam	0.8	8.3		
Koenig, 1994	BBA 2.1	Sand	0.5	6.3	31 days at 20 °C and 40 % MWHC	
Koenig, 1995b	BBA 2.2	Sandy loam	2.3	7.0	22 days at 20 °C and 40 % MWHC	

Table 2.8-33: Distribution of radioactivity in leachate of all acceptable soil column leaching studies with dimethenamid (= DMTA)

Reference	Soil	Soil type	Leachate

			TR*	DMTA	M656H023	M656H027	M656H031
			% AR				
Koenig, 1995a	BBA 2.1	Sand	40.2	33.4	1.4	0.5	1.6
	BBA 2.2	Sandy loam	4.9	n.d.**	0.8	0.7	2.5
	BBA 2.3	Loamy sand	8.7	3.3	0.9	2.8	1.4
	Möhlin	Silt loam	5.2	0.6	0.5	1.4	1.3
	Flaach	Sandy clay loam	3.3	1.7	0.5	1.1	0.1
Koenig, 1994	BBA 2.1	Sand	23.8	2.1	16.7	0.7	1.0
Koenig, 1995b	BBA 2.2	Sandy loam	22.7	0.2	10.9	2.4	2.3

* TR total radioactivity
** n.d. not detected

Without aging of the active substance, dimethenamid showed a high mobility in the soil column of the sand soil, where a maximum of 33.4 % was found in the leachate. In the remaining 4 soils, only small amounts of dimethenamid were found in the leachate with a maximum of 3.3 %. The metabolites M656H023, M656H027 and M656H031 were found in low concentrations with a maximum of 2.8 % AR M656H027.
After aging of the active substance for 31 and 22 days, the amount of dimethenamid decreased to a maximum 2.1 % in the leachate of the sand soil and 0.2 % in the leachate of the sandy loam soil. The concentrations of the metabolites M656H027 and M656H031 remained low with a maximum of 2.4 % M656H027 in the leachate of both soils, but M656H023 concentrations increased up to a maximum of 16.7 %.

2.8.1.4.2 Lysimeter and field leaching studies

The mobility of dimethenamid was investigated in one field lysimeter study. A brief summary of the study conditions of the lysimeter study is given in Table 2.8-34. Four additional studies were performed with the aim to elucidate 17 unknown radioactive fractions found in the original lysimeter study: one mini-lysimeter study Fent, 2008, two studies Staudenmaier 2009 with 2014b and Staudenmaier & Kuhnke (2014) with additional investigations on the structure elucidations of metabolites in the unknown fractions and one study Staudenmaier (2014b) to assign the newly elucidated metabolites to the unknown lysimeter fractions and to estimate their concentrations. Since these studies were only performed to elucidate the 17 unknown radioactive fractions but are not used for further risk or exposure assessments, the study conditions of these studies are not summarised here. The maximum estimated annual average concentrations of dimethenamid and its metabolites (converted to dimethenamid-P and its equivalent metabolites) in the lysimeter leachate over the three years duration of the lysimeter study Burgener, 1996 are presented in Table 2.8-35. The metabolism scheme of dimethenenamid-P in the soil column is presented in Figure 2.8-1.

Table 2.8-34: Study conditions of lysimeter study Burgener, 1996 performed with dimethenamid

Parameter	Conditions
Duration	3 years (Mai 1992 - Mai 1995)
location	Itingen, Switzerland
Number of lysimeter	2 lysimeter,
Dimensions of lysimeter	depth: 1.2 m, area: 1.0 m^2
Application rate (g/ha)	1 x 1440 g/ha on lysimeter 1 2 x 1440 g/ha on lysimeter 2
Application date	First application on the 21st May 1992

	Second application on the 14th May 1993
Crop cultivation	Pre-emergence application one day after sowing of corn in May 1992 After harvest of corn, sowing of winter rye (first year) and winter whear (second year) in October 1992 and 1993 After harvest sowing of winter rape in August 1994
Soil properties of upper soil horizon (0-30 cm depth)	Borstel Sandy soil: 83.5 % sand 5.6 % clay 1.05 % oc pH 6.1
Total precipitation (mm)	3140
Total amount of leachate (L)	Lysimeter 1: 1178 Lysimeter 2: 1332

Table 2.8-35: Maximum estimated annual concentrations of dimethenamid and its metabolites (converted to dimethenamid-P and its equivalent metabolites) in the lysimeter leachate over the three years duration of the lysimeter study Burgener, 1996

Compound	Maximum estimated annual concentration in lysimeter leachate [µg/L]	Compound	Maximum estimated annual concentration in lysimeter leachate [µg/L]
Dimethenamid-P	< 0.05	M656PH051	1.1
M656PH003	0.1	M656PH052	0.9
M656PH010	0.07	M656PH053 (isomer 1)	1.6
M656PH023	1	M656PH053 (isomer 2)	2
M656PH027 (rotamer 1+2)	4	M656PH054 (rotamer 1+2)	3.3
M656PH032	1.5	M656H055	0.7
M656PH043 (rotamer 1+2)	1.2	M656PH059 (isomer 1)	0.8
M656PH045 (rotamer 1+2)	2	M656PH059 (isomer 2)	0.4
M656PH047 (rotamer 1+2)	1.2	M656PH059 (isomer 3)	1.6
M656PH049	1	M656PH062	2
M656PH050	0.5		

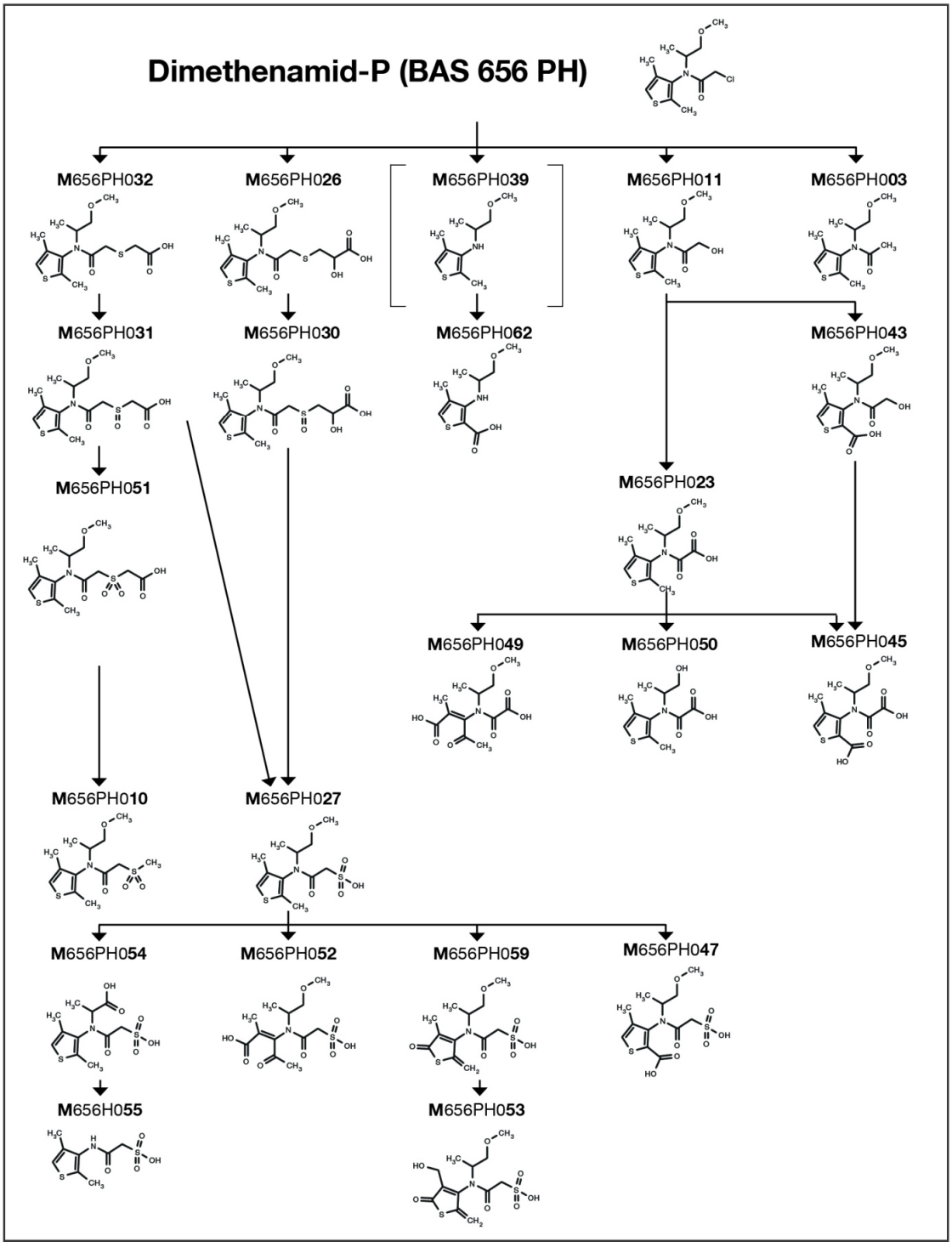


Figure 2.8-1: Metabolism scheme of dimethenamid-P in the soil column

The conditions of the lysimeter study were compared to climatic and soil conditions throughout Europe. The results show, that the annual average precipitation at the lysimeter study location over the three years of the lysimeter study (= 1046.5 mm/a) is higher than 98.1 % of the annual average precipitation of the whole agricultural area of Europe (although it was not stated which years of precipitation were used for comparison). The results further indicate that the organic matter content in the top 30 cm of the lysimeter soil (0.0181 kg/kg) is lower than 81.4 % of the agricultural area of Europe. Besides the Borstel soil exhibits a more coarse soil texture than the majority of the European soils.

2.8.2 Summary of fate and behaviour in water and sediment

2.8.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation):

The hydrolytic degradation of dimethenamid and dimethenamid-P was investigated in one acceptable study each (Fostiak & Hsieh, 1988 and Guirguis, 1997a). Both dimethenamid and dimethenamid-P were stable to hydrolysis at 25 °C and pH 5, pH 7 and pH 9.
The direct photochemical degradation of of dimethenamid and dimethenamid-P was investigated in one acceptable study each. A brief summary of the study conditions and the results of the aqueous photolysis studies is given in Table 2.8-36.

Table 2.8-36: Study conditions of aqueous photolysis studies with dimethenamid and dimethenamid-P

Investigated Compound	pH	T (°C)	Light intensity (W/m^2)	DT_{50} (d)	Kinetic model	Metabolites	Reference
dimethenamid	7	25	8.55×10^2	17.29	SFO	All < 5 %	Sabat, 1992
dimethenamid-P	7	25	1.1×10^3	15.56	SFO	All < 5 %	Guirguis, 1997b

After irradiation with an average intensity of $8.55 \cdot 10^2$ W/m^2, dimethenamid degraded in an aqueous solution with a DT_{50} value of 17.29 d. After irradiation with an average intensity of $1.1 \cdot 10^3$ W/m^2, dimethenamid-P degraded in an aqueous solution with a DT_{50} value of 15.56 d. No metabolites in concentrations > 5 % AR were formed. No difference in aqueous photolysis of dimethenamid and dimethenamid-P could be determined.
A quantum yield $\Phi = 0.007402$ for dimethenamid was determined in the study Sen & Yu, 1994. Based on the quantum yield and the UV/VIS spectrum of dimethenamid, a photolytical half-life in the top layer of aqueous systems of 13.67 h in April and of 15.44 h in May was calculated for European conditions.

2.8.2.2 Route and rate of biological degradation in aquatic systems:

No ‘ready biodegradability’ study with dimethenamid-P was submitted. Dimethenamid-P is considered as not ready biodegradable.

One acceptable study on the aerobic mineralisation of dimethenamid-P in surface water was submitted. Dimethenamid-P did not significantly degrade in the investigated surface water without suspended sediment of a Pond close to Biederthal. After 63 days more than 94.8 % AR was recovered as the unchanged active substance. The enantiomer ratio of dimethenamid-P remained constant in all analysed samples.

The distribution and degradation of dimethenamid and of dimethenamid-P in water and sediment systems was investigated in one study each. A brief summary of the study conditions of the two water/sediment studies is given in Table 2.8-37. An overview over the radioactive distribution in the investigated water/sediment systems is given in Table 2.8-38. The degradation and dissipation rates of dimethenamid and dimethenamid-P in the investigated water/sediment systems are presented in Table 2.8-39 and Table 2.8-40.

Table 2.8-37: Study conditions of all acceptable water/sediment studies under aerobic conditions with dimethenamid (=DMTA) and/or dimethenamid-P (DMTA-P)

Reference	W/S system	Water pH*	Sediment Class	TOC (%)	pH*	T (°C)	Duration (d)	Investigated Compound
Wyss-Benz, 1994	River Rhine	7.46 [c]	Loamy sand	0.78	7.06 [b]	20	105	DMTA
	Pond Anwil	7.60 [c]	Sandy loam	1.42	6.98 [b]			
Voelkel, 2014	River Rhine	8.14 [a]	Sandy loam	0.14	7.70 [a]	20	100	DMTA-P

* Before or at start of incubation
[a] measured in water, [b] measured in KCl, [c] type of buffered solution not given

Table 2.8-38: Radioactive distribution in all investigated water/sediment studies under aerobic conditions with dimethenamid (=DMTA) or dimethenamid-P (DMTA-P)

Reference	W/S system	CO_2 at study end (%)	Bound residues at study end (%)	Metabolites in water	Metabolites in sediment
Wyss-Benz, 1994	River Rhine	2.7	53.5	M656H023: < 5 % M656H027: not investigated M656H003: max. 9.1 % on d 105 (end of study)	M656H023: < 5 % M656H027: not investigated M656H003: 5.2 % on d 105 (end of study)
	Pond Anwil	2.1	49.3	M656H023: < 5 % M656H027: not investigated M656H003: 8 % on d 105 (end of study)	M656H023: < 5 % M656H027: not investigated M656H003: < 5 %
Voelkel, 2014	River Rhine	6.6	35.6	M656H023: 9.6 % on d 100 (end of study) M656H027: 6.3 % on d 100 (end of study) M656H003: 5.7 % on d 56	M656H023: < 5 % M656H027: < 5 % M656H003: < 5 %

Table 2.8-39: Degradation rates of dimethenamid and/or dimethenamid-P in the whole system of all investigated water/sediment studies under aerobic conditions (modelling and trigger endpoints)

Water/ Sediment System	Temp. (°C)	Whole system			Reference
		$DegT_{50}$ (d)	$DegT_{90}$ (d)	Kinetic model	
River Rhine	20	19.8	65.8	SFO	Wyss-Benz, 1994/ Bastiansen, 2011
Pond Anwil	20	35.1	116.5	SFO	
River Rhine	20	28	93.1	SFO	Voelkel, 2014
Geometric Mean (n=3)		31.35			

Table 2.8-40: Dissipation rates of dimethenamid and/or dimethenamid-P from the water and the sediment of all investigated water/sediment studies under aerobic conditions (trigger endpoints)

Water/ Sediment System	Temp. (°C)	Water			Sediment			Reference
		$DisT_{50}$ (d)	$DisT_{90}$ (d)	Kinetic model	$DisT_{50}$ (d)	$DisT_{90}$ (d)	Kinetic model	
River Rhine	20	11.1	57.7	FOMC	28.5	94.7	SFO	Wyss-Benz, 1994/ Bastiansen, 2011
Pond Anwil	20	21.4	86.2	DFOP	38.2	126.9	SFO	
River Rhine	20	15.36	74.99	DFOP	38	126	SFO	Voelkel, 2014

After aerobic degradation of dimethenamid and dimethenamid-P in water and sediment systems, mineralisation amounted to 2.1 – 2.7 % after 105 d and to 6.6 % after 100 d, respectively. 49.3 – 53.5 % non-extractable residues were formed from dimethenamid and 35.6 % non-extractable residues were formed from dimethenamid-P after 105 and 100 d. Maximum amounts of dimethenamid-P found in the sediment amounted to 18.15 – 22.8 % at day 7 – 14 with subsequent decline to 2 – 4.6 % at the end of the studies.
Three metabolites were formed in the water of the water/sediment systems in significant concentrations. The metabolite M656H023 remained < 5 % in the water/sediment study with dimethenamid, but amounted to a maximum of 9.6 % after 100 d in the water/sediment system with dimethenamid-P. The metabolite M656H027 was only investigated in the water/sediment system with dimethenamid-P were it reached a maximum of 6.3 % after 100 d. The metabolite M656H003 was formed from dimethenamid with maximum concentrations between 8 – 9.1 % AR after 105 d. From dimethenamid-P, M656H003 was formed with a maximum of 5.7 % on day 56 d with subsequent decline.
In the sediment, the metabolite M656H003 was formed in significant concentrations of max. 5.2 % at day 105 in one of the two water/sediment systems incubated with dimethenamid. In the remaining two water/sediment systems, M656H003 concentrations in the sediment remained < 5 %.
The ratio between both types of enantiomers of dimethenamid-P remained constant throughout the incubation time in the investigated water/sediment system (the amount of R-enantiomer ranged between 5.3 and 6.4 %, while the amount of S-enantiomer ranged from 93.6 to 94.7 %).
While dimethenamid and dimethenamid-P were not investigated in water/sediment systems sampled both at the same time and the same place, the degradation and dissipation rates in the whole system and in the water and sediment phases of the three investigated systems were in the same range. Besides, no change in the ratio of the R- and S-enantiomer of dimethenamid-P was observed during incubation. The degradation route of dimethenamid and dimethenamid-P appeared slightly different with different metabolites being formed in concentrations >5 %. However, differences between the studies with dimethenamid and dimethenamid-P were not dramatic and all formed metabolites remained < 10 %. It was decided thus by the RMS to use the amalgamated results of all investigated water/sediment studies both with dimethenamid-P and with racemic dimethenamid, for environmental fate assessment of dimethenamid-P.

2.8.3 Summary of fate and behaviour in air

Dimethenamid-P has a vapour pressure of 3.47 x 10^{-3} Pa (20 °C). Hence dimethenamid-P is regarded as semivolatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by dimethenamid-P due to volatilisation with subsequent deposition is possible. This was confirmed by one acceptable volatilisation study of dimethenamid-P in the formulation BAS 656 12 H which measured 17.5 % to 26.1 % volatilisation of dimethenamid-P from plant surfaces after 24 h.

The photochemical oxidative degradation half life of dimethenamid-P in the air was estimated in one acceptable study. The calculated half life of dimethenamid-P is 0.2 d for a 12 h day and an OH radicals concentration of 1.5 10^6 cm^{-3}. Distribution of the active substance via long range transport

through the atmosphere is therefore not expected.

2.8.4 Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

2.8.4.1 Monitoring data of groundwater

2.8.4.1.1 Groundwater monitoring in Germany

One monitoring study of groundwater at 20 groundwater wells in Germany for the dimethenamid-P metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047 and M656PH054 was submitted by the applicant.
The selection of the groundwater wells and the field work of the study including sampling are summarised in Schmidt et al (2010), Schmidt & Schulz (2012) and Schmidt & Schneider (2013). The analytical results of the groundwater samples for the metabolites of dimethenamid-P are presented in Class (2013) and Mewis (2014a).

The 20 wells used for monitoring were situated in four maize growing regions with 1 to 10 m distance of groundwater to soils surface (see Table 2.8-41). Groundwater samples were taken on a bimonthly interval between May 2007 and March 2010 and on a quarterly interval between June 2010 and March 2013.

Table 2.8-41: Groundwater monitoring regions and number and location of wells of the groundwater monitoring study in Germany

Groundwater Monitoring regions in Germany	No. of wells	Locations of wells
Southern Upper Rhine Valley	4	Rheinau, Ichenheim, Oberhausen, Hartheim
Lower Bavarian Hilly Country	5	Glaslern, Osterholzen, Pfarrkirchen, Rossbach, Asing
Altmark/ Prignitz region	3	Gardelegen, Quadendambeck, Drewen
Northwest German Lowlands	8	Albersloh, Ostbevern, Veltrup, Flechum, Vinnen-Ahmsen, Wedel, Krogaspe, Brekendorf

In the years 2007 to 2009, the plant protection products Clio® Super or Clio® Top Pack were provided for free to farmers, which cultivate maize fields within a distance of approx. 1 km up-gradient from the monitoring wells. The number and the size of the treated field upstream of the wells and the distance of treated field with regards to the wells were recorded. In the years 2007 and 2008, 1.8 L/ha Clio® Super, which is equivalent to 968.4 g/ha dimethenamid-P and in the year 2009, 1.5 L/ha Clio® Super, which is equivalent to 807 g/ha dimethenamid-P, was applied onto maize in the BBCH growth stage range 12-16.
In the study Haering & Mewis (2014) the response time of the wells to the application peaks 2007, 2008 and 2009 were assessed using groundwater modelling with FOCUS PEARL 4.4.4 to model the time necessary for the metabolites to reach groundwater level together with hydrogeological data to estimate the travel time of the groundwater from the treated fields to the wells.
According to the modelled arrival times of the application peaks at the different wells, the sampling campaign was too short for the groundwater wells Asing, Quadendambeck and Drewen. For Gardelegen, no arrival times of the peak concentrations could be modelled, however the arrival times of the breakthrough concentrations of the application 2008 and 2009 was also outside of the period of the sampling campaign. At some additional wells, Glaslern, Osterholzen, Ostbevern, Rheinau and Vinnen-Ahmsen, not all of the yearly peaks arrived in time, however at least two of the application peaks should have reached the wells in time. Overall for 16 of the 20 wells, the travel times are considered sufficient to monitor the expected metabolite peaks of the sponsored applications from 2007 to 2009.

The maximum concentrations and the number of groundwater wells, where the metabolites were detected are summarised again in Table 2.8-42.

Table 2.8-42: Maximum concentrations and number of groundwater wells where the metabolites were detected in the German monitoring (20 groundwater wells, measurements from May 2007 to March 2013)

Metabolite	No of wells with positive detections	Percent of all 20 wells with positive detections	Maximum concentrations [µg/L]
M656PH003	0	0 %	<LOQ
M656PH010	0	0 %	<LOQ
M656PH027	5	25 %	1.680
M656PH023	3	15 %	0.379
M656PH031	0	0 %	<LOQ
M656PH032	0	0 %	<LOQ
M656PH043	0	0 %	<LOQ
M656PH045	2	10 %	0.045
M656PH047	4	20 %	0.149
M656PH054	1	5 %	0.047

The four groundwater wells, Asing, Quadendambeck and Drewen and Gardelegen, where all application peaks would arrive outside of the sampling campaign, belonged to the wells where none of the metabolites were detected.

2.8.4.1.2 Groundwater monitoring in The Netherlands:

One monitoring study (Mewis, 2014b) of groundwater at 80 groundwater wells in the Netherlands for the dimethenamid-P metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047 and M656PH054 was submitted by the applicant.

Groundwater specimens were sampled once in the period from 08 January to 16 April 2013 from groundwater monitoring wells with shallow groundwater located in corn producing areas of the province North Brabant, The Netherlands.

No information on the amount of use and the duration of use of dimethenamid-P containing products in the catchment of the wells, the distance of the wells to areas treated with dimethenamid-P and the amount of areas treated with dimethenamid-P upstream of the wells were provided.
Besides, no information was provided on the hydrogeology, pedology or climate of the agricultural area or on the catchment of the wells or their response time.

The maximum concentrations and the number of groundwater wells, where the metabolites were detected are summarised in Table 2.8-43.

Table 2.8-43: Maximum concentrations and number of groundwater wells where the metabolites were detected in the Dutch Monitoring (80 groundwater wells, 1 sample collected in the period from 08 January to 16 April 2013)

Metabolite	No of wells with positive detections	Percent of wells with positive detections	Maximum concentrations [µg/L]
M656PH003	0	0 %	<LOQ
M656PH010	1	1 %	0.033
M656PH027	30	38 %	1.509
M656PH023	23	29 %	0.810
M656PH031	1	1 %	0.042
M656PH032	0	0 %	<LOQ
M656PH043	0	0 %	<LOQ
M656PH045	13	16 %	0.213
M656PH047	3	4 %	0.459
M656PH054	5	6 %	0.076

2.8.4.1.3 Groundwater monitoring in Germany (open literature study):

Besides, one open literature monitoring study Hames & Freudenberger (2011) the dimethenamid-P metabolites M656PH027 and M656PH023 in Germany was available. The metabolites M656PH027 and M656PH023 were measured from 2006 to 2008 at 228 and 232 monitoring points located in three federal states of Germany. M656PH027 and M656PH023 were not detected in concentrations >1 µg/L in any of the groundwater samples. No information was available on the amount of use and the duration of use of dimethenamid-P containing products in the catchment of the wells, the distance of the wells to areas treated with dimethenamid-P and the amount of areas treated with dimethenamid-P upstream of the wells is provided. Besides, no information was provided on the hydrogeology, pedology or climatic conditions of the areas upstream of the wells or the depth of the groundwater level tapped by the wells. No information is provided on the catchment of the wells or their response time.

2.8.4.2 Monitoring data of surface water

One monitoring study Laabs (2010) of surface water for dimethenamid-P and its metabolites M656H003, M656H027, M656H023, and M656H031 in 5 European rivers was submitted by the applicant. Samples were collected from the Rott river (eastern Bavaria, Germany), the Adda and Oglio rivers (northern tributaries of the Po river, ltaly) and the Sió and Danube river (central-western part of Hungary) since they all drain areas with relatively intensive cultivation of corn. No precise information on the catchments and on the area of the catchments that is used for cultivation with crops and the area that were treated with dimethenamid-P was provided. Information on the amount of dimethenamid-P used in the catchments is also missing. Surface water samples were taken in 2009, biweekly during the application season and weekly thereafter for five months (April to beginning of September in Italy, May to end of September in Hungary) or weekly from May to November (Germany).
Dimethenamid-P was frequently detected in surface water samples in this study. Its maximum concentration reached 0.46 µg/L (Germany, Rott) to 0.51 µg/L (Hungray, Sió) at two sampling locations, while much lower peak concentrations were measured at the other sampling locations (<LOQ to 0.02 µg/L).
Dimethenamid-P metabolites were detected in traces at all sampling sites. At the German sampling site, peak concentrations of the metabolites were highest and ranged from 0.02 to 0.13 µg/L (M656PH027 ≈ M656PH031 ≈ M656PH023 > M656PH003). The metabolite maximum peak was recorded roughly one month after the highest observance of the active substance. While in the sampled Italian river bodies only sporadic traces of dimethenamid-P metabolites were measured, the metabolites M656PH023, M656PH027, and M656PH031 were frequently detected at the two Hungarian sites, however at low maximum concentrations ≤0.02 µg/L. M656PH003 was never detected in Italian or Hungarian surface water samples.

Additionally, one open literature monitoring study Chevre et al (2008) of dimethenamid-P in surface water of the Geneva Lake was available. Samples were taken two times in April 26, 2004 and April 26, 2005 at different depths from a site situated in the middle of the lake. Dimethenamid was detected only at one sampling date at both depth ranges with an average concentration of 0.001 µg L^{-1}. Information on the catchment of the Lake Geneva and on the area of the catchment that is used for agriculture and that was treated with dimethenamid-P was not provided. Information on the amount of dimethenamid-P used in the catchment in the Lake is also missing.

Finally, one open literature study Leu et al (2004) on surface water measurements in a small area of the catchment of the Lake Greifensee, 25 km southeast of Zurich, Switzerland, which drains into the river Aa Mönchaltorf was available. In the study, dimethenamid and two other pesticides were investigated over a period of 67 days after a controlled application of 0.75 kg ha^{-1} on 13 cornfields on May 8, 2000. The first 9 days after application remained very dry with only 3 mm of rain. During the two following weeks, three rain events resulted in a total of 51 mm precipitation. However, only the 6th rainfall event (46 mm, ~ 20 - 30 days after application) caused the first substantial hydrolical response from the catchment as well as major loss of herbicides. Total mass losses of dimethenamid from the fields of the catchment accounted for 0.27 % of its total amount applied. Since dimethenamid-P degrades in soil under aerobic conditions with a DT_{50} value of 11.5 d, it can be assumed that at the time of the 6th rain event a major amount of dimethenamid would have been already degraded on the field surface. The dissipation of dimethenamid from soil was described by first-order kinetics with a field DT_{50} of 13 days as median value from 11 fields.

2.8.4.3 Monitoring data of air

One open literature monitoring study (Coscolla et al, 2010) of dimethenamid-P in air of Central France was available. For the study, dimethenamid-P among other pesticides was measured on three rural sites (Saint Martin d'Auxigny, Oysonville and Saint Aignan) and two urban sites (Tour and Orléans) in 3 sampling campaigns in 2006, 2007 and 2008. The rural sampling site at Saint Martin d'Auxigny was surrounded by orchards, the agricultural area of the sampling site Saint Aignan was dominated by vineyards and the agricultural area of the sampling site Oysonville was dominated by arable crops such as maize, wheat, soybean, barley and sunflowers.
Dimethenamid was detected at a low frequency of 2 % at concentrations ranging from 0.16 - 0.74 ng m^{-3} in the 262 air samples, however no information was given, if dimethenamid-P was really applied in any of the areas close to the sampling site during the sampling campaigns, the size and distance of any treated areas or the amount of dimethenamid-P used on any areas in vicinity of the sampling site.

2.8.5 Definition of the residues in the environment requiring further assessment

2.8.5.1 Soil

Dimethenamid-P and the metabolites M656PH023, M656PH027 and M656PH031 are the relevant residues for further risk assessment in soil.

2.8.5.2 Surface water

Dimethenamid-P and the metabolites M656PH003, M656PH023, M656PH027 and M656PH031 are the relevant residues for further risk assessment in surface water.

2.8.5.3 Sediment

Dimethenamid-P and the metabolites M656PH003 are the relevant residues for further risk assessment in sediment.

2.8.5.4 Groundwater

Dimethenamid-P and the metabolites M656PH003, M656PH010, M656PH023, M656PH027 and M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053 (isomer 1 und 2), M656PH054, M656H055, M656PH059 (isomer 1, 2 und 3) and M656PH062 are the relevant residues for further risk assessment in groundwater.

2.8.5.5 Air

Dimethenamid-P is the relevant residue for further risk assessment in air.

2.8.6 Summary of exposure calculations and product assessment

2.8.6.1 Predicted concentration in soil (PEC_{soil})

2.8.6.1.1 Product BAS 656 12 H with 720 g/L dimethenamid-P

Predicted environmental concentrations in soil (PEC_{soil}) were calculated for dimethenamid-P and its soil metabolites M656PH023, M656PH027 and M656PH031 for one pre-emergence application of 864 g dimethenamid-P per hectare to maize as worst case application scenario assuming a soil depth of 5 cm and a soil bulk density of 1.5 g/cm^3.
Since the maximum DT_{50} values of the metabolites M656PH023 and M656PH031 in soil exceed 90 days, the potential of accumulation of these metabolites in soil was assessed. For this purpose, the plateau concentration in soil at steady state ($PEC_{soil,plateau}$) and the overall accumulation PEC in soil ($PEC_{soil,accu}$) after application of dimethenamid-P over many years were determined assuming a tillage depth of 20 cm.

For details on the PEC_{soil} calculations please refer to Volume 3 CP, B 8.2 of the product BAS 656 12 H.

2.8.6.1.2 Product BAS 830 01 H with 333 g/L dimethenamid-P & 167 g/L quinmerac

Predicted environmental concentrations in soil (PEC_{soil}) were calculated for dimethenamid-P and its soil metabolites M656PH023, M656PH027 and M656PH031 for one pre-emergence application of 500 g dimethenamid-P per hectare to winter oilseed rape, as worst case application scenario assuming a soil depth of 5 cm and a soil bulk density of 1.5 g/cm^3.
Since the maximum DT_{50} values of the metabolites M656PH023 and M656PH031 in soil exceed 90 days, the potential of accumulation of these metabolites in soil was assessed. For this purpose, the plateau concentration in soil at steady state ($PEC_{soil,plateau}$) and the overall accumulation PEC in soil ($PEC_{soil,accu}$) after application of dimethenamid-P over many years were determined assuming a tillage depth of 20 cm.

For details on the PEC_{soil} calculations and for the PEC_{soil} of quinmerac and its metabolites BH 518-2 and BH 518-5 please refer to Volume 3 CP, B 8.2 of the product BAS 830 01 H.

2.8.6.2 Predicted concentration in groundwater ($PEC_{groundwater}$)

2.8.6.2.1 Product BAS 656 12 H with 720 g/L dimethenamid-P

Predicted tier 1 environmental concentrations (PEC_{GW}) of the active substance dimethenamid-P in the formulation BAS 656 12 H and the metabolites M656PH023, M656PH027 and M656PH031 were derived with the programs FOCUS PELMO 5.5.3. The PEC_{GW} of the metabolites only found in the lysimeter leachate M656PH003, M656PH010, M656PH023, M656PH027, M656PH031 M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 were estimated using transfer factors derived from the ratio of the modelled groundwater concentration of M656H027 and the M656H027 concentrations measured in the lysimeter.
PEC_{GW} were derived for the intended uses of dimethenamid-P in the formulation BAS 656 12 H listed in Table 2.8-44 as worst case scenarios.

Table 2.8-44: Worst case application scenarios used for PEC_{GW} modelling

Crop	application rate (g/ha)	Growth stage	Interception (%)	Soil relevant application rate (g/ha)	Application date
maize	1 x 864	BBCH 00	0	1 x 864	7 days before crop emergence
maize	1 x 864	BBCH 10	25	1 x 648	7 days after crop emergence
soybeans & sunflowers	1 x 864	BBCH 00	0	1 x 864	7 days before crop emergence
sugar beet	1 x 864	BBCH 00	0	1 x 864	7 days before crop emergence
sugar beet	1 x 720	BBCH 12	20	1 x 576	7 days after crop emergence

Dimethenamid-P remained < 0.1 µg/L in the groundwater in all modelled scenarios for all application scenarios.

The metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031 M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 were modelled in groundwater concentrations ≥ 0.1 µg/L in several or all FOCUS scenarios. The number of scenarios where the metabolites exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/ or the 10 µg/L trigger and the maximum modelled groundwater concentrations are listed for all representative uses of BAS 656 12 H in Table 2.8-45 to Table 2.8-62.

The overall maximum PEC_{GW} of all modelled scenarios of all application scenarios for the metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 are listed inTable 2.8-63.

For all the metabolites maximum groundwater concentrations ≥ 0.1 µg/L were modelled. Thus, a relevance assessment of these metabolites is required.

Table 2.8-45: Number of scenarios where M656PH003 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	6	2	0	0	0.1
864 g/ha post-emergence application to maize	8	7	1	0	0	0.1
864 g/ha pre-emergence application to soybeans	1	1	0	0	0	<0.1
864 g/ha pre-emergence application to sunflowers	2	2	0	0	0	<0.1
864 g/ha pre-emergence application to sugarbeet	9	4	5	0	0	0.2
720 g/ha post-emergence application to sugarbeet	9	7	2	0	0	0.1

Table 2.8-46: Number of scenarios where M656PH010 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	8	0	0	0	<0.1
864 g/ha post-emergence application to maize	8	8	0	0	0	<0.1
864 g/ha pre-emergence application to soybeans	1	1	0	0	0	<0.1
864 g/ha pre-emergence application to sunflowers	2	2	0	0	0	<0.1
864 g/ha pre-emergence application to sugarbeet	9	8	1	0	0	0.1
720 g/ha post-emergence application to sugarbeet	9	9	0	0	0	<0.1

Table 2.8-47: Number of scenarios where M656PH023 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	1	2	5	0	1.3
864 g/ha post-emergence application to maize	8	2	4	2	0	0.98
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.4
864 g/ha pre-emergence application to sunflowers	2	1	0	1	0	1.0
864 g/ha pre-emergence application to sugarbeet	9	0	3	5	0	1.15
720 g/ha post-emergence application to sugarbeet	9	1	8	0	0	0.7

Table 2.8-48: Number of scenarios where M656PH027 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	1	7	0	5.0
864 g/ha post-emergence application to maize	8	0	1	7	0	4.0
864 g/ha pre-emergence application to soybeans	1	0	0	1	0	1.7
864 g/ha pre-emergence application to sunflowers	2	0	0	2	0	3.0
864 g/ha pre-emergence application to sugarbeet	9	0	0	9	0	7.4
720 g/ha post-emergence application to sugarbeet	9	0	0	9	0	5.1

Table 2.8-49: Number of scenarios where M656PH031 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	0	6	2	14.4
864 g/ha post-emergence application to maize	8	0	0	7	1	11.3
864 g/ha pre-emergence application to soybeans	1	0	0	1	0	5.0
864 g/ha pre-emergence application to sunflowers	2	0	0	2	0	7.8
864 g/ha pre-emergence application to sugarbeet	9	0	0	1	8	25.0
720 g/ha post-emergence application to sugarbeet	9	0	0	8	1	17.2

Table 2.8-50: Number of scenarios where M656PH032 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	3	5	0	1.9
864 g/ha post-emergence application to maize	8	0	4	4	0	1.1
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.6
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	1.1
864 g/ha pre-emergence application to sugarbeet	9	0	0	9	0	2.8
720 g/ha post-emergence application to sugarbeet	9	0	1	8	0	1.9

Table 2.8-51: Number of scenarios where M656PH043 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	4	4	0	1.5
864 g/ha post-emergence application to maize	8	0	5	3	0	1.2
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.5
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	0.9
864 g/ha pre-emergence application to sugarbeet	9	0	1	8	0	2.2
720 g/ha post-emergence application to sugarbeet	9	0	3	6	0	1.5

Table 2.8-52: Number of scenarios where M656PH045 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	2	6	0	2.5
864 g/ha post-emergence application to maize	8	0	2	6	0	2.0
864 g/ha pre-emergence application to soybeans	1	0	0	1	0	0.9
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	1.5
864 g/ha pre-emergence application to sugarbeet	9	0	0	9	0	3.7
720 g/ha post-emergence application to sugarbeet	9	0	0	9	0	2.6

Table 2.8-53: Number of scenarios where M656PH047 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	4	4	0	1.5
864 g/ha post-emergence application to maize	8	0	5	3	0	1.2
864 g/ha pre-emergence application to soybeans	1	0	0	1	0	0.5
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	0.9
864 g/ha pre-emergence application to sugarbeet	9	0	1	8	0	2.2
720 g/ha post-emergence application to sugarbeet	9	0	3	6	0	1.5

Table 2.8-54: Number of scenarios where M656PH049 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	5	3	0	1.3
864 g/ha post-emergence application to maize	8	0	7	1	0	1.0
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.4
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	0.8
864 g/ha pre-emergence application to sugarbeet	9	0	1	8	0	1.8
720 g/ha post-emergence application to sugarbeet	9	0	5	4	0	1.3

Table 2.8-55: Number of scenarios where M656PH050 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	8	0	0	0.6
864 g/ha post-emergence application to maize	8	0	8	0	0	0.5
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.2
864 g/ha pre-emergence application to sunflowers	2	0	2	0	0	0.4
864 g/ha pre-emergence application to sugarbeet	9	0	8	1	0	0.9
720 g/ha post-emergence application to sugarbeet	9	0	9	0	0	0.6

Table 2.8-56: Number of scenarios where M656PH051 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	4	4	0	1.4
864 g/ha post-emergence application to maize	8	0	6	2	0	1.1
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.5
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	0.8
864 g/ha pre-emergence application to sugarbeet	9	0	1	8	0	2.0
720 g/ha post-emergence application to sugarbeet	9	0	3	6	0	1.4

Table 2.8-57: Number of scenarios where M656PH052 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	5	3	0	1.1
864 g/ha post-emergence application to maize	8	0	7	1	0	0.9
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.4
864 g/ha pre-emergence application to sunflowers	2	0	2	0	0	0.7
864 g/ha pre-emergence application to sugarbeet	9	0	4	5	0	1.7
720 g/ha post-emergence application to sugarbeet	9	0	6	3	0	1.2

Table 2.8-58: Number of scenarios where M656PH053-isomers 1 & 2 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	M656PH053-isomer 1					
	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	2	6	0	2.0
864 g/ha post-emergence application to maize	8	0	3	5	0	1.6
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.7
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	1.2
864 g/ha pre-emergence application to sugarbeet	9	0	0	9	0	2.9
720 g/ha post-emergence application to sugarbeet	9	0	1	8	0	2.0
Application scenario	**M656PH053-isomer 2**					
	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	2	6	0	2.5
864 g/ha post-emergence application to maize	8	0	2	6	0	2.0
864 g/ha pre-emergence application to soybeans	1	0	0	1	0	0.9
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	1.5
864 g/ha pre-emergence application to sugarbeet	9	0	0	9	0	3.7
720 g/ha post-emergence application to sugarbeet	9	0	0	9	0	2.6

Table 2.8-59: Number of scenarios where M656PH054 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	1	7	0	4.2
864 g/ha post-emergence application to maize	8	0	1	7	0	3.3
864 g/ha pre-emergence application to soybeans	1	0	0	1	0	1.4
864 g/ha pre-emergence application to sunflowers	2	0	0	2	0	2.5
864 g/ha pre-emergence application to sugarbeet	9	0	0	9	0	6.1
720 g/ha post-emergence application to sugarbeet	9	0	0	9	0	4.2

Table 2.8-60: Number of scenarios where M656H055 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	6	2	0	0.9
864 g/ha post-emergence application to maize	8	0	8	0	0	0.7
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.3
864 g/ha pre-emergence application to sunflowers	2	0	2	0	0	0.5
864 g/ha pre-emergence application to sugarbeet	9	0	5	4	0	1.3
720 g/ha post-emergence application to sugarbeet	9	0	7	2	0	0.9

Table 2.8-61: Number of scenarios where M656H059, isomers 1, 2 and 3 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	M656PH059-isomer 1					
	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	5	3	0	1.0
864 g/ha post-emergence application to maize	8	0	7	1	0	0.8
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.3
864 g/ha pre-emergence application to sunflowers	2	0	2	0	0	0.6
864 g/ha pre-emergence application to sugarbeet	9	0	5	4	0	1.5
720 g/ha post-emergence application to sugarbeet	9	0	7	2	0	1.0
Application scenario	**M656PH059-isomer 2**					
	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	8	0	0	0.5
864 g/ha post-emergence application to maize	8	0	8	0	0	0.4
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.2
864 g/ha pre-emergence application to sunflowers	2	0	2	0	0	0.3
864 g/ha pre-emergence application to sugarbeet	9	0	9	0	0	0.7
720 g/ha post-emergence application to sugarbeet	9	0	9	0	0	0.5
Application scenario	**M656PH059-isomer 3**					
	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	2	6	0	2.0
864 g/ha post-emergence application to maize	8	0	3	5	0	1.6
864 g/ha pre-emergence application to soybeans	1	0	1	0	0	0.7
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	1.2
864 g/ha pre-emergence application to sugarbeet	9	0	0	9	0	2.9
720 g/ha post-emergence application to sugarbeet	9	0	1	8	0	2.0

Table 2.8-62: Number of scenarios where M656H062 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 656 12 H

Application scenario	Number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
864 g/ha pre-emergence application to maize	8	0	2	6	0	2.5
864 g/ha post-emergence application to maize	8	0	2	6	0	2.0
864 g/ha pre-emergence application to soybeans	1	0	0	1	0	0.9
864 g/ha pre-emergence application to sunflowers	2	0	1	1	0	1.5
864 g/ha pre-emergence application to sugarbeet	9	0	0	9	0	3.7
720 g/ha post-emergence application to sugarbeet	9	0	0	9	0	2.6

Table 2.8-63: Overall maximum PEC_{GW} of the metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 for all representative uses of BAS 656 12 H

Metabolite	Maximum concentrations [µg L^{-1}]	FOCUS scenario	Crop and application scenario
M656PH003	0.2	Jokoinen	864 g/ha pre-emergence application to sugar beet
M656PH010	0.1		
M656PH023	2.6	Hamburg	864 g/ha pre-emergence application to maize
M656PH027	7.4	Jokoinen	864 g/ha pre-emergence application to sugar beet
M656PH031	25.0		
M656PH032	2.8		
M656PH043	2.2		
M656PH045	3.7		
M656PH047	2.2		
M656PH049	1.8		
M656PH050	0.9		
M656PH051	2.0		
M656PH052	1.7		
M656PH053 (iso 1)	2.9		
M656PH053 (iso 2)	3.7		
M656PH054	6.1		
M656H055	1.3		
M656PH059 (iso 1)	1.5		
M656PH059 (iso 2)	0.7		
M656PH059 (iso 3)	2.9		
M656PH062	3.7		

iso= isomer, rota= rotamer

For more details on the PEC_{GW} calculations please refer to Volume 3 CP, B 8.3 of the product BAS 656 12 H.

2.8.6.2.2 Product BAS 830 01 H with 333 g/L dimethenamid-P & 167 g/L quinmerac

Predicted tier 1 environmental concentrations (PEC_{GW}) of the active substance dimethenamid-P in the formulation BAS 656 12 H and the metabolites M656PH023, M656PH027 and M656PH031 were derived with the programs FOCUS PELMO 5.5.3. The PEC_{GW} of the metabolites only found in the lysimeter leachate M656PH003, M656PH010, M656PH023, M656PH027, M656PH031 M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 were estimated using transfer factors derived from the ratio of the modelled groundwater concentration of M656H027 and the M656H027 concentrations measured in the lysimeter.
PEC_{GW} were derived for the intended uses of dimethenamid-P in the formulation BAS 830 01 H listed in Table 2.8-64 as worst case scenarios.

Table 2.8-64: Worst case application scenarios used for PEC_{GW} modelling

Crop	application rate (g/ha)	Growth stage	Interception (%)	Soil relevant application rate (g/ha)	Application date
Winter oilseed rape	1 x 500	BBCH 00	0	1 x 500	7 days before crop emergence
Winter oilseed rape	1 x 500	BBCH 10	40	1 x 300	7 days after crop emergence

Dimethenamid-P remained < 0.1 µg/L in the groundwater in all modelled scenarios for all application scenarios.

The metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031 M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 were modelled in groundwater concentrations ≥ 0.1 µg/L in several or all FOCUS scenarios. The number of scenarios were the metabolites exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/ or the 10 µg/L trigger and the maximum modelled groundwater concentrations are listed for all representative uses of BAS 656 12 H in Table 2.8-65 to Table 2.8-82.

The overall maximum estimated PEC_{GW} of the metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 of all modelled scenarios of all application scenarios are listed in Table 2.8-83.

For all the metabolites maximum groundwater concentrations ≥ 0.1 µg/L were modelled. Thus, a relevance assessment of these metabolites is required.

Table 2.8-65: Number of scenarios where M656PH003 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	2	5	0	0	0.2
500 g/ha post-emergence application to winter oilseed rape	6	1	5	0	0	0.1

Table 2.8-66: Number of scenarios where M656PH010 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	5	1	0	0	0.1
500 g/ha post-emergence application to winter oilseed rape	6	6	0	0	0	<0.1

Table 2.8-67: Number of scenarios where M656PH023 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	1	5	0	1.6
500 g/ha post-emergence application to winter oilseed rape	6	0	6	6	0	0,7

Table 2.8-68: Number of scenarios where M656PH027 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	6.4
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	3.9

Table 2.8-69: Number of scenarios where M656PH031 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	5	1	12.3
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	7.6

Table 2.8-70: Number of scenarios where M656PH032 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	2.4
500 g/ha post-emergence application to winter oilseed rape	6	0	1	5	0	1.5

Table 2.8-71: Number of scenarios where M656PH043 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	1.9
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	1.2

Table 2.8-72: Number of scenarios where M656PH043 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	3.2
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	2.0

Table 2.8-73: Number of scenarios where M656PH047 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	1.9
500 g/ha post-emergence application to winter oilseed rape	6	0	5	1	0	1.2

Table 2.8-74: Number of scenarios where M656PH049 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	1.6
500 g/ha post-emergence application to winter oilseed rape	6	0	5	1	0	1.0

Table 2.8-75: Number of scenarios where M656PH050 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	5	1	0	0.8
500 g/ha post-emergence application to winter oilseed rape	6	0	6	0	0	0.5

Table 2.8-76: Number of scenarios where M656PH051 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	1.7
500 g/ha post-emergence application to winter oilseed rape	6	0	5	1	0	1.1

Table 2.8-77: Number of scenarios where M656PH052 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	4	2	0	1.4
500 g/ha post-emergence application to winter oilseed rape	6	0	5	1	0	0.9

Table 2.8-78: Number of scenarios where M656PH053, isomers 1 &2 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	M656PH053- isomer 1					
	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	2.5
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	1.6
Application scenario	**M656PH053- isomer 2**					
	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	3.2
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	2.0

Table 2.8-79: Number of scenarios where M656PH054 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	5.2
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	3.2

Table 2.8-80: Number of scenarios where M656H055 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	5	1	0	1.1
500 g/ha post-emergence application to winter oilseed rape	6	0	5	1	0	0.7

Table 2.8-81: Number of scenarios where M656PH059, isomers 1, 2 & 3 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	M656PH059- isomer 1					
	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	4	2	0	1.3
500 g/ha post-emergence application to winter oilseed rape	6	0	5	1	0	0.8
Application scenario	**M656PH059- isomer 2**					
	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	6	0	0	0.6
500 g/ha post-emergence application to winter oilseed rape	6	0	6	0	0	0.4
Application scenario	**M656PH059- isomer 3**					
	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	2.5
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	1.6

Table 2.8-82: Number of scenarios where M656H062 exceeded the 0.1 µg/L trigger, the 0.75 µg/L trigger and/or the 10 µg/L trigger and the maximum modelled concentrations in groundwater for each representative use of BAS 830 01 H

Application scenario	number of FOCUS scenarios	Number of scenarios with PEC_{GW}				Maximum PEC_{GW} (µg/L)
		<0.1 µg/L	≥ 0.1 µg/L	≥ 0.75 µg/L	≥ 10 µg/L	
500 g/ha pre-emergence application to winter oilseed rape	6	0	0	6	0	3.2
500 g/ha post-emergence application to winter oilseed rape	6	0	0	6	0	2.0

Table 2.8-83: Overall maximum PEC_{GW} of the metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 for all representative uses of BAS 830 01 H

Metabolite	Maximum concentrations [µg L^{-1}]	FOCUS scenario	Crop and application scenario
M656PH003	0.2	Hamburg	Pre-emergence application to winter oilseed rape
M656PH010	0.1		
M656PH023	2.7		
M656PH027	6.3		
M656PH031	12.3		
M656PH032	2.4		
M656PH043	1.9		
M656PH045	3.2		
M656PH047	1.9		
M656PH049	1.6		
M656PH050	0.8		
M656PH051	1.7		
M656PH052	1.4		
M656PH053 (iso 1)	2.5		
M656PH053 (iso 2)	3.2		
M656PH054	5.2		
M656H055	1.1		
M656PH059 (iso 1)	1.3		
M656PH059 (iso 2)	0.6		
M656PH059 (iso 3)	2.5		
M656PH062	3.2		

iso= isomer, rota= rotamer

For details on the PEC_{GW} calculations and for the PEC_{GW} of quinmerac and its metabolites BH 518-2 and BH 518-5 please refer to Volume 3 CP, B 8.3 of the product BAS 830 01 H.

2.8.6.3 Predicted concentration in surface water and sediment (PEC_{sw} and PEC_{sed})

2.8.6.3.1 Product BAS 656 12 H with 720 g/L dimethenamid-P

Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for dimethenamid-P, the active substance in the formulated product BAS 656 12 H, and the metabolites M656PH003, M656PH023, M656PH027 and M656PH031.
For FOCUS SW Step 1 and Step 2 calculations, the model STEPS1-2 in FOCUS, version 2.1, was used. FOCUS SW Step 3 calculations were performed using the software tool SWASH version 3.1. Within SWASH, the model versions FOCUS-PRZM 3.1.1 and FOCUS-MACRO 4.4.2 together with FOCUS-TOXSWA 3.3.1 were used. Step 4 calculations were performed using SWAN version 2.0.0.

FOCUS SW Step 1 and Step 2 PEC_{sw} and PEC_{sed} were derived dimethenamid-P and the metabolites M656PH003, M656PH023, M656PH027 and M656PH031 for the worst case scenarios listed in Table 2.8-84.

Table 2.8-84 Worst case application scenarios used for FOCUS SW Step 1 and Step 2 modelling

Crop	application rate (g/ha)	Growth stage	Interception (%)	Application window
maize	1 x 864	BBCH 00	No interception	March - May
maize	1 x 864	BBCH 10	Minimal crop cover	March - May
Soybeans, sunflowers & sugar beet	1 x 864	BBCH 00	No interception	March - May
sugar beet	1 x 720	BBCH 12	minimal crop cover	March - May

FOCUS SW Step 3 PEC_{sw} and PEC_{sed} were derived for dimethenamid-P for the worst case scenarios listed in Table 2.8-85.

Table 2.8-85: Worst case application scenarios used for FOCUS SW Step 3 and 4 modelling

Crop	application rate (g/ha)	Growth stage	Application window
maize	1 x 864	BBCH 00	30 d before emergence
maize	1 x 864	BBCH 10	30 d after emergence
Soybeans, sunflowers & sugar beet	1 x 864	BBCH 00	30 d before emergence
sugar beet	1 x 720	BBCH 12	30 d after emergence

Additionally, FOCUS SW Step 4 PEC_{sw} and PEC_{sed} were derived for dimethenamid-P for pre- and post application of BAS 656 12 H to maize and sugar beet applying 5 m, 10 m and 20 m drift buffer and 10 & 20 drift and run-off buffer as risk mitigation measures.

For details on the PEC_{sw} and PEC_{sed} calculations please refer to Volume 3 CP, B.8.5 of the product BAS 656 12 H.

2.8.6.3.2 Product BAS 830 01 H with 333 g/L dimethenamid-P & 167 g/L quinmerac

Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for dimethenamid-P, the active substance in the formulated product BAS 830 01 H, and the metabolites M656PH003, M656PH023, M656PH027 and M656PH031.
For FOCUS SW Step 1 and Step 2 calculations, the model STEPS1-2 in FOCUS, version 2.1, was used. FOCUS SW Step 3 calculations were performed using the software tool SWASH version 3.1. Within SWASH, the model versions FOCUS-PRZM 3.1.1 and FOCUS-MACRO 4.4.2 together with FOCUS-TOXSWA 3.3.1 were used. Step 4 calculations were performed using SWAN version 2.0.0.

FOCUS SW Step 1 and Step 2 PEC_{sw} and PEC_{sed} were derived dimethenamid-P and the metabolites M656PH003, M656PH023, M656PH027 and M656PH031 for the worst case scenarios listed in Table 2.8-86.

Table 2.8-86: Worst case application scenarios used for FOCUS SW Step 1 and Step 2 modelling

Crop	application rate (g/ha)	Growth stage	Interception (%)	Application window
Winter oilseed rape	1 x 500	BBCH 00	No interception	Oct - Feb
Winter oilseed rape	1 x 500	BBCH 10	Minimal crop cover	Oct - Feb

FOCUS SW Step 3 PEC_{sw} and PEC_{sed} were derived for dimethenamid-P for the worst case scenarios listed in Table 2.8-87.

Table 2.8-87: Worst case application scenarios used for FOCUS SW Step 3 and 4 modelling

Crop	application rate (g/ha)	Growth stage	Application window
Winter oilseed rape	1 x 500	BBCH 00	30 d before emergence
Winter oilseed rape	1 x 500	BBCH 10	30 d after emergence

Additionally, FOCUS SW Step 4 PEC_{sw} and PEC_{sed} were derived for dimethenamid-P for pre- and post application of BAS 830 01 H to winter oilseed rape applying 5 m, 10 m and 20 m drift buffer and 10 & 20 drift and run-off buffer as risk mitigation measures.

For details on the PEC_{sw} and PEC_{sed} calculations and for the PEC_{sw} and PEC_{sed} calculations of quinmerac and its metabolites BH 518-2 and BH 518-5please refer to Volume 3 CP, B.8.5 of the product BAS 830 01 H.

2.8.6.4 Predicted concentration in air (PEC_{air}):

No risk assessment of dimethenamid-P in the formulations BAS 656 12 H and BAS 830 01 H for air was performed.

Dimethenamid-P has a vapour pressure: 3.47 x 10^{-3} Pa (20 °C). Hence dimethenamid-P is regarded as semivolatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by dimethenamid-P due to volatilisation with subsequent deposition should be considered. This path was considered for PEC_{sw} and PEC_{sed} calculations as described in more detail under Volume 3 CP, B.8.5 of the products BAS 656 12 H and BAS 830 01 H.

2.8.6.5 Predicted environmental concentrations from other routes of exposure:

No other routes of exposure are considered relevant for the representative uses of dimethenamid-P in the formulations BAS 656 12 H and BAS 830 01 H.

2.9 Effects on non-target species

2.9.1 Summary of effects on birds and other terrestrial vertebrates

Dimethenamid is one of many organic substances that occur as "racemic" 50/50 mixtures of the M and P stereoisomers, i.e. mirror-image isomers. When dimethenamid was originally registered in Europe and other countries around the world, all toxicology studies were conducted with the 50/50 racemic mixture (SAN 582 H), which is the active substance that has been manufactured and marketed to this point. Recently it was discovered that only the P isomer (dimethenamid-P; SAN 1289) has useful herbicidal activity.

The avian reproduction studies (study codes 131-177; AVS9600046 and 131-178; AVS9600047) as well as the mammalian reproductive study (study code 2012065) and the mammalian developmental studies were conducted with racemic dimethenamid and not with dimethenamid-P. An extensive evaluation of toxicological studies carried out with racemic dimethenamid as well as dimethenamid-P showed that the elimination of the M-isomer from the racemic dimethenamid does not increase the toxicity of the resulting P-isomer (as confirmed in the EU evaluation of dimethenamid-P). Thus, the

use of endpoints derived from the reproduction studies with racemic dimethenamid is justified for the evaluation of dimethenamid-P.

Birds

A number of different avian acute oral, short-term dietary and long-term reproduction studies had been carried out with dimethenamid-P and dimethenamid-racemate and were already evaluated during the initial EU assessment of dimethenamid-P.

In the following table an overview of endpoints and effect values that have been identified as relevant for the quantitative risk assessment according to the current EFSA Guidance Document is given. Values in bold were chosen by RMS for risk assessment. A discussion on the selection of endpoints for risk assessment is included below the table.

Table 2.9-1: Summary of avian toxicity endpoints for dimethenamid-P and the representative formulations BAS 656 12 H and BAS 830 01 H

Species	Substance	Exposure System	Results	Reference
Colinus virginianus	Dimethenamid-P	1 d Acute oral	LD_{50} = **1068** mg/kg bw	[redacted] 03.06.1996 131-187; BASF RegDoc #1996/5419 *[1)]
Colinus virginianus	Dimethenamid-P	5 d Short-term dietary	LD_{50} > 5620 ppm (> 1737 mg/kg bw/d)	[redacted] 30.07.1996 131-185; BASF RegDoc #1996/5412 *[1)]
Anas platyrhynchos	Dimethenamid-P	5 d Short-term dietary	LD_{50} > 5620 ppm	[redacted] 30.07.1996 131-186; AVS1999-61; BASF RegDoc #1996/5410 *[1)]
Colinus virginianus	Dimethenamid-racemate	140 d reproduction	NOAEC = **900** ppm; NOAEL = 114 mg as/kg bw/d [2)]	[redacted] 06.05.1994 131-177; BASF RegDoc # 1994/11900 *[1)]
Anas platyrhynchos	Dimethenamid-racemate	140 d reproduction	NOEC = 1800 ppm	[redacted] 06.05.1994 131-178; BASF RegDoc # 1994/11899*[1)]

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003
[1)] For summary and evaluation of the study please refer to Dimethenamid-P_RAR_11_Volume_3CA_B-9
[2)] Daily dose [mg/kg bw/d] calculated based on study data for food consumption and body weight

No avian study on acute toxicity of the representative formulations BAS 656 12 H and BAS 830 01 H are available. In the study on acute toxicity of dimethenamid-P conducted with *Colinus virginianus* mortality was observed in the two highest treatment groups (1350 and 2250 mg/kg, respectively) and the LD_{50} value was reported as 1068 mg as/kg bw. This endpoint can be used in the quantitative risk assessment for the active substance as well as for the representative formulations BAS 656 12 H and BAS 830 01 H.

Short-term dietary toxicity studies with birds targeted at determining an LC_{50} are no longer used in the standard risk assessment. They may be taken into account in specific cases where accumulation of compounds or effects would affect mortality of birds in such a way that it would not be addressed by acute oral toxicity testing. However, there are no indications that this would be the case for

dimethenamid-P. Hence, these studies are no longer considered in the assessment.

In order to obtain the relevant toxicity endpoint to be used in the screening and tier 1 reproductive risk assessment, the lowest NOEL from available bird reproduction studies and the 'assessment factor LD_{50}' [LD_{50} (overall geometric mean)/10] from acute toxicity studies (EFSA/2009/1438) have to be considered. During the long-term reproduction study in mallard duck, dimethenamid racemate incorporated into the diet had no effects on any toxicological and reproductive parameter up to 1800 ppm, the highest concentration tested. At this dose egg shell thickness was reduced in the study with bobwhite quails. Therefore, the study on bobwhite quails resulting in a NOEL of 900 ppm is used in the risk assessment. Recalculation of dietary concentration of dimethenamid to ingested daily doses resulting in 114 mg as/kg bw/d for bobwhite quail. The acute toxicity endpoint was calculated to give an LD_{50} = 1068 mg as/kg b.w. The tenth of this value is 106.8 mg as/kg b.w. Since the lowest of both, is the assessment factor LD_{50}, the value of 106.8 mg as/kg bw/d will be used in the screening step and the tier 1 reproductive risk assessment for dimethenamid-P.

Proposed avian toxicity endpoints for use in risk assessment:

Dimethenamid-P: Representative formulations BAS 656 12 H and BAS 830 01 H:
No study with the formulations BAS 656 12 H and BAS 830 01 H have been submitted. Therefore the risk assessment is based on the toxicity of the individual substance and, in the case of BAS 830 01 H on a calculation of mixture toxicity.

Acute: LD_{50} = **1068** mg as /kg bw (*Colinus virginianus*, *Anas platyrhynchos*)
Long-term/reproductive: LD_{50} (overall geometric mean)/10 = **106.8** mg as/kg bw

Mammals
A number of different mammalian acute oral and long-term reproduction studies had been carried out with dimethenamid-P and dimethenamid racemate and were already evaluated during the initial EU assessment of dimethenamid-P.

In the following table an overview of endpoints and effect values that have been identified as relevant for the quantitative risk assessment according to the current EFSA Guidance Document is given. Values in bold were chosen by RMS for risk assessment. A discussion on the selection of endpoints for risk assessment is included below the table. Mammalian toxicology studies are summarised and evaluated in the section toxicology of the RAR (Dimethenamid-P_RAR_08_Volume_3CA_B-6).

Table 2.9-2: Endpoints used for risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Dimethenamid-P	Acute oral	LD_{50} = 429 mg/kg bw (male) LD_{50} = 531 mg/kg bw (female) **LD_{50} = 466 mg/kg bw (combined)**	[redacted] 17.07.1996 94-1404; BASF RegDoc # 1996/11087*[1)]
Rat	Dimethenamid-racemate Keto-enol process Undiluted, no carrier	Acute oral	LD_{50} = 397 mg/kg bw 90 % at 600 mg/kg bw; 10 % at 300 mg/kg bw 0 % at 150 mg/kg bw	[redacted] 1991 1991/11940; BASF RegDoc# 1991/11940 [4)]
Rat	BAS 656 08 H	Acute oral	500 mg/kg bw < LD_{50} > 2000 mg/kg bw	[redacted]. 2006 BASFDoc#2006/1026825[4)]
Rat	Dimethenamid-racemate	Long-term (2-generation-study)	NOAEL = 500 mg as/kg diet NOAEL = **33.3 mg/kg bw/day** [3)]	[redacted] 17.05.1989 2012065; BASF Doc# 1990/11140 [1) 4)]
Rat	Dimethenamid-racemate	Develop-mental toxicity	$NOEL_{Maternal}$ = 50 mg as/kg bw/d $NOEL_{Developmental} \leq$ 215 mg as/kg bw/d	[redacted], 1987 BASF Doc# 11225
Rat	Dimethenamid-P	Develop-mental toxicity	$NOEL_{Maternal}$ < 25 mg as/kg bw/d $NOEL_{Developmental}$ = 25 mg as/kg bw/d	[redacted] 1997 BASF Doc# 5274
Rabbit	Dimethenamid-racemate	Develop-mental toxicity	$NOAEL_{Maternal}$ = 37.5 mg as/kg bw/d $NOAEL_{Developmental}$ = 75 mg as/kg bw/d	[redacted] 1988 BASF Doc# 11376

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003
1) For summary and evaluation of the study please refer to Dimethenamid-P_RAR_11_Volume_3CA_B-9
2) For summary and evaluation of the study please refer to Dimethenamid-P_RAR_08_Volume_3CA_B-6
3) Daily dose [mg/kg bw/d] calculated based on study data for food consumption and body weight
4) Endpoint from EFSA Scientific Report (2005) 53, 1-73, Conclusion on the peer review of dimethenamid

In the initial assessment the acute oral LD_{50} of dimethenamid-P for rats is 429 mg/kg body weight. According to EFSA 2009/1438 the relevant endpoint to be used in the acute risk assessment is LD_{50} (sexes combined) = 466 mg as/kg bw since the difference between the sexes does not exceed 25 %. This value has been confirmed by the acute oral toxicity study with dimethenamid racemate resulting in a LD_{50} = 397 mg/kg body weight for rats.

Regarding the long-term risk, the initial assessment was based on 500 ppm, which was the NOAEL in a multi-generation study with rats for racemic dimethenamid (see section B.06, Toxicology). This endpoint is used in the current risk assessment. Therefore, the daily dose NOAEL = 33.3 mg/kg bw/day was calculated based on study data for food consumption and body weight.

In order to obtain the relevant reproductive toxicity endpoint to be used in the tier 1 reproductive risk assessment, the lowest NOAEL from the two-generation rat study (study code 2012065) and the lowest relevant endpoint from the developmental studies (study codes 11225; 5274; 11376) have to be considered. The two developmental studies in rats follow both the same test protocol and show similar dose-responses. Thus, it is possible to jointly evaluate these two studies and merge the two datasets resulting in an overall NOEL for effects on offspring of 50 mg as/kg bw/d. The lowest dose where effects are reported is 150 mg as/kg bw/d. From the developmental study in rabbits the

$NOEL_{developmental}$ is 75 mg as/kg bw/d. As a consequence the $NOEL_{developmental}$ endpoints are consistently higher than the EU agreed NOAEL = 33.3 mg as/kg bw/d from the two-generation reproduction rat study supporting the thesis that a NOAEL of 33.3 mg as/kg bw/d is protective for developmental parameters.

Proposed mammalian toxicity endpoints for use in risk assessment:

Dimethenamid-P:
Acute: LD_{50} = **466** mg as/kg bw (acute oral toxicity, rat)
Long-term/reproductive: NOEL = 500 ppm (**33.3** mg as /kg bw/d, rat, 2-generation-study)

Representative formulation BAS 656 12 H:
Acute: 500 mg BAS 656 08 H /kg bw < LD_{50} > 2000 mg BAS 656 08 H /kg bw (acute oral toxicity, rat)

Representative formulation BAS 830 01 H:
No study with the formulation BAS 830 01 H has been submitted. Therefore the risk assessment is based on the toxicity of the individual substances and a calculation on mixture toxicity.

2.9.2 Summary of effects on aquatic organisms

In the following table an overview of all available aquatic endpoints is given. Values in **bold** were chosen by RMS for risk assessment. A discussion on the selection of endpoints for risk assessment is included below the tables. Please note that the studies listed under the active substance dimethenamid-P comprise data on both the racemic mixture (SAN 582 H) and the P isomer (dimethenamid-P; SAN 1289). For the same reasons as explained in chapter 2.9.1 data for these substances were considered equally since there was no significant difference in toxicity among these isomeric compounds.

Active substance and formulated product

Table 2.9-3: Summary of the toxicity values of the active substance dimethenamid-P and the formulated products BAS 656 12 H and BAS 830 01 H for aquatic organisms

Organism	Endpoint	Value [mg/L]	Reference
dimethenamid-P			
Fish			
Oncorhynchus mykiss	96 h LC_{50}	6.3	[redacted], 1996/5417
Oncorhynchus mykiss [3]	96 h LC_{50}	**2.6**	[redacted] 1988/11366
Lepomis macrochirus	96 h LC_{50}	10.0	[redacted], 1996/5414
Lepomis macrochirus [3]	96 h LC_{50}	6.4	[redacted], 1988/11368
Cyprinodon variegatus [1), 2)]	96 h LC_{50}	12.0	[redacted] 1996/5416
Oncorhynchus mykiss [3]	21 d NOEC	0.630	[redacted] 1991/11906
Oncorhynchus mykiss [3]	90 d NOEC (ELS)	**0.120**	[redacted] 1992/12456
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	12	Graves & Swigert, 1996/5415
Americamysis bahia [1),2)] (former name: *Mysidopsis bahia*)	48 h LC_{50} 96 h LC_{50}	> 9.2 **3.2**	Graves & Swigert, 1996/5413
Daphnia magna [3]	21 d NOEC	1.36	Holmes & Swigert, 1992/12455
Daphnia magna [3]	21 d NOEC	**0.68**	Jenkins, 1991/11952
Algae [4]			
Pseudokirchneriella subcapitata (syn. *Selenastrum capricornutum*)	72 h E_rC_{50} 72 h E_yC_{50} 72 h E_bC_{50} 96 h E_rC_{50} 96 h E_yC_{50} 96 h E_bC_{50} 120 h E_rC_{50} 120 h E_yC_{50} 120 h E_bC_{50}	0.0303 0.0185 0.0191 0.0339 0.0168 **0.0140** 0.0378 0.0188 0.0143	Hoberg, 1997/10746 Amendment: Kubitza, 2004/1025684 [5)]
	72 h E_rC_{50} 72 h E_yC_{50} 72 h E_bC_{50}	0.0663 0.0138 **0.0138**	Backfisch, 2013/1078075 [1)]
	geometric mean 72 h E_bC_{50}	**0.0139**	--
Desmodesmus subspicatus [1)]	72 h E_rC_{50} 72 h E_yC_{50}	> 0.0509 **0.0183**	Backfisch, 2012/1246638
Navicula pelliculosa [5)]	72 h E_rC_{50} 72 h E_bC_{50} 96 h E_rC_{50} 96 h E_bC_{50} 120 h E_rC_{50} 120 h E_bC_{50}	0.287 **0.154** 4.048 0.596 1.717 0.352	Hoberg, 1997/5171 Amendment: Kubitza, 2005/1003999
Ankistrodesmus bibraianus [1)]	72 h E_rC_{50} 72 h E_yC_{50}	0.0370 **0.0097**	Backfisch, 2012/1246639
Chlamydomonas reinhardtii [1)]	72 h E_rC_{50} 72 h E_yC_{50}	0.2245 **0.0854**	Backfisch, 2013/1078084

Organism	Endpoint	Value [mg/L]	Reference
Monoraphidium griffithii [1)]	72 h E_rC_{50} 72 h E_yC_{50}	0.0250 **0.0066**	Backfisch, 2013/1078078
Neochloris aquatica [1)]	72 h E_rC_{50} 72 h E_yC_{50}	> 1.000 **0.3680**	Backfisch, 2012/1246637
Planktosphaeria botryoides [1)]	72 h E_rC_{50} 72 h E_yC_{50}	0.9120 **0.1110**	Backfisch, 2013/1078081
Schroederia setigera [1)]	72 h E_rC_{50} 72 h E_yC_{50}	> 0.4055 **0.1267**	Backfisch, 2013/1078077
Aquatic macrophytes [4)]			
Lemna gibba	14 d E_rC_{50} 14 d E_bC_{50}	0.01314 [9)] **0.00599** [7)]	Hoberg, 1997/10742 Amendment Kubitza, 2004/1025686 [5)]
Lemna gibba [1)]	7 d E_rC_{50} 7 d E_yC_{50}	0.0568 [8)] / 0.0434 [9)] **0.0168** [8)] / 0.0190 [9)]	Backfisch & Kubitza, 2012/1215555
Lemna gibba [1)] *(with sediment)*	7 d E_rC_{50} 7 d E_yC_{50}	0.0763 [8)] / > 0.1242 [9)] **0.0255** [8)] / 0.0380 [9)]	
Glyceria maxima [1)]	14 d E_rC_{50} 14 d E_yC_{50}	> 1.0 [9)] / 0.184 [10)] / 0.402 [11)] 0.934 [9)] **/0.109** [10)]/0.221 [11)]/0.318 [12)]	Janson, 2013/1286172
Acorus calamus [15)]	13 d E_yC_{50}	> 1.314 [10), 11), 13)]	Kubitza & Dohmen, 2002/1012788 Amendments: Kubitza, 2013/1361973 & 2014/1082325
Iris pseudacorus [15)]	13 d E_yC_{50}	> 0.754 [10), 13)] / **0.154** [11)]	
Ludwigia palustris [15)]	13 d E_yC_{50}	**0.033** [10)] / 0.043 [11)]	
Mentha aquatica [15)]	13 d E_yC_{50}	**0.206** [10)] / > 1.088 [11)]	
Sparganium erectum [15)]	13 d E_yC_{50}	> 0.451 [10), 13)] / **0.373** [11)]	
Veronica beccabunga [15)]	13 d E_yC_{50}	**0.104** [10)] / 0.323 [11)]	
Ceratophyllum demersum [16)]	9 d E_yC_{50}	**0.0133** [10)] / 0.0276 [11)]	Kubitza & Dohmen, 2002/1012789
Crassula recurva [16)]	12 d E_yC_{50}	**0.0865** [10)] / > 0.340 [11)]	
Elodea densa [16)]	12 d E_yC_{50}	**0.208** [10)] / > 0.239 [11)]	
Myriophyllum spicatum [16)]	9 d E_yC_{50}	**0.088** [10)] / > 0.3065 [11)]	
Potamogeton crispus [16)]	9 d E_yC_{50}	**0.174** [10)] / > 0.214 [11)]	
Vallisneria spiralis [16)]	12 d E_yC_{50}	> 0.261 [10), 11)]	
Time-to-Effect Studies [4)]			
Monoraphidium griffithii [1)] (TTE study)	E_rC_{50} / E_yC_{50} (different exposure durations + 72 h growth phase)	> 2.4 (6 h exposure period) > 1.2 (24 h exposure period)	Backfisch, 2013/1299407
Pseudokirchneriella subcapitata [1)] (TTE study)	E_rC_{50} / E_yC_{50} (different exposure durations + 72 h growth phase)	> 2.4 (6 h exposure period) **> 1.2** (extrapolated**:** 2.485) / 0.388 (24 h exposure period)	Backfisch, 2013/1299405
Lemna gibba [1)] (TTE study)	<u>Scenario A:</u> E_rC_{50} / E_yC_{50} (different exposure durations + 7 d growth phase)	12 h exposure period: > 0.500 [8), 9)] 24 h exposure period: **>** 0.500 [8), 9)] **/ 0.288** [9)] 36 h exposure period: 0.458 [9)] **/ 0.253** [9)]	Hoffmann & Grund, 2012/1084264 Amendment: Hoffmann, 2012/1202274
	<u>Scenario B:</u> E_rC_{50} / E_yC_{50} (double peak exposure + 7 d growth phase)	"0.250 mg/L max. peak": > 0.250 peak [8), 9)] "0.500 mg max. peak": > 0.500 peak [8), 9)]	

Organism	Endpoint	Value [mg/L]	Reference
Lemna gibba [1), 14)] (non-GLP TTE)	E_rC_{50} / E_yC_{50} (2 x 24 h peaks separated by non-exposure periods varying between 1 and 7 d + 6 d growth phase)	2x 24 h exposure peak (non-exposure period between peaks 1 - 7 d): > 0.250 mg/L [8)]	Kubitza & Grund, 2013/1291744
Ceratophyllum demersum [1)] (TTE study)	E_rC_{50} / E_yC_{50} (different exposure durations + 7 d growth phase)	> 3.0 [9), 10), 11)] (24 h exposure period) > 3.0 [9), 10), 11)] (48 h exposure period)	Janson, 2013/1286175
Endpoints derived from higher tier calculations [4)]			
SSD, 9 species (algae) [17)]	HC_5	0.00405	--
SSD, 13 species (higher aquatic plants) [17)]	HC_5	0.01543	--
BAS 656 12 H *			
Fish			
Oncorhynchus mykiss	96 h LC_{50}	7.94	[redacted], 1999/10317
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	17.1	Jatzek, 1999/10316
Algae [4)]			
Desmodesmus subspicatus (syn. Scenedesmus subspicatus)	72 h E_rC_{50} 72 h E_yC_{50}	**0.1327** 0.0492	Reuschenbach, 1999/10315
Aquatic macrophytes [4)]			
Lemna gibba	7 d E_rC_{50} 7 d E_yC_{50}	**0.054** [8)] 0.0085 [8)]	Dohmen, 1999/10314
BAS 830 01 H			
Fish			
Oncorhynchus mykiss	96 h LC_{50}	19.8	[redacted] 2013/1168360
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	58.7	Zawadsky, 2013/1168361
Algae [4)]			
Pseudokirchneriella subcapitata	72 h E_rC_{50} 72 h E_yC_{50}	0.166 0.0656	Backfisch, 2013/1311299
Aquatic macrophytes [4)]			
Lemna gibba	7 d E_rC_{50} 7 d E_yC_{50}	0.573 [8)] / > 0.810 [9)] 0.0863 [8)] / 0.1302 [9)]	Turek, 2013/1250860

Bold figures: Where several endpoints are available for the same group or where several endpoints are available for one study based on different effect parameters (*e.g.* for algae and macrophytes), the relevant endpoint is used in the TER / SSD calculations.

ELS = early life stage; TTE = Time-To-Effect/Event; SSD = Species Sensitivity Distribution; HC_5 = 5 % hazardous concentration

1) Study has not been submitted during the Annex I inclusion process of dimethenamid-P; a study summary is provided in chapter 8.2 of the MCA dossier part for Annex I renewal.

2) Marine / saltwater species

3) Study conducted with dimethenamid (racemate) as acute studies with dimethenamid-P showed similar or even lower toxicity to fish and daphnids (for details see Appendix I below).

4) The higher sensitive parameter 'biomass/yield' are considered for the risk assessment for algae and macrophytes (for details see paragraph “Selection of endpoints for the active substance and the formulated products” below).

5) The endpoints of some of the older (partly EU agreed) algae / aquatic plant studies have been (re-)calculated from original data

6) Two independent studies have been performed on the standard green alga *P. subcapitata* (Syn. *S. capricornutum*) and also on the standard aquatic plant species *L. gibba*. Both the old and the new studies are valid, however in the old study,

the study duration is much longer as compared to the recent guideline, and only the endpoints based on biomass were generated. In the meantime the growth rate endpoints were calculated in addition and are presented in the corresponding amendments. Nevertheless, endpoints like dry weight for the current valid test duration cannot be recalculated.

7) based on dry weight

8) based on frond number 9) based on dry weight 10) based on total length

11) based on fresh / wet weight 12) based on number of leaves 13) based on root formation

14) For *Lemna gibba* two consecutive 24 hour peaks of 0.250 mg dimethenamid-P/L can be considered toxicologically independent from each other if the interval between the single peaks is longer than 2 days. In this case, the second peak did not contribute to the magnitude of the response anymore.

15) emergent aquatic plants 16) submersed aquatic plants

17) For details on SSD calculations for dimethenamid-P please refer to "Refined Risk Assessment" presented below.

Table 2.9-4: Summary of the toxicity values obtained in the studies with the metabolites of dimethenamid-P for aquatic organisms

Organism	Endpoint	Value [mg/L]	Reference
M656H003 (Reg. No. 360717, M3)			
Fish			
Oncorhynchus mykiss	96 h LC_{50}	60.8	[redacted] 1997/10271
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	> 101.6	Gruetzner, 1997/10272
Algae [1)]			
Desmodesmus subspicatus (syn. Scenedesmus subspicatus)	72 h E_rC_{50} 72 h E_bC_{50}	97.4 68.5	Gruetzner, 1997/10274
M656H023 (Reg. No. 360 715, M23)			
Fish			
Oncorhynchus mykiss	96 h LC_{50}	> 87	[redacted], 1995/11318
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	> 95	van der Kolk, 1995/11319
Algae [1)]			
Selenastrum capricornutum (syn. Pseudokirchneriella subcapitata)	72 h E_rC_{50} 72 h E_bC_{50}	> 100 > 94	van der Kolk, 1995/11320
M656H027 (Reg. No. 360 714, M27)			
Fish			
Oncorhynchus mykiss	96 h LC_{50}	> 100	[redacted] 1995/11330
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	> 100	van der Kolk, 1995/11331
Algae [1)]			
Selenastrum capricornutum (syn. Pseudokirchneriella subcapitata)	72 h E_rC_{50} / E_bC_{50}	> 208	van der Kolk, 1995/11332
M656H031 (Reg. No. 360 712, M31) [2)]			
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	> 100	Janson, 2008/1042207
Algae [1)]			

Organism	Endpoint	Value [mg/L]	Reference
Pseudokirchneriella subcapitata	72 h E_rC_{50} / E_yC_{50}	> 100	Hoffmann, 2008/1035874
Aquatic macrophytes [1]			
Lemna gibba	7 d E_rC_{50} / E_yC_{50}	> 100 [3), 4)]	Hoffmann, 2008/1035918
M656H062 (= M62; tested with Reg. No. 403 121) [2), 5)]			
Aquatic macrophytes [1]			
Lemna gibba	7 d E_rC_{50} 7 d E_yC_{50}	> 100 [3), 4)] 54.57 [3)] / 72.87 [4)]	Swierkot 2013/1191249
M656PH043 (Reg. No. 5 917 262, M43) [2]			
Aquatic macrophytes [1]			
Lemna gibba	7 d E_rC_{50} / E_yC_{50}	> 100 [3), 4)]	Swierkot 2013/1191248
M656H055 (Reg.No. 5 749 263, M55) [2]			
Aquatic macrophytes [1]			
Lemna gibba	7 d E_rC_{50} / E_yC_{50}	> 143 [3), 4)]	Swierkot 2013/1063800

Bold figures: Where several endpoints are available for the same group or where several endpoints are available for one study based on different effect parameters (*e.g.* for algae and macrophytes), the lowest (most sensitive) endpoint is used in the TER calculations.

1) In contrast to the applicant's risk assessment, only E_bC_{50} or E_yC_{50} values were considered in the present risk assessment.

2) The studies for this metabolite have not been submitted during the Annex I inclusion process of dimethenamid-P; a study summary is provided in chapter 8.2 of the MCA dossier part for Annex I renewal.

3) based on frond number 4) based on dry weight

5) The metabolite M656H062 (M62) cannot be synthesised; thus, the test was performed with Reg. No. 403 121 which is the hydrochloride of metabolite M656H039 (= PL 15-88) which itself is the putative metabolic precursor of M656H062.

Table 2.9-5: Summary of the toxicity values obtained in the studies with process intermediates of dimethenamid-P for aquatic organisms

Organism	Endpoint	Value [mg/L]	Reference
Reg.No. 364 801			
Fish			
Oncorhynchus mykiss	96 h LC_{50}	9.0	[redacted] 2010/1123696
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	4.87	Salinas, 2010/1212802
Algae			
Pseudokirchneriella subcapitata	72 h E_rC_{50} 72 h E_yC_{50}	22.6 17.6	Salinas, 2010/1185631
Reg.No. 364 802 (= metabolite M656H039 = PL 1588[redacted])			
Algae			
Pseudokirchneriella subcapitata	72 h E_rC_{50} 72 h E_yC_{50}	97.0 58.9	Salinas, 2010/1079231
Reg.No. 395 233			
Algae			
Pseudokirchneriella subcapitata	72 h E_rC_{50} 72 h E_yC_{50}	19.2 6.32	Salinas, 2010/1154437 Amendment: Salinas, 2011/1255812

Selection of endpoints for the active substance and the formulated products:

Acute fish:
For the risk assessment, the applicant proposed to use the fish acute study by [redacted] (1996), resulting in a LC_{50} of 6.3 mg/L. However, the RMS decided to use a LC_{50} of 2.6 mg/L, which is the lowest available acute endpoint obtained from [redacted] (1988; Report Doc# 1988/11366) with rainbow trouts and using the racemate of dimethenamid, SAN-582-H, as test substance.

Chronic fish:
An early life stage test with rainbow trout is available ([redacted], 1992; Report Doc# 1992/12456). The 60 days NOEC from this study is 0.120 mg/L (mean measured).

Acute Daphnia:
Up to now, an EC_{50} of 12 mg/L for *Daphnia magna* has been used in previous risk assessments. In the current AIR III dossier, a new 96-h toxicity study on the saltwater mysid *Americamysis bahia* (formerly *Mysidopsis bahia*) which has not been evaluated previously on EU level was submitted.
The applicant proposed to use the 48-h endpoint (LC_{50} >9.2 mg/L) from this toxicity study for the reason that, firstly, this endpoint describes the data requirements for active substances according to EU Regulation 283/2013 (European Commission, 2013), secondly, the EFSA advises to use the 48-h endpoint (EFSA, 2013), and thirdly, this procedure harmonises the duration of acute toxicity tests among aquatic arthropods. The RMS, however, does not agree with this approach as no clear advice with respect to harmonisation procedures is given in available guidance documents.
Contrary to the applicant's argumentation, the RMS treated ecotoxicological findings from marine and freshwater test organisms equally in the risk assessment of dimethenamid-P.
Thus, the more sensitive 96-hour LC_{50} of 3.2 mg/L from the toxicity study on the saltwater mysid *Americamysis bahia* (former name: *Mysidopsis bahia*) will be used for the acute risk assessment.

Chronic Daphnia:
Two chronic studies, namely one flow-through study by Holmes & Swigert (1992) and one semi-static study by Jenkins (1991) with the dimethenamid racemate SAN 582 H are available, which were already evaluated in the old DAR. The lowest $NOEC_{repro}$ of 0.68 mg as/L obtained from Jenkins (1991) will be used for the risk assessment.

Algae:
Several freshwater and marine algae studies are available, comprising different taxonomic groups such as green algae, diatoms and blue-green algae (cyanobacteria). A total of 17 algae studies for the active substance have been evaluated, of which only 10 were considered acceptable and appropriate for risk assessment purposes since the remaining studies did not meet the validity criteria according to OECD 201 (mainly the criterion “mean coefficient of variation for section-by-section specific growth rates”).
11 new studies on different green algae were submitted by the applicant, of which the green algae *Monoraphidium griffithii* turned out to be the most sensitive species with an E_yC_{50} of 6.66 µg/L based on nominal concentrations.

Aquatic macrophytes:
Effect data on the active substance are available for a total of 14 different macrophyte species.
Lemna gibba turned out to be the most sensitive species with a E_yC_{50} of 5.99 µg/L (geometric mean measured), following re-evaluation by the RMS. Analytical measurements revealed a sharp decline after 3 days, therefore, endpoints had to be re-calculated by the RMS based on geometric mean concentrations (see table 3 below, copied from the original study report).

Table 3. Concentrations of SAN 1289H (expressed as the s-isomer of SAN 1289H) measured in the exposure solutions over one renewal period during the 14-day toxicity test with *Lemna gibba*.

Nominal Concentration (mg A.I./L)	Measured Concentration (mg A.I./L)[a]			
	Day 0[b]	Day 0 Percent Nominal	Day 3[c]	Day 3 Percent Nominal
Control	<0.0003	NA[d]	<0.0003	NA
0.0010	0.0012	120	0.00015[e]	15
0.0030	0.0032	110	0.00067	22
0.0089	0.0073	82	0.0019	21
0.027	0.026	95	0.0084	31
0.081	0.074	92	0.029	36
QC[f]#1 0.00100	0.00112	112	0.000923	92.3
QC#2 0.0200	0.0200	100	0.0204	102
QC#3 0.100	0.0956	95.6	0.0936	93.6

[a] Calculated values are based on actual analytical results and not on rounded values presented in this table.
[b] Freshly prepared solutions which are representative of day 0, 3, 6 and 12 freshly prepared solutions.
[c] Three-day-old solutions which are representative of day 6, 9 and 12 aged solutions.
[d] NA = Not applicable
[e] Extrapolated value
[f] QC = Quality Control sample

C*eratophyllum demersum* was the most sensitive species among the submersed aquatic plant species, generating an E_yC_{50} of 0.021 mg BAS 656 08 H/L (0.0133 mg as/L) based on length data (geometric mean of the measured concentrations). With regards to the emergent aquatic plant species, *Ludwigia palustris* was the most sensitive species, generating an E_yC_{50} of 0.053 mg BAS 656 08 H/L (0.033 mg as/L) based on length data (geometric mean of the measured concentrations).

Primary producers (algae/macrophytes):
Further, the applicant considered by referring to the EFSA Aquatic GD (EFSA, 2013) only EC_{50} values for the endpoint (or "response variable" in terms of OECD TG) 'growth rate' (E_rC_{50}) in the risk assessment for the reason that this endpoint is scientifically more appropriate and robust against deviations in test conditions and allows better interpretation of studies. The RMS, however, considered the E_bC_{50} or E_yC_{50} values in the present risk assessment for the following reasons:

- Regarding which method is the most suitable to derive/calculate the endpoints, the recent EFSA Aquatic GD (EFSA, 2013) states that an E_rC_{50} should be used for algae and macrophytes combined with an assessment factor of 10 to derive the RAC for the Tier 1 assessment. Furthermore, it is stated in a footnote that other, usually more sensitive endpoints such as yield may also be used if growth rate endpoints are not provided. Even though the E_rC_{50} can be regarded as more robust endpoint and less dependent on the test design (e.g. test duration and/or growth rate of the respective test species), it should be pointed out that E_rC_{50} values are usually by a factor of at least 2-3 higher (less sensitive) compared to E_bC_{50} or E_yC_{50} values, leading to a considerable decrease in protection level for algae/macrophytes if there are no adaptations in the acceptability criteria or assessment factors (Swarowsky et al, 2015)[1].
- From the RMS' point of view, it is realistic to anticipate that the protection level of E_rC_{50}-based risk assessment is significantly lower compared to E_yC_{50}- or E_bC_{50}-based risk

[1] Swarowsky K, Duquesne S, Hönemann L, Matezki S, Kühnen U, Aagard A, Aldrich A, Berchtold J, Poulsen V, van Vliet P, Virtanen V, Wogram J, 2015. Aquatic primary producers in pesticide risk assessment: endpoints and level of protection. Poster presentation at the SETAC Europe 25th Annual Meeting, 6-9 May 2015 - Barcelona, Spain

assessments. The RMS does support using the new EFSA Aquatic GD (EFSA, 2013), however, due to the reasons above, the RMS considers it justified to deviate from the recommendations of the recent EFSA Aquatic GD (EFSA, 2013) in this particular case until the issue on the protection level has been completely clarified on EU level. However, all endpoints (EbC_{50}, E_yC_{50} and ErC_{50}) are included in the LoEP.

Endpoints selected for calculation of the Species Sensitivity Distribution Analysis (SSD):
Since additional laboratory toxicity tests are available for the most sensitive organisms group "primary producers" (algae/macrophytes) a tier 2 effect assessment was provided by the applicant.
However, the present SSD analysis for algae and macrophytes, respectively, differs from the applicant in the following way:

- the median HC_5 (based on EC_{50} data) for both algae and macrophytes is calculated and used separately in the risk assesment as the presence of sediment in all macrophyte studies may have affected bioavailability, and thus, toxicity when compared to sediment free algal test systems.
- only E_bC_{50} or E_yC_{50} values were considered in the present risk assessment as the proposed change from biomass/yield to growth rate endpoints would lead to a significant decrease of the protection level for both algae and macrophytes if no specific corrections in the assessment factors were made (see further explanation above).
- geometric mean of measured test concentrations were considered in studies in cases where recovery fell below 80 % of nominal over the entire study period
- geometric mean (instead of arithmetic mean) EC_{50} values if more than one study is available for the same species
- in line with the EFSA GD (2013), unbound values ("greater-than" values) in the SSD were excluded from the SSD unless "greater-than" values corresponded to the highest toxicity value.
- several algae tests were excluded from the SSD analysis as the validity criterion (cv % for section-by-section specific growth rate ≤35 %) were not met (see Volume 3CA, B.9 for further details).

The SSD analysis presented below was performed with the software ETX 2.0 by RIVM.

SSD for algae (Tier 2B):

Table 2.9-6: Species sensitivity distribution (SSD) for algae

Data no	Toxicity data [µg/L]	Species
1	6.6	*Monoraphidium griffithii*
2	9.7	*Ankistrodesmus bibraianus*
3	13.9	*Pseudokirchneriella subcapitata* (geometric mean, n=2)
4	18.3	*Desmodesmus subspicatus*
5	85.4	*Chlamydomonas reinhardtii*
6	111	*Planktosphaeria botryoides*
7	127	*Schroederia setigera*
8	154	*Navicula pelliculosa*
9	368	*Neochloris aquatica*

Table 2.9-7: Results of the goodness-of-fit test

Anderson-Darling test for normality			
Sign. level	**Critical**	**Normal?**	**AD Statistic: 0.466**
0.1	0.631	Accepted	**n: 9**
0.05	0.752	Accepted	
0.025	0.873	Accepted	

0.01	1.035	Accepted	

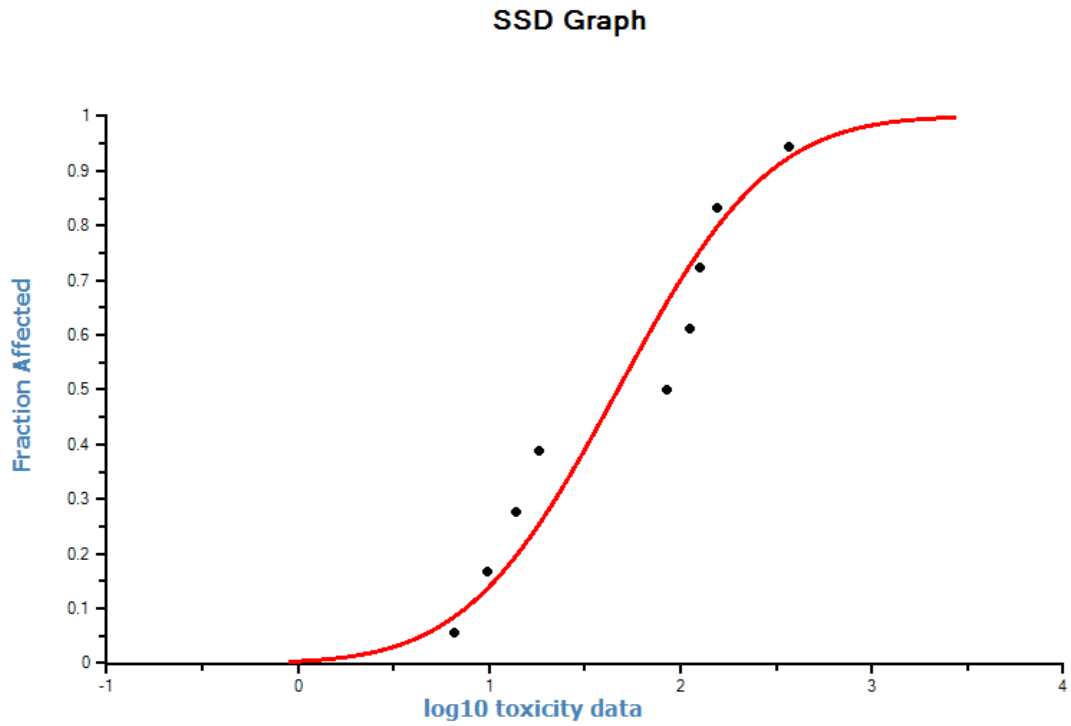


Figure 2.9-1: Species sensitivity distribution (SSD) for algae

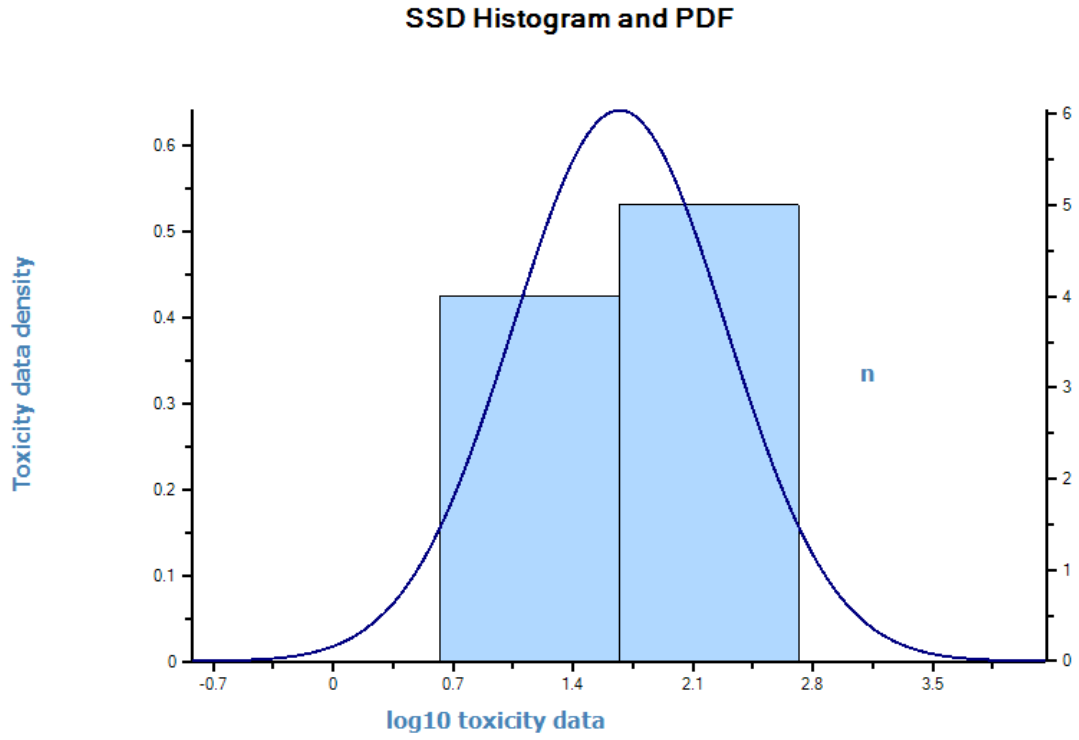


Figure 2.9-2: SSD histogram and PDF for algae

Table 2.9-8: Parameters of the normal distribution

Name	Value	Description
mean	1.672	mean of the log toxicity values
s.d.	0.623	sample standard deviation
n	9	sample size

Table 2.9-9: HC_5 results

Name	Value [µg/L]	log10(Value)	Description
LL HC_5	0.609	-0.216	lower estimate of the HC_5
HC_5	**4.051**	**0.608**	**median estimate of the HC_5**
UL HC_5	11.360	1.055	upper estimate of the HC_5
sprHC$_5$	18.667	1.271	spread of the HC_5 estimate

SSD for macrophytes (Tier 2B):

Table 2.9-10: Species sensitivity distribution (SSD) for aquatic plants

Data no	Toxicity data [µg/L]	Species [1)]
1	13.3	*Ceratophyllum demersum*
2	25.5	*Lemna gibba* [2)]
3	33.5	*Ludwigia palustris*
4	86.5	*Crassula recurva*

5	88.4	*Myriophyllum spicatum*
6	104	*Veronica beccabunga*
7	109	*Glyceria maxima*
8	154	*Iris pseudoacorus*
9	174	*Potamogeton crispus*
10	206	*Mentha aquatica*
11	208	*Elodea densa*
12	373	*Sparganium erectum*
13	>1314	*Acorus calamus*

[1)]*Vallisneria spiralis* E_yC_{50} >269 µg/L was excluded from the SSD analysis as it is not recommended to include unbound values (greater-than or lower-than values) in the SSD (see EFSA GD, 2013).
[2)] The *Lemna* study with sediment was used in order to increase comparability among the remaining macrophyte endpoints.

Table 2.9-11: Results of the goodness-of-fit test

Anderson-Darling test for normality			
Sign. level	**Critical**	**Normal?**	**AD Statistic: 0.318**
0.1	0.631	Accepted	**n: 13**
0.05	0.752	Accepted	
0.025	0.873	Accepted	
0.01	1.035	Accepted	

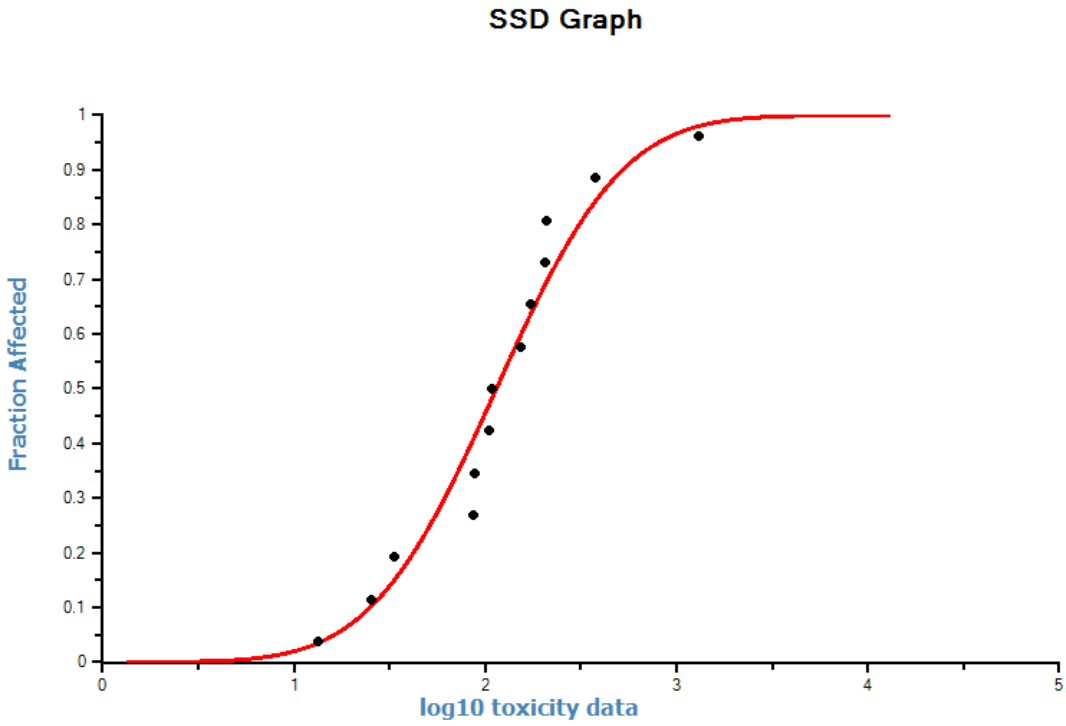


Figure 2.9-3: Species sensitivity distribution (SSD) for algae

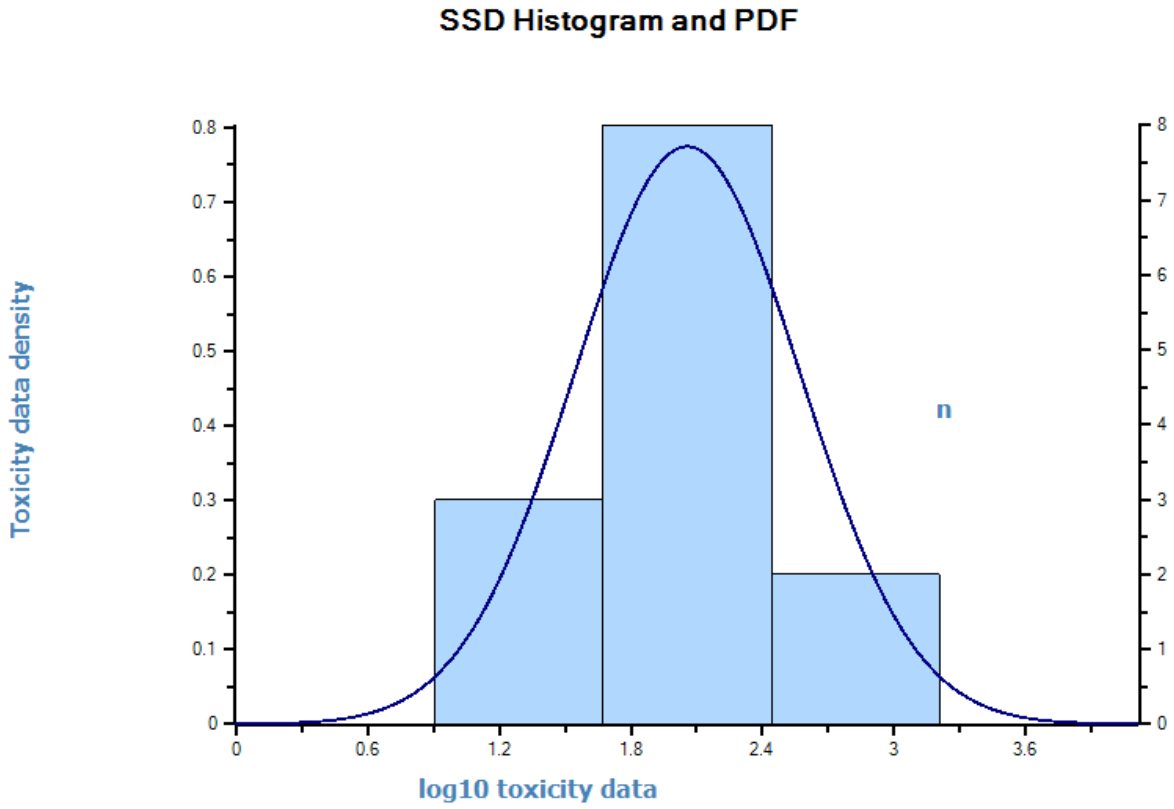


Figure 2.9-4: SSD histogram and PDF for algae

Table 2.9-12: Parameters of the normal distribution

Name	Value	Description
mean	2.057	mean of the log toxicity values
s.d.	0.515	sample standard deviation
n	13	sample size

Table 2.9-13: HC_5 results

Name	Value [µg/L]	log10(Value)	Description
LL HC_5	4.808	0.682	lower estimate of the HC_5
HC_5	**15.43**	**1.188**	**median estimate of the HC_5**
UL HC_5	31.64	1.500	upper estimate of the HC_5
sprHC_5	6.581	0.818	spread of the HC_5 estimate

Conclusion on the SSD analysis:
HC_5 values were 4.05 and 15.4 µg as/L for algae and macropyhtes, respectively. For the risk assessment, the lowest corresponding **RAC of 1.35 µg as/L** is used, taking into account an AF of 3 for primary producers in line with the EFSA GD (2013).

Time-to-effect/event (TTE) studies
In support of the higher tier risk assessment, the applicant has submitted refined exposure laboratory tests ("time-to-effect/event" (TTE) studies) on the sensitive aquatic plant species *L. gibba* and *C. demersum* as well as on two alga species *P. subcapitata* and *M. griffithii* with dimethenamid-P using exposure durations representative for moving water bodies like streams and ditches.

Generally, the aim of TTE-studies is to mimic short exposure durations, which might result from running water bodies like streams or ditches in order to demonstrate that these exposure patterns elicit lower impacts on sensitive aquatic primary producers in comparison to long-term exposure durations simulated in the standard studies (Tier 1). In the present case, the results of the TTE studies simulating realistic short pulse exposure scenarios suggest that exposure durations strongly influence the toxicity of dimethenamid-P to aquatic primary producers.
According to the applicant, the results of these studies may directly be used for TER calculation since exposure patterns in the studies are comparable to the predicted exposure patterns that should be representative for streams and ditches used for calculation of PECs as proposed by the ELink workshop (Brock et al., 2009).
In order to define if the peak concentrations of short-term exposure profiles for dimethenamid-P are covered by the results of the TTE studies, for each exposure peak higher than a critical threshold level, a detailed characterisation of the exposure profile in the relevant FOCUS surface water stream scenarios has been performed by the applicant in the dossier using the Exposure Pattern Analysis Tool (EPAT; Wang, 2010). This was done by comparing Area-under-the-curve concentrations (AUC) derived for respective peak durations from the simulated exposure profiles to the AUCs obtained from the TTE-studies.

However, EPAT-generated PEC values in conjunction with TTE studies are shown to be unsuitable for the higher tier assessment for several reasons:

i) The underlying concept of EPAT, for which no EU guidance is available so far, does not consider multiple years of application and consequently, an overall worst case concentration pattern for each scenario could not be defined (for further information, see also conclusions in chapter B.8.5 annex point KCP 9.2. ‚Acceptability of PEC_{SW} and PEC_{SED} values – dimethenamid-P‘).
ii) Furthermore, an increase of effects over time (“carry-over of effects”) occurred in the TTE studies during the growth phase (see chapter B.9.5 annex point KCA 8.2.7/1 for more information) which supports the conclusion that repeated exposures are not ecotoxicologically independent.

Overall, it can be concluded that considerable uncertainties remain with regard to both the TTE-derived toxicity values and exposure modelling approaches such as EPAT, and therefore, the respective risk refinement approaches were not further presented in the renewal assessment report.

Metabolites of dimethenamid-P (BAS 656 H)

Aquatic organisms may be exposed to residues of the active substance dimethenamid-P. Therefore, the risk to aquatic organisms also needs to be assessed. The results of toxicity tests on representative freshwater species, which were exposed to the metabolites found in aquatic systems, are summarised in Table 2.9-4.

The active substance is more than 100-fold less toxic to fish and daphnids than to green algae or *Lemna gibba*. Furthermore, none of the other metabolites was toxic to fish and daphnids. Since the metabolites M656H031, M656H062, M656PH043 and M656H055 showed no toxicity to *Lemna* and/or algae, which represent the most sensitive species for the active substance, as well as for animal welfare reasons, no additional studies on fish and/or daphnids were performed with these metabolite.

The metabolite M656H062 (M62) cannot be synthesised; thus, the test was performed with Reg. No. 403 121 which is the hydrochloride of metabolite M656H039 (= PL 15-88) which itself is the putative metabolic precursor of M656H062.

Process intermediates of dimethenamid-P (BAS 656 H)

Toxicity studies on fish, daphnids and/or algae have been performed with several process-intermediates of dimethenamid-P (see Table 2.9-5). These studies were conducted due to U.S. data requirements and have not been evaluated previously on EU level. The endpoints obtained in the studies on fish and daphnids indicate that the toxicity of the process intermediates to these groups of aquatic organism is comparable to the toxicity of the active substance. For algae, the most sensitive

group of aquatic organisms for dimethenamid-P exposure, a significantly lower toxicity of the process-intermediates was demonstrated when compared to the toxicity data for the active substance. Thus, the standard and refined risk assessment presented for the active substance is considered to cover also the risk resulting from the process intermediates and no TER calculations have been performed for the process intermediates.

2.9.3 Summary of effects on arthropods

2.9.3.1 Bees

BAS 656 12 H

The acute toxicity of BAS 656 12 H in terms of LD_{50} values was assessed in accordance with the *EPPO/OEPP, 2003: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145*) for honeybees. For bumblebees the acute toxicity of BAS 656 12 H was assessed in the same way, because no specific scheme is currently available for this group of pollinators.

Table 2.9.3.1-1: Acute Toxicity of BAS 656 12 H to honeybees and bumblebees

Test substance	Application rate [g as/ha]	Endpoint	LD_{50}	Hazard quotient HQ	Trigger
honeybee					
BAS 656 12 H*	864	48 h acute, oral	118.8 µg as/bee	7.3	50
		48 h acute, contact	93.8 µg as/bee	9.2	
bumblebee					
dimethenamid-P (BAS 656 H)	864	48 h oral	> 158 as/bee	-- [1)]	
		48 h contact	> 200 as/bee		

* tested as technical dimethenamid-P (Zenker K., 2011; 2010/1126065)
[1)] HQvalues are not validated for bumblebees.

Due to the results of laboratory tests BAS 656 12 H is considered to be practically non-toxic to honeybees as well as bumble bees. All HQs are considerably below the trigger value of 50, indicating that the intended use poses a low risk to bees in the field.

BAS 830 01 H

The acute toxicity of BAS 830 01 H in terms of LD_{50} values was assessed in accordance with the *EPPO/OEPP, 2003: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145*) for honeybees.

Table 2.9.3.1-2: Acute Toxicity of BAS 830 01 H to honeybees

Test substance	Application rate [g/ha]	Endpoint	LD_{50}	Hazard quotient HQ	Trigger
honeybee					
BAS 830 01 H	1702.5 *	48 h acute, oral	233.9 µg product/bee	7.3	50
		48 h acute, contact	> 454.0 µg product/bee	< 3.8	
		48 h contact	> 200 as/bee		

* taking into account the density of BAS 830 01 H of 1.135 g/cm³.

Due to the results of laboratory tests BAS 830 01 H is considered practically non-toxic to honey bees. HQs are considerably below the trigger value of 50, indicating that the intended use poses a low risk to bees in the field.

2.9.3.2 Other NTAs

A set of studies using the formulation BAS 656 07 H (representing the representative formulation of the initial assessment) as well as BAS 656 08 H was submitted (both formulations were found to be similar to BAS 656 12), which were performed according to current guidance (SANCO/10329/2002). It is concluded that the results of those studies can also be used to assess the toxicity of the active substance dimethenamid-P to terrestrial arthropods.

In the following table an overview of endpoints and effect values that have been identified as in principle relevant for the quantitative risk assessment according to the current EFSA Guidance Document is given. Values in bold were chosen by RMS for risk assessment. A discussion on the selection of endpoints for risk assessment is included below the table.

Table 2.9-14: Toxicity endpoints and effect values of non-target arthropods

Species	Test substance	Exposure System	Results	Reference
Laboratory testing on inert substrate, standard species				
Typhlodromus pyri (protonymphs)	BAS 656 07 H [1)]	Laboratory test glass plates, 2D	**LR_{50} > 1.400 L/ha** **ER_{50} > 1.400 L/ha**	Kühner, C. 18.11.1998 GAB 98303/01-NLTp (BASF 98/11279)*
Aphidius rhopalosiphi (adults)	BAS 656 08 H[2)]	Laboratory test glass plates, 2D	**LR_{50} = 0.0663 L prep./ha**	Fussell, S. 24.03.2003 BASF-03-8 2003/1006351
Aphidius rhopalosiphi (adults)	BAS 656 07 H [1)]	Laboratory test glass plates, 2D	LR_{50} < 1.400 L/ha (100 % mortality)	Kühner, C. 14.12.1998 GAB 98303/01-NLAP (BASF 98/11333)*
Typhlodromus pyri (protonymphs)	BAS 830 01 H	Laboratory test glass plates, 2D	**LR_{50} > 3 L prep./ha**	Röhlig, U. 09.09.2013 13 10 48 033A; BASF RegDoc# 2013/1132521
Aphidius rhopalosiphi (adults)	BAS 830 01 H	Laboratory test glass plates, 2D	**LR_{50} = 0.0336 L prep./ha**	Röhlig, U. 28.10.2013 13 10 48 032A; BASF RegDoc# 2013/1132522
Laboratory testing on inert substrate, additional species				
Aleochara bilineata (adults)	BAS 656 07 H [1)]	laboratory test, Quartz sand, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Kemmeter, F. 22.07.1999 GAB 99010/01-NLAb (BASF 99/10856)*
Chrysoperla carnea	BAS 656 07 H [1)]	laboratory test, Glass plate, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Kühner, C. 14.12.1998 GAB 98303/02-NLCc (BASF 98/11334)*
Poecilus cupreus	BAS 656 07 H [1)]	laboratory test, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Kühner, C. 20.11.1998 GAB 98303/01-NLPc (BASF 98/11278)*
Pardosa sp.	BAS 656 07 H [1)]	laboratory test, 2D	LR_{50} > 1.400 L/ha ER_{50} > 1.400 L/ha	Schmitzer, S. 29.06.1999 5672065 (BASF 99/10751)*
Extended laboratory testing				
Aphidius rhopalosiphi (adults)	BAS 656 07 H [1)]	Extended laboratory test, barley seedlings, 3D	**LR_{50} > 1.400 L/ha** **ER_{50} > 1.400 L/ha**	Schuld, M. 09.06.1999 GAB 99010/01-NEAP (BASF 99/10669)
Aphidius rhopalosiphi (adults)	BAS 830 01 H	Extended laboratory test, barley seedlings, 3D	**LR_{50} > 3 L/ha** **ER_{50} > 3 L/ha**	Stevens, J. 02.09.2013 702505; BASF RegDoc# 2013/1132523
Aleochara bilineata (adults)	BAS 830 01 H	Extended laboratory test, sandy soil, 2D	**ER_{50} > 3 L/ha**	Röhlig, U. 04.11.2013 13 10 48 034 A; BASF RegDoc#2013/1132520

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003
[1)] Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H).
[2)] Study was carried out with BAS 656 08 H (a similar formulation to BAS 656 12 H).
Values in **bold** were chosen by RMS for risk assessment.

Laboratory tests with the standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* are available for both representative formulations. For *Aphidius rhopalosiphi* one study indicated an LR_{50} < 1.400 L BAS 656 07 H /ha (Kühner, 1998, GAB 98303). Since another study has been submitted indicating an LR_{50} = 0.0663 L BAS 656 07 H/ha (Fussell, 2003/1006351), the first study (Kühner, 1998, GAB 98303) is no longer relevant for the risk assessment.

2.9.4 Summary of effects on non-target soil meso- and macrofauna

In the following table an overview of endpoints and effect values that have been identified as in principle relevant for the quantitative risk assessment according to the current EFSA Guidance Document (SANCO/10329/2002) is given. Values in bold were chosen by RMS for risk assessment. A discussion on the selection of endpoints for risk assessment is included below the table.

Under commission regulation 283/2013 and 284/2013 acute toxicity data with earthworms are no longer required. Nonetheless, since it is indicated in the current EFSA Guidance Document a risk assessment on the acute toxicity has been performed.

Table 2.9-15: Summary of toxicity endpoints for for earthworms and other soil macro- and mesofauna for dimethenamid-P and the representative formulations BAS 656 12 H and BAS 830 01 H

Species	Test substance	Exposure System	Results	Reference
Earthworm acute				
Eisenia foetida	Dimethenamid-racemate	Acute, 14 d; 10 % peat	LC_{50} = 294.4 mg/kg dw $LC_{50\ corr.}$ **= 147.2** mg/kg dw[2)]	Van Dijk, A. 22.06.1988 204614*
Eisenia foetida	M 23	Acute, 14 d; 10 % peat	LC_{50} > 1264 mg/kg dw $LC_{50\ corr.}$ **> 632** mg/kg dw[2)]	Krieg, W. 19.03.1998 47842*
Eisenia foetida	M 27	Acute, 14 d; 10 % peat	LC_{50} > 1264 mg/kg dw $LC_{50\ corr.}$ **> 632** mg/kg dw[2)]	Krieg, W. 20.03.1998 47843*
Eisenia fetida	M 31	Acute, 14 d; 10 % peat	LC_{50} > 1000 mg/kg dw $LC_{50\ corr.}$ **>500** mg/kg dw[2)]	Krome, K. 26.09.2008 RRA 12620
Eisenia foetida	BAS 656 07 H [1)]	Acute, 14 d; 10 % peat	LC_{50} = 596.3 mg/kg dw (corresponding to 387 mg as/kg dw) [3)] $LC_{50\ corr.}$ = **298.2** mg/kg dw[2)] (corresponding to 193.5 mg as/kg dw)	Krieg, W. 02.03.1999 49224 (BASF 99/10267)*
Earthworm chronic				
Eisenia foetida	Dimethenamid-P	Chronic; 5 % peat	NOEC = **25.4** mg as/kg dw Reproduction, biomass, mortality	Friedrich S. 06.11.2007 12 10 48 093 S; BASF RegDoc# 2012/1129456
Eisenia foetida	M 23	Chronic; 5 % peat	NOEC ≥ **8.32** mg as/kg dw [5)] Reproduction, biomass, mortality	Lührs, U. 08.11.2007 37431022; BASF RegDoc# 2007/1037731
Eisenia foetida	M 27	Chronic; 5 % peat	NOEC ≥ **10.56** mg as/kg dw[5)] Reproduction, biomass, mortality	Lührs, U. 08.11.2007 37421022; BASF RegDoc# 2007/1037732
Eisenia fetida	M 31	Chronic; 5 % peat	NOEC ≥ **100** mg as/kg dw[5)] Reproduction, biomass, mortality	Lührs, U. 08.01.2009 46551022; BASF RegDoc# 2008/1070910*
Eisenia foetida	BAS 656 12 H	Chronic; 5 % peat	NOEC = 80 mg as/kg dw (mortality); NOEC = 40 mg ai/kg dw (biomass); NOEC = **20** mg as/kg dw (corresponding to 31 mg prep.kg dw) [4)] (reproduction)	Friedrich, S. 07.12.2010 10 10 48 085 S; BASF RegDoc# 2010/1068962

Species	Test substance	Exposure System	Results	Reference
Eisenia foetida	BAS 830 01 H	Chronic; Incorporated, 10 % peat	NOEC ≥ 178 mg prep./kg dw [5)] (mortality); NOEC ≥ 178 mg prep./kg dw [5)] (biomass); NOEC = 89 mg prep./kg dw (reproduction)	Friedrich, S. 30.10.2013 13 10 48 148 S; BASF RegDoc# 2013/1132513
Mesofauna chronic				
Folsomia candida	Dimethenamid-P	Chronic; Incorporated, 5 % peat	**NOEC = 12.5 mg as/kg dw** mortality NOEC = 25 mg as/kg dw reproduction EC_{50} = 41.6 mg as/kg dw reproduction LC_{50} = 118.3 mg as/kg dw Mortality	Friedrich, S. 29.03.2011 11 10 48 015 S; BASF RegDoc# 2011/1000481S
Hypoaspis aculeifer	Dimethenamid-P	Chronic; Incorporated, 5 % peat	NOEC = 1000 mg as/kg dw (mortality) NOEC = 500 mg as/kg dw (reproduction)	Schulz, L. 05.11.2012 12 10 48 097 S; BASF RegDoc# 2012/1129457
Folsomia candida	M 23	Chronic; Incorporated, 5 % peat	NOEC = 200 mg as/kg dw [5)] (mortality, reproduction)	Friedrich, S. 18.12.2012 12 10 48 101 S; BASF RegDoc# 2012/1129536
Hypoaspis aculeifer	M 23	Chronic; Incorporated, 5 % peat	NOEC = 200 mg as/kg dw [5)] (mortality) **NOEC = 100 mg ai/kg dw** (reproduction)	Schulz, L. 20.12.2012 12 10 48 101 S; BASF RegDoc# 2012/1129538
Folsomia candida	M 27	Chronic; Incorporated, 5 % peat	**NOEC = 200 mg as/kg dw** [5)] (mortality, reproduction)	Friedrich, S. 26.11.2012 12 10 48 105 S; BASF RegDoc# 2012/1129537
Hypoaspis aculeifer	M 27	Chronic; Incorporated, 5 % peat	NOEC = 200 mg as/kg dw [5)] (mortality, reproduction)	Schulz, L. 20.12.2012 12 10 48 102 S; BASF RegDoc# 2012/1129539
Folsomia candida	M 31	Chronic; Incorporated, 5 % peat	**NOEC = 200 mg as/kg dw** [5)] Mortality & reproduction	Friedrich, S. 13.01.2011 10 10 48 110 S; BASF RegDoc# 2011/1000222
Hypoaspis aculeifer	M 31	Chronic; Incorporated, 5 % peat	NOEC = 500 mg as/kg dw [5)] (mortality, reproduction)	Schulz, L. 06.01.2014 13 10 48 113 S; BASF RegDoc# 2013/1103674
Folsomia candida	BAS 656 12 H	Chronic; Incorporated, 5 % peat	**NOEC = 18.75 mg prep./kg dw** (reproduction)	Friedrich, S. 11.11.2010 10 10 48 086 S; BASF RegDoc# 2010/1068966 + Amendment BASF RegDoc# 2013/1335427

Species	Test substance	Exposure System	Results	Reference
Folsomia candida	BAS 830 01 H	Chronic; Incorporated, 5 % peat	**NOEC = 75 mg prep./kg dw** (reproduction)	Friedrich, S. 08.10.2013 13 10 48 149 S; BASF RegDoc#2013/1132514
Hypoaspis aculeifer	BAS 830 01 H	Chronic; Incorporated, 5 % peat	NOEC = 1000 mg prep./kg dw [5)] (reproduction)	Schulz, L. 30.10.2013 13 10 48 150 S; BASF RegDoc#2013/1132515

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003
[1)] Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H from the EU review of dimethenamid-P).
[2)] According to the EPPO risk assessment scheme the toxicity data from tests with artificial soil are divided by the factor of 2 because logPow for the active substance is greater than 2 .
[4)] Based on a nominal content of 720 g dimethenamid-P/L in BAS 656 12 H and a density of 1.119 g/cm^3.
[5)] Highest concentration testet.
Values in **bold** were chosen by RMS for risk assessment.

All listed studies are valid and can be used for risk assessment.

2.9.5 Summary of effects on soil nitrogen transformation

Soil nitrogen transformation studies on the effect of the representative formulations BAS 656 07 H and BAS 830 01 H, dimethenamid-racemate and the metabolites of the active substance dimethenamid-P M23, M27, and M31 were submitted. Also, studies on the effect of the representative formulation BAS 656 07 H, dimethenamid-racemate and the metabolites of the active substance dimethenamid-P M23, M27, and M31 on C-mineralisation were submitted as additional information according to the applicant. Under commission regulation 283/2013 and 284/2013 data on effects on microbial C-mineralisation are no longer required. Nonetheless, in the risk assessment below the studies on C-mineralisation are included, since it also concerns a soil microbial process.

In the following table an overview of endpoints and effect values that have been identified as in principle relevant for the quantitative risk assessment according to the current EFSA Guidance Document (SANCO/10329/2002) is given. Values in bold were chosen by RMS for risk assessment. A discussion on the selection of endpoints for risk assessment is included below the table.

Table 2.9-16: EU agreed endpoints and new endpoints for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	SAN 582 H (dimethenamid-racemate), 2.4 mg/kg, 12 mg/kg (5 x)	28 d; loamy sand; clay silt	The study was evaluated in the initial DAR: Not valid because no nitrification occurred. 28 d (1x: NH_4^+ +30.8 %, NO_3^- +42.9 %, total-N +36.4 %; 5 x: NH_4^+ +27.5 %, NO_3^- +49.6 %, total-N +37.6 %	Danneberg, G. 01.08.1991 BE-S-7-91-01; TDS BS 2451; BE-S-7-91-01-DEH-01; BMF1999-42; BMF96-00042; BASF DocID# 91/11908
C-mineralisation	SAN 582 H (dimethenamid-racemate), 2.4 mg/kg, 12 mg/kg (5 x)	Dehydrogenase activity; BBA 1-1 (C) 28 d loamy sand; clay silt	< 25 % 1.8 kg as/ha and 9.0 kg as/ha Re-evaluating the study, it is not considered valid anymore since plastic bags are used.	Danneberg, G. 01.08.1991 BE-S-7-91-01; TDS BS 2451; BE-S-7-91-01-DEH-01; BMF1999-42; BMF96-00042; BASF DocID# 91/11908 *(only the endpoint on C-mineralisation)
N-mineralisation	M 23 (metabolite of dimethenamid-P)	28 d aerob	**< 25 %** difference from the control at 0.2 and 1 mg as/kg dw	Schulz, L. 19.12.2008 08 10 48 062 C; BASF RegDoc# 2008/1065116
C-mineralisation	M 23 (metabolite of dimethenamid-P)	28 d aerob	**< 25 %** difference from the control at 0.2 and 1 mg as/kg dw	Schulz, L. 19.12.2008 08 10 48 062 N; BASF RegDoc# 2008/1065117
N-mineralisation	M 27 (metabolite of dimethenamid-P)	28 d aerob	**< 25 %** difference from the control at 0.2 and 1 mg as/kg dw	Schulz, L. 19.12.2008 08 10 48 063 N; BASF RegDoc# 2008/1065119*
C-mineralisation	M 27 (metabolite of dimethenamid-P)	28 d aerob	**< 25 %** difference from the control at 0.2 and 1 mg as/kg dw	Schulz, L. 19.12.2008 08 10 48 063 C; BASF RegDoc# 2008/1065118
N-mineralisation	M 31 (metabolite of dimethenamid-P)	28 d aerob	**< 25 %** difference from the control at 0.2 and 1 mg as/kg dw	Schulz, L. 19.12.2008 08 10 48 064 N; BASF RegDoc# 2008/1065115
C-mineralisation	M 31 (metabolite of dimethenamid-P)	28 d aerob	**< 25 %** difference from the control at 0.2 and 1 mg as/kg dw	Schulz, L. 19.12.2008 08 10 48 064 C; BASF RegDoc# 2008/1065109
N-mineralisation	BAS 656 07 H	28 d Aerob; loamy sand	< 25 % difference from the control at 1.4 and	Krieg, W. 1999 49223; BMF1999-49; BMF1999-48;

Endpoint	Substance	Exposure System	Results	Reference
			7.0 L prep./ha Equivalent to 0.99 **and 4.93 kg as/ha,** respectively	BASF RegDoc# 99/10134 **1)
C-mineralisation	BAS 656 07 H	28 d Aerob; loamy sand	< 25 % difference from the control at 1.4 and **7.0 L prep./ha** equivalent to 0.99 and **4.93 kg as/ha**, respectively	Krieg, W. 04.02.1999 49223; BMF1999-48; BASF RegDoc# 99/10134 **1)
N-mineralisation	BAS 830 01 H	28 d aerob	< 25 % difference from the control at 22.7 mg prep./kg dry soil, equivalent to **15.0 L prep./ha.**	Krieg, W. 1999 49222; BMF1999-49; BASF RegDoc# 99/10265 **1)

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003
** Study evaluated in the initial monograph, 2000.
1) Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H from the EU review of dimethenamid-P).
2) 1.87 µL BAS 656 07 H per kg soil (corresponding to a field application rate of 1.4 L BAS 656 07 H per ha) and 9.33 µL BAS 656 07 H per kg soil corresponding to an field application rate of 7.0 L BAS 656 07 H per ha; related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3).
Values in **bold** were chosen by RMS for risk assessment.

No valid study on N-transformation is available with the active substance dimethenamid-P. Studies submitted previously during the initial evaluation process of dimethenamid-P and dimethenamid (racemate) were considered not valid since no nitrification occurred.

The applicant used the study conducted with the formulation BAS 656 07 H (720 g as/L) as surrogate.

As agreed in the initial EU evaluation, no effects on the soil microflora due to dimethenamid-P and its metabolites M23, M27, and M31 were seen up to a concentration of 4.93 kg/ha for the active substance (tested as formulation BAS 656 07 H) and 1.0 mg/kg soil for the metabolites.

2.9.6 Summary of effects on terrestrial non-target higher plants

In the following table an overview of endpoints and effect values that have been identified as in principle relevant for the quantitative risk assessment according to the current EFSA Guidance Document (SANCO/10329/2002) is given. Values in bold were chosen by RMS for risk assessment. A discussion on the selection of endpoints for risk assessment is included below the table.

Table 2.9-17: EU agreed endpoints and new endpoints for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Avena fatua, m *Bromus tectorum, m* *Echinochloa crus-galli, m* *Setaria viridis, m* *Abutilon theophrasti, d* *Amaranthus retroflexus, d* *Sinapis alba, d* *Solanum nigrum, d*	M 23 and M 27	Pre- and post emergence 250 und 1000 g metabolite/ha Parent 0.16 g as/ha	no herbicidal effects (visual observation) ER_{50} >1000 g metabolite/ha ER_{50} >0.16 g as/ha	Kaethner, M. 30.01.1995 TDS-BS5094; PFL2002-227 and PFL2002-228*
Digitaria sanguinalis, m *Setaria viridis, m* *Lolium multiflorum, m* *Setaria faberi, m* *Echinocloa crus-galli, m* *Poa annua, m* *Capsella bursa-pastoris, d* *Chenopodium album, d* *Matricaria inodora, d* *Stellaria media, d*	M 31	21 d, pre-emergence screening, 684 and 1008 g as/ha	no herbicidal effects (visual observation) ER_{50} >1008 g metabolite/ha	Dutillie, H. and Sack, D. 26.09.2008 353446*
Bromus inermis, m *Echinochloa crus-galli, m* *Setaria viridis, m* *Lolium multiflorum, m* *Geranium dissectum, d* *Chenopodium album, d*	soil metabolites M656PH023, M656PH030, M656PH031, M656PH032,M656 PH043, M656PH045, M656PH047, M656PH054, M656H055, the Na salt of M656PH027 and the ethylester derivative for M656PH062 parent dimethenamid-P BAS 656 12 H	21 d; Pre- and post emergence Blank formulation + 4 rates Blank formulation, 43.2; 86.4; 172.8, and 864 g as/ha Blank formulation, 60, 120, 240, and 1200 mL prep./ha	no herbicidal effects (visual observation) Effects on *Lolium multiflorum* based on phytotoxicity (at day 21): ER_{50} (SE) < 43.2 g as/ha (80 % effect) ER_{50} (VV) = 93.3 g as/ha (Probit analysis) ER_{50} (SE) < 43.2 g as/ha (96 % effect) ER_{50} (VV) = 62.3 g as/ha (Probit analysis)	N.N. (Doc ID 2014/ 1101480, cited in Document N4 of the dossier) **(study can only be used subject to the submission of the document and to the evaluation by RMS)**
Lactuca sativa, d *Zea mays, m* *Triticum aestivum,m* *Lolium multiflorum, m* *Allium cepa, m*	BAS 656 12 H	21 d Seedling emergence	ER_{50} = 0.0286 L prep./ha dry biomass reduction	Marquardt, J. 2013 2013/1134944*

Species	Substance	Exposure System	Results	Reference
Daucus carota, d *Glycine max, d* *Brassica oleracea, d* *Solanum sp., d* *Brassica napus, d*			Effects on *Lolium multiflorum* (at day 21) based on i) biomass: Probit analysis: ER_{50} (SE) = 0.0614 L prep./ha, corresponding to 44.2 g as/ha ii) phytotoxicity: 9 % at 38.4 mL prep./ha 43 % at 96 mL prep./ha 88 % at 240 mL prep./ha Probit analysis: ER_{50} (SE) = 264 mL prep./ha, corresponding to 190 g as/ha The results of the study are questionable due to increased temperature in the study. Also other studies indicate a lower endpoint.	
Daucus carota L.; d *Lactuca sativa L.; d* *Brassica napus L. ssp. napus, d* *Brassica oleracea L. var. capitata L.; d* *Glycine max L.; d* *Lycopersicon esculentum Mill.; d* *Allium cepa L.; m* ***Lolium multiflorum** L.; m* *Avena sativa L.; m* *Zea mays L.; m*	BAS 830 01 H	21 d Seedling emergence	ER_{50} > **0. 094 L prep./ha** dry biomass reduction	Strömel, C. et al. 30.10.2013 AC/BASF/13/18; BASF RegDoc #2013/1134946
Lactuca sativa, d *Zea mays, m* *Triticum aestivum,m* *Lolium multiflorum, m* *Allium cepa, m* *Daucus carota, d* *Glycine max, d* *Brassica oleracea, d* *Solanum sp., d* *Brassica napus, d*	BAS 656 12 H	21 d Vegetative vigour	ER_{50} > 0.240 L prep./ha dry biomass reduction Effects on *Lolium multiflorum* (at day 21) based on i) biomass: Probit analysis: ER_{50} (SE) = 478 mL prep./ha, corresponding to	Marquardt, J. 2013 2013/1134945*

Species	Substance	Exposure System	Results	Reference
			344 g as/ha ii) phytotoxicity: 5 % at 90 mL prep./ha, corresponding to 64.8 g as/ha 12 % at 240 mL prep./ha, corresponding to 173 g as/ha The results of the study are questionable due to increased temperature in the study. Also other studies indicate a lower endpoint.	
Daucus carota L.; d *Lactuca sativa L.; d* *Brassica napus L. ssp. napus, d* *Brassica oleracea L. var. capitata L.; d* *Glycine max L.; d* *Lycopersicon esculentum Mill.; d* *Allium cepa L.; m* ***Lolium multiflorum L.**; m* *Avena sativa L.; m* *Zea mays L.; m*	BAS 830 01 H	21 d Vegetative vigour	[1)] ER_{50} emergence > 0.750 L prep./ha [2)] ER_{50} plant weight = **0.527 L prep./ha** [3)] ER_{50} plant height > 0.750 L prep./ha	Strömel, C. et al. 06.11.2013 AC/BASF/13/19; BASF RegDoc #2013/1134947

* Endpoint differing from LoEP / new study submitted
Values in **bold** were chosen by RMS for risk assessment.

The most sensitive plants species towards BAS 656 12 H in the studies of Marquardt (2013) turned out to be *Lactuca sativa* with an ER_{50} = 28.6 mL prep./ha in the seedling emergence test and ER_{50} = 240 mL prep./ha in the vegetative vigour test. The results of the test are not suitable for risk assessment for the following reasons:

i) Irregularity within the test (higher temperature than required according to test guidelines OECD 208 and OECD 227); availability of dimethenamid-P might be affected.
ii) A study on herbicide toxicity using dimethenamid-P and BAS 656 12 H as positive controls show clearly more pronounced effects. The study was not yet submitted and could therefore not have been evaluated in detail. According to the summary provided by the applicant in document N4 of the renewal dossier, the test design of the study is comparable with that of guidelines OECD 208 and OECD 227 (21 d greenhouse test, dose-response, 4 rates, 4 replicates).

A comparison of the results reveals that the endpoint derived from the studies of Marquardt (2013) could be too high. Note that according to the studies of Marquardt (2013) biomass is even the more sensitive parameter compared to phytotoxicity.

Table 2.9-18: Comparison of the results of the studies of Marquardt (2013) and herbicidal screening study (according to document N4)

Marquardt (2013)	Herbicidal screening study (results according to document N4)
Pre-emergence application	
Effects on biomass: *Lactuca sativa:* ER_{50} = 28.6 mL BAS 656 12 H/ha (20.6 g as/ha) *Lolium multiflorum:* ER_{50} = 61.4 mL BAS 656 12 H/ha (44.2 g as/ha) Effects on phytotoxicity: *Lactuca sativa:* ER_{50} =32 mL BAS 656 12 H/ha (23 g as/ha) *Lolium multiflorum:* ER_{50} = 264 mL BAS 656 12 H/ha (190 g as/ha)	Effects on biomass: Not evaluated Effects on phytotoxicity: *Lactuca sativa:* Not evaluated *Lolium multiflorum:* ER_{50} < 60 mL BAS 656 12 H/ha (> 43.2 g as/ha) At 43.2 g as/ha 80 % effects; at 172.8 g as/ha 98 % effects)
Post-emergence application	
Effects on biomass: *Lactuca sativa:* ER_{50} > 240 mL BAS 656 12 H/ha (> 172.8 g as/ha) *Lolium multiflorum:* ER_{50} = 478 mL BAS 656 12 H/ha (344 g as/ha) Effects on phytotoxicity: *Lactuca sativa:* ER_{50} > 240 mL BAS 656 12 H/ha (> 172.8 g as/ha) *Lolium multiflorum:* ER_{50} > 240 mL BAS 656 12 H/ha (> 172.8 g as/ha)	Effects on biomass: Not evaluated Effects on phytotoxicity: *Lactuca sativa:* Not evaluated *Lolium multiflorum:* ER_{50} = 87 mL BAS 656 12 H/ha (62.3 g as/ha) At 172.8 g as/ha 86 % effects

Therefore, an adequate Tier 2 test with the formulation BAS 656 12 H is required or data proving that the studies of Marquardt (2013) can be used in the risk assessment.

The most sensitive plants species towards BAS 830 01 H turned out to be *Lolium multiflorum* with an ER_{50} > 94 mL prep./ha in the seedling emergence test and an ER_{50} = 527 mL prep./ha in the vegetative vigour test. For the risk assessment the ER_{50} > 94 mL prep. /ha is used.

2.9.7 Summary of effects on other terrestrial organisms (flora and fauna)

Under this data requirement carbon mineralisation studies were submitted by the applicant. This information is taken into account in the RAR, Vol. 3, B.9.9.

2.9.8 Summary of effects on biological methods for sewage treatment

An activated sludge respiration inhibition test in accordance with OECD guideline 209 was submitted for the active substance and a NOEC of 100 mg/L was determined. Therefore, effects on biological methods of sewage treatment plants or aquatic microflora are not to be expected.

2.9.9 Summary of product exposure and risk assessment

2.9.9.1 Risk assessment for birds and other terrestrial vertebrates

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) No 284/2013, Part A, Annex point 10.1)

Table 2.9-19: BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets at 1 x 864 g as/ha

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
Bare soil BBCH 00-09	Small granivorous bird	Acute	21.3	50	10
Maize/Sugar Maize BBCH 10-16	Small omnivorous bird	Acute	137.2	**7.8**	10
Sugar Beet BBCH 12-18[1)]	Small omnivorous bird	Acute	114.3	**9.3**	10
Bare soil BBCH 00-09	Small granivorous bird	Long-term	5.22	20.1	5
Maize/Sugar Maize BBCH 10-16	Small omnivorous bird	Long-term	29.67	**3.6**	5
Sugar Beet BBCH 12-18[1)]	Small omnivorous bird	Long-term	24.73	**4.3**	5
Tier 1 (Birds)					
Maize/Sugar Maize BBCH 10-29	Medium granivorous bird 100 % seed	Acute	5.702	187	10
Maize/Sugar Maize BBCH 10-19 Leaf development	Small insectivorous bird 100 % soil dwelling arthropods	Acute	9.072	118	10
Maize/Sugar Maize BBCH 10-29	Small omnivorous bird 25 % crop leaves 25 % weed seeds 50 % ground arthropods	Acute	20.736	52	10
Maize/Sugar Maize BBCH 10-29	Medium herbivorous/granivorous bird 100 % leaves	Acute	48.038	22	10
Maize/Sugar Maize BBCH 10-19	Small insectivorous bird 50 % ground arthropods 50 % foliar arthropods	Acute	23.155	46	10
Sugar Beet BBCH 10-19[1)]	Small insectivorous bird 100 % soil dwelling arthropods	Acute	10.9	136	10
Sugar Beet BBCH 10-19[1)] (spring)	Small omnivorous bird 25 % crop leaves 25 % weed seeds 50 % ground arthropods	Acute	24.0	17.28	10
Maize/Sugar Maize BBCH 10-29	Medium granivorous bird 100 % seed	Long-term	1.374	78	5
Maize/Sugar Maize BBCH 10-19	Small insectivorous bird 100 % soil dwelling arthropods	Long-term	2.610	41	5
Maize/Sugar Maize BBCH 10-29	Small omnivorous bird 25 % crop leaves 25 % weed seeds 50 % ground arthropods	Long-term	4.991	21	5

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Maize/Sugar Maize BBCH 10-29	Medium herbivorous/granivorous bird 100 % leaves	Long-term	10.395	10	5
Maize/Sugar Maize BBCH 10-19	Small insectivorous bird 50 % ground arthropods 50 % foliar arthropods	Long-term	5.174	21	5
Sugar Beet BBCH 10-19[1)]	Small insectivorous bird 100 % soil dwelling arthropods	Long-term	2.25	47.4	5
Sugar Beet BBCH 10-19[1)] (spring)	Small omnivorous bird 25 % crop leaves 25 % weed seeds 50 % ground arthropods	Long-term	4.15	25.7	5
Higher tier (birds):					
Not required					
Screening Step (Mammals)					
Bare soil BBCH 00-10	Small granivorous mammal	Acute	12.442	37.5	10
Maize/Sugar Maize BBCH 10-16	Small herbivorous mammal	Acute	117.85	**4.0**	10
Sugar Beet BBCH 12-18[1)]	Small herbivorous mammal	Acute	85.25	**5.5**	10
Bare soil BBCH 00-10	Small granivorous mammal	Long-term	3.022	11.1	5
Maize/Sugar Maize BBCH 10-16	Small herbivorous mammal	Long-term	53.1	**1.0**	5
Sugar Beet BBCH 12-18[1)]	Small herbivorous mammal	Long-term	16.6	**2.0**	5
Tier 1 (Mammals)					
Maize/Sugar Maize BBCH 10-19	Small insectivorous mammal 100 % ground arthropods	Acute	10.306	>48.5	5
Maize/Sugar Maize BBCH 10-29	Small herbivorous mammal All maize shoots + later grass	Acute	184.96	**>2.7**	5
Maize/Sugar Maize BBCH 10-29	Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	Acute	23.323	>21.4	5
Sugar Beet BBCH 10-19[1)]	Small insectivorous mammal 100 % ground arthropods	Acute	8.588	>58.2	5
Sugar Beet BBCH 10-39[1)]	Large herbivorous mammal 100 % crop leaves	Acute	39.663	>12.6	5
Sugar Beet BBCH 10-39[1)]	Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	Acute	19.436	>25.7	5
Maize/Sugar Maize BBCH 10-19	Small insectivorous mammal 100 % ground arthropods	Long-term	1.923	17.3	10

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Maize/Sugar Maize BBCH 10-29	Small herbivorous mammal All maize shoots + later grass	Long-term	33.11	**1.0**	10
Maize/Sugar Maize BBCH 10-29	Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	Long-term	3.57	9.3	10
Sugar Beet BBCH 10-19[1)]	Small insectivorous mammal 100 % ground arthropods	Long-term	1.6	20.8	10
Sugar Beet BBCH 10-39[1)]	Large herbivorous mammal 100 % crop leaves	Long-term	5.46	6.1	10
Sugar Beet BBCH 10-39[1)]	Small omnivorous mammal 25 % weeds 50 % weed seeds 25 % ground arthropods	Long-term	2.98	11.2	10
Higher tier (Mammals): No data adequate for risk assessment submitted.					

Risk from bioaccumulation and food chain behaviour not relevant Log kow ≤ 3

Risk from consumption of contaminated water

Scenarios	Indicator or focal species	Time scale	PEC_{dw}xDWR	TER	Trigger
Puddle scenario, Screening step 1) Birds: Application rate (in g as/ha) /EP: 864 / 106.8 = 8.1; 50 < Koc < 500 L/kg), TER calculation not needed 2) Mammals: Application rate (in g as/ha)/ EP: 864/ 33.3 = 26; 50 <Koc < 500 L/kg), TER calculation not needed					

TER values shown in **bold** are below the relevant trigger.
[1)] Includes splitting.

Table 2.9-20: BAS 830 01 H (contains 333 g/L dimethenamid-P and 67 g/L quinmerac) in winter oilseed rape at 1 x 1.5 L preparation/ha, corresponding to 500 g dimethenamid-P/ha

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Tier 1 (Birds)					
Bare soil BBCH 00-09	Small granivorous bird "finch"	Acute	a) 12.35 b)	a) 86.5 b) 68.3	10
Bare soil BBCH 00-09	Small omnivorous bird "lark"	Acute	a) 8.7 b)	a) 123 b) 96.9	10
Bare soil BBCH 00-09	Small insectivorous bird "wagtail"	Acute	a) 5.45 b)	a) 196 b) 155	10
Oilseed rape BBCH 10-18 (shoots)	Large herbivorous bird "goose"	Acute	a) 19.5 b)	a) 54.8 b) 43.2	10
Oilseed rape BBCH 10-18	Small omnivorous bird "lark"	Acute	a) 12 b)	a) 89.0 b) 70.3	10
Oilseed rape BBCH 10-18	Medium herbivorous/granivorous bird "pigeon"	Acute	a) 27.8 b)	a) 38.4 b) 30.3	10
Oilseed rape BBCH 10-18	Small insectivorous bird "wagtail"	Acute	a) 5.45 b)	a) 196 b) 154.7	10
Bare soil BBCH 00-09	Small granivorous bird "finch"	Long-term	a) 3.02 b)	a) 35.4 b) 27.1	5
Bare soil BBCH 00-09	Small insectivorous bird "wagtail"	Long-term	a) 1.56 b)	a) 68.5 b) 52.3	5
Bare soil BBCH 00-09	Small omnivorous bird "lark"	Long-term	a) 2.17 b)	a) 49.2 b) 37.6	5
Oilseed rape BBCH 10-18 (shoots)	Large herbivorous bird "goose"	Long-term	a) 4.21 b)	a) 25.4 b) 19.4	5
Oilseed rape BBCH 10-18	Small omnivorous bird "lark"	Long-term	a) 2.89 b)	a) 37.0 b) 28.3	5
Oilseed rape BBCH 10-18	Medium herbivorous/granivorous bird "pigeon"	Long-term	a) 6.02 b)	a) 17.7 b) 13.5	5
Oilseed rape BBCH 10-18	Small insectivorous bird "wagtail"	Long-term	a) 1.56 b)	a) 68.5 b) 52.3	5
Higher tier (birds):					
Not required					
Tier 1 (Mammals)					
Bare soil BBCH 00-10	Small omnivorous mammal "mouse"	Acute	7.15	65	10
Oilseed rape BBCH 10-19	Small insectivorous mammal "shrew"	Acute	3.8	122	10
Oilseed rape (all season)	Large herbivorous mammal "largomorph"	Acute	17.6	26.6	10
Oilseed rape BBCH 10-29	Small omnivorous mammal "mouse"	Acute	8.6	54.2	5
Bare soil BBCH 00-10	Small omnivorous mammal "mouse"	Long-term	a) 1.56 b)	a) 22 b) 18.9	5
Oilseed rape BBCH 10-19	Small insectivorous mammal "shrew"	Long-term	a) 1.11 b)	a) 29.9 b) 25.6	5
Oilseed rape (all season)	Large herbivorous mammal "largomorph"	Long-term	a) 3.79 b)	a) 8.79 b) 7.54	5
Oilseed rape BBCH 10-29	Small omnivorous mammal "mouse"	Long-term	a) 2.07 b)	a) 16.1 b) 13.4	5
Higher tier (Mammals):					
Not required					

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Risk from bioaccumulation and food chain behaviour not relevant Log kow ≤ 3					
Risk from consumption of contaminated water					
Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Puddle scenario, Screening step 1) Birds: Application rate (in g as/ha) /EP = 500 / 106.8 = 4.6; 50 < koc < 500 L/kg), TER calculation not needed 2) Mammals: Application rate (in g as/ha) /EP = 500/ 33.3 = 15; 50 < koc < 500 L/kg), TER calculation not needed					

TER values shown in **bold** are below the relevant trigger.
a) Active substance dimethenamid-P
b) Representative formulation BAS 830 01 H: TER values for birds are calculated via LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50}(as_i)]^{-1}$ = 1265 for acute assessment and via TER (mix) for long-term assessment, respectively.
Note that dimethenamid-P is driving the acute risk for mammals and no additional mixture toxicity assessment is necessary to adress the acute risk for mammals.

Birds

Dietary risk assessment for the representative formulation BAS 656 12 H

The risk assessment for birds in the intended use is based on the scenarios “bare soil”, “maize” and “sugar beet”, thereupon considering the corresponding generic focal species in the Tier 1 assessment. All calculated TER values are above the respective acceptability criteria of 10 for acute and 5 for long-term exposure, respectively.

Dietary risk assessment for the representative formulation BAS 830 01H

The risk assessment for birds in the intended uses is based on the scenarios “bare soil” and “winter oilseed rape”, thereupon considering the corresponding generic focal species at the Tier 1. The calculated TER values are above the respective acceptability criterion of 10 and 5 for the acute and long-term exposure, respectively.

Risk for birds from exposure to contaminated drinking water

Since the intended uses for BAS 656 12 H and BAS 830 01 H do not include critical crops and growth stages for the formation of pools in leaf whorls, only the scenario of puddles formed on soil needs to be considered, in principle, for an assessment of the risk from the uptake of contaminated drinking water. However, as the ratio of the highest application rate for BAS 656 12 H (864 g as/ha g as /ha) and for BAS 830 01 H (500 g as/ha g as /ha) to lowest relevant endpoint (NOEL = 33.3 mg as /kg bw/d) for dimethenamid-P only amounts to 26 and 15, respectively, the risk can be considered acceptable without the need for further calculations.

Bioaccumulation and food chain behaviour for birds

Due to the low $\log P_{OW}$ = 1.89, dimethenamid-P is not likely to possess a potential for bioaccumulation that might result in unacceptable risks for organisms at higher trophic levels. Therefore, an assessment of the potential risk of secondary poisoning is not triggered and due to the low lipophilicity no risk of bioaccumulation is assumed.

Overall, the risk to birds from the intended uses of dimethenamid-P in BAS 656 12 H and BAS 830 01 H is considered acceptable.

Mammals

Dietary risk assessment for the representative formulation BAS 656 12 H
As for the avian risk assessment, the risk assessment for mammals in the intended uses is based on the scenarios "bare soil", "maize" and "sugar beet", thereupon considering the corresponding generic focal species at the Tier 1. The calculated TER values are above the respective acceptability criterion of 10 for the acute exposure. Tier 1 assessment considering the respective generic focal species and shortcut values for the scenario "maize BBCH 10-29" and "sugar beet BBCH 10-19" and "sugar beet BBCH 10-39" resulted in TER values above the respective acceptability criterion of 5 for long-term exposure for all scenarios but not for voles in "maize BBCH 10-29" (small herbivorous mammal; all maize shoots + later grass).

Refined assessment
The data provided by the applicant was not deemed suitable to address the risk to voles in Maize/Sugar Maize at early post emergence.

Unacceptable acute and reproductive risk remains for the use of BAS 656 12 H in Maize/Sugar Maize at early post emergence (uses 2 and 4).

Dietary risk assessment for the representative formulation BAS 830 01H

As for the avian risk assessment, the risk assessment for mammals in the intended uses is based on the scenarios "bare soil"and "winter oilseed rape", thereupon considering the corresponding generic focal species at the Tier 1. The calculated TER values are above the respective acceptability criterion of 10 and 5 for the acute and long-term exposure, respectively.

Risk for mammals from exposure to contaminated drinking water

Since the intended uses for BAS 656 12 H and BAS 830 01 H do not include critical crops and growth stages for the formation of pools in leaf whorls, only the scenario of puddles formed on soil needs to be considered, in principle, for an assessment of the risk from the uptake of contaminated drinking water. However, as the ratio of highest application rate for BAS 656 12 H (864 g as/ha g as /ha) and for BAS 830 01 H (500 g as/ha g as /ha) to lowest relevant endpoint (NOEL = 33.3 mg as /kg bw/d) for dimethenamid-P only amounts to 26 and 15, respectively, the risk can be considered acceptable without the need for further calculations.

Bioaccumulation and food chain behaviour for mammals

Due to the low $\log P_{OW}$ = 1.89, dimethenamid-P is not likely to possess a potential for bioaccumulation that might result in unacceptable risks for organisms at higher trophic levels. Therefore, an assessment of the potential risk of secondary poisoning is not triggered and due to the low lipophilicity no risk of bioaccumulation is assumed.

Overall, the risk to mammals from the intended uses of dimethenamid-P in BAS 830 01 H is considered acceptable. The risk to mammals from the intended uses of dimethenamid-P in BAS 656 12 H is considered acceptable in the uses 1, 3, 5-10, whereas unacceptable acute and reproductive risk remains for the uses of BAS 656 12 H in Maize/Sugar Maize at early post emergence (uses 2 and 4).

2.9.9.2 Risk assessment for aquatic organisms

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

BAS 656 12 H

Table 2.9-21: FOCUS$_{sw}$ step 1 and 2 - TERs for dimethenamid-P – BAS 656 12 H in maize, soybeans and sunflowers at 1 x 864 g as/ha and FOCUS$_{SW}$ step 3 in maize (pre-/post-emergence) at 1 x 864 g a.s./ha

Scenario	PEC global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphi-dium griffithii*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		2600 µg/L	120 µg/L	3200 µg/L	680 µg/L	6.60 µg/L	5.99 µg/L
FOCUS Step 1							
	243.39	**10.68**	**0.49**	**13.15**	**2.79**	**0.03**	**0.02**
FOCUS Step 2*							
North Europe	43.14	**60.27**	**2.78**	**74.17**	15.76	**0.15**	**0.14**
South Europe	79.99	**32.51**	**1.50**	**40.01**	**8.50**	**0.08**	**0.07**
FOCUS Step 2+							
North Europe	43.14	**76.63**	**3.54**	**94.31**	20.04	**0.19**	**0.18**
South Europe	79.99	**42.23**	**1.95**	**51.98**	11.05	**0.11**	**0.10**
FOCUS Step 3* pre-emergence							
D3/ditch	4.524	574.71	26.53	707.34	150.31	**1.46**	**1.32**
D4/pond	0.212	12264.15	566.04	15094.34	3207.55	31.13	28.25
D4/stream	3.721	698.74	32.25	859.98	182.75	**1.77**	**1.61**
D5/pond	0.215	12093.02	558.14	14883.72	3162.79	30.70	27.86
D5/stream	4.025	645.96	29.81	795.03	168.94	**1.64**	**1.49**
D6/ditch	4.578	567.93	26.21	699.00	148.54	**1.44**	**1.31**
R1/pond	0.33	7878.79	363.64	9696.97	2060.61	20.00	18.15
R1/stream	10.478	248.14	11.45	305.40	64.90	**0.63**	**0.57**
R2/stream	7.504	346.48	15.99	426.44	90.62	**0.88**	**0.80**
R3/stream	16.982	153.10	**7.07**	188.43	40.04	**0.39**	**0.35**
R4/stream	46.07	**56.44**	**2.60**	**69.46**	14.76	**0.14**	**0.13**
FOCUS Step 3* post-emergence							
D3/ditch	4.528	574.20	26.50	706.71	150.18	**1.46**	**1.32**
D4/pond	0.226	11504.42	530.97	14159.29	3008.85	29.20	26.50
D4/stream	3.954	657.56	30.35	809.31	171.98	**1.67**	**1.51**
D5/pond	0.24	10833.33	500.00	13333.33	2833.33	27.50	24.96
D5/stream	3.636	715.07	33.00	880.09	187.02	**1.82**	**1.65**
D6/ditch	4.532	573.70	26.48	706.09	150.04	**1.46**	**1.32**
R1/pond	0.655	3969.47	183.21	4885.50	1038.17	10.08	**9.15**
R1/stream	11.503	226.03	10.43	278.19	59.12	**0.57**	**0.52**
R2/stream	9.647	269.51	12.44	331.71	70.49	**0.68**	**0.62**
R3/stream	25.173	103.29	**4.77**	127.12	27.01	**0.26**	**0.24**
R4/stream	28.803	**90.27**	**4.17**	111.10	23.61	**0.23**	**0.21**
Trigger**		100	10	100	10	10	10

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]
TERs shown in **bold** fall below the relevant trigger
* based on a single application in pre-emergence maize/soybeans/sunflowers
+ based on a single application in post-emergence maize

The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger value of 10 and 100 based on FOCUS Step 1 and 2 calculations for application in sugar beets,

indicating high aquatic risk.
Based on FOCUS Step 3, an acceptable risk has been demonstrated for 3 out of 11 FOCUS scenarios in the maize pre-emergence use (D4/pond, D5/pond and R1/pond), whereas only 2 FOCUS scenarios are acceptable in the maize post-emergence use (D4/pond and D5/pond).
The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger value of 10 and 100 based on FOCUS Step 1 and 2 calculations for the remaining FOCUS scenarios in maize, indicating high risk to algae and macrophytes, driving the risk assessment. Therefore, TER-calulations based on FOCUS Step 4 including risk mitigating measures are presented for these crop scenarios in the tables below.

Table 2.9-22: **$FOCUS_{sw}$ step 1-3 - TERs for dimethenamid-P — BAS 656 12 H: FOCUS step 1-3 calculations in sugar beets at 1 x 864 g a.s./ha (pre-emergence) and 1 x 720 g a.s./ha (post-emergence), respectively, and FOCUSsw step 3 - TERs for dimethenamid-P — BAS 656 12 H and FOCUS step 3 calculations in soybeans and sunflowers at 1 x 864 g as/ha**

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		2600 µg/L	120 µg/L	3200 µg/L	680 µg/L	6.60 µg/L	5.99 µg/L
FOCUS Step 1							
	202.83	**12.82**	**0.59**	**15.78**	**3.35**	**0.03**	**0.03**
FOCUS Step 2*							
North Europe	29.81	**87.22**	**4.03**	107.34	22.81	**0.22**	**0.20**
South Europe	54.37	**47.82**	**2.21**	**58.85**	12.51	**0.12**	**0.11**
FOCUS Step 2+							
North Europe	29.81	**87.22**	**4.03**	107.34	22.81	**0.22**	**0.20**
South Europe	42.09	**61.77**	**2.85**	**76.02**	16.15	**0.16**	**0.14**
Step 3, Soybeans, 864 g/ha, pre-emergence							
R3/stream	23.084	112.63	**5.20**	138.62	29.46	**0.29**	**0.26**
R4/stream	13.805	188.34	**8.69**	231.80	49.26	**0.48**	**0.43**
Step 3, Sugar beets, 864 g/ha, pre-emergence							
D3/ditch	4.524	574.71	26.53	707.34	150.31	1.46	1.32
D4/pond	0.219	11872.15	547.95	14611.87	3105.02	30.14	27.35
D4/stream	3.727	697.61	32.20	858.60	182.45	1.77	1.61
R1/pond	1.972	1318.46	60.85	1622.72	344.83	3.35	3.04
R1/stream	20.477	126.97	5.86	156.27	33.21	0.32	0.29
R3/stream	38.356	67.79	3.13	83.43	17.73	0.17	0.16
Step 3, Sugar beets, 720 g/ha, post-emergence							
D3/ditch	3.772	689.29	31.81	848.36	180.28	**1.75**	**1.59**
D4/pond	0.192	13541.67	625.00	16666.67	3541.67	34.38	31.20
D4/stream	3.16	822.78	37.97	1012.66	215.19	**2.09**	**1.90**
R1/pond	0.279	9319.00	430.11	11469.53	2437.28	23.66	21.47
R1/stream	3.597	722.82	33.36	889.63	189.05	**1.83**	**1.67**
R3/stream	5.7	456.14	21.05	561.40	119.30	**1.16**	**1.05**
Step 3, Sunflowers, 864 g/ha, pre-emergence							
D5/pond	0.215	12093.02	558.14	14883.72	3162.79	30.70	27.86
D5/stream	3.745	694.26	32.04	854.47	181.58	**1.76**	**1.60**
R1/pond	0.355	7323.94	338.03	9014.08	1915.49	18.59	16.87

R1/stream	9.407	276.39	12.76	340.17	72.29	**0.70**	**0.64**
R3/stream	43.354	**59.97**	**2.77**	**73.81**	15.68	**0.15**	**0.14**
R4/stream	37.897	**68.61**	**3.17**	**84.44**	17.94	**0.17**	**0.16**
Trigger		100	10	100	10	10	10

TERs shown in **bold** fall below the relevant trigger
* based on a single application in sugar beets between March-May
+ based on a single application in sugar beets between June-September

The table above shows that no acceptable risk has been demonstrated for the use in soybeans.
However, acceptable risks have been demonstrated for 2 FOCUS scenarios in sugar beets (D4/pond and R1/pond) and in sunflowers (D5/pond and R1/pond), respectively. The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger value of 10 and 100 based on FOCUS Step 1 and 2 calculations for the remaning FOCUS scenarios, indicating high risk to aquatic organisms. Therefore, TER-calulations based on FOCUS Step 4 including risk mitigating measures are presented for these crop scenarios in the tables below.

Table 2.9-23: FOCUS$_{sw}$ step 4 - TERs dimethenamid-P – BAS 656 12 H in maize at 1 x 864 g as/ha in pre-emergence and post-emergence maize

FOCUS Scenarios	Algae SSD - RAC [µg as/L]	FOCUS Step 4 – maize (pre-emergence)		FOCUS Step 4 – maize (post-emergence)	
		PEC$_{sw,max}$ [µg/L]	TER (RAC/PEC)	PEC$_{sw,max}$ [µg/L]	TER (RAC/PEC)
5 m Drift mitigation					
D3/ditch	1.35	1.483	**0.91**	1.484	**0.91**
D4/pond		0.187	7.22	0.198	6.82
D4/stream		1.577	**0.86**	1.683	**0.80**
D5/pond		0.19	7.11	0.212	6.37
D5/stream		1.706	**0.79**	1.542	**0.88**
D6/ditch		0.535	2.52	1.506	**0.90**
R1/pond		0.314	4.30	0.632	2.14
R1/stream		10.478	**0.13**	11.503	**0.12**
R2/stream		7.504	**0.18**	9.647	**0.14**
R3/stream		16.982	**0.08**	25.173	**0.05**
R4/stream		46.07	**0.03**	28.803	**0.05**
10 m Drift mitigation					
D3/ditch	1.35	0.786	1.72	0.792	1.70
D4/pond		0.137	9.85	0.145	9.31
D4/stream		0.842	1.60	0.902	1.50
D5/pond		0.139	9.71	0.159	8.49
D5/stream		0.911	1.48	0.825	1.64
D6/ditch		0.838	1.61	0.813	1.66
R1/pond		0.282	4.79	0.589	2.29
R1/stream		10.478	**0.13**	11.503	**0.12**
R2/stream		7.504	**0.18**	9.647	**0.14**
R3/stream		16.982	**0.08**	25.173	**0.05**
R4/stream		46.07	**0.03**	28.803	**0.05**
20 m Drift mitigation					
D3/ditch	1.35	0.409	3.30	0.416	3.25
D4/pond		0.09	15.00	0.095	14.21
D4/stream		0.44	3.07	0.471	2.87
D5/pond		0.093	14.52	0.109	12.39
D5/stream		0.476	2.84	0.434	3.11
D6/ditch		0.46	2.93	0.437	3.09
R1/pond		0.253	5.34	0.55	2.45
R1/stream		10.478	**0.13**	11.503	**0.12**
R2/stream		7.504	**0.18**	9.647	**0.14**
R3/stream		16.981	**0.08**	25.173	**0.05**
R4/stream		46.07	**0.03**	28.803	**0.05**
10 m Drift + runoff mitigation					
D3/ditch	1.35	0.786	1.72	0.792	1.70
D4/pond		0.137	9.85	0.145	9.31
D4/stream		0.842	1.60	0.902	1.50
D5/pond		0.139	9.71	0.159	8.49
D5/stream		0.911	1.48	0.825	1.64
D6/ditch		0.838	1.61	0.813	1.66
R1/pond		0.164	8.23	0.305	4.43
R1/stream		4.442	**0.30**	5.208	**0.26**
R2/stream		3.362	**0.40**	4.247	**0.32**
R3/stream		6.946	**0.19**	11.382	**0.12**
R4/stream		20.86	**0.06**	13.093	**0.10**
20 m Drift + runoff mitigation					
D3/ditch	1.35	0.409	3.30	0.416	3.25
D4/pond		0.09	15.00	0.095	14.21
D4/stream		0.44	3.07	0.471	2.87

FOCUS Scenarios	Algae SSD - RAC [µg as/L]	FOCUS Step 4 – maize (pre-emergence)		FOCUS Step 4 – maize (post-emergence)	
		$PEC_{sw,max}$ [µg/L]	TER (RAC/PEC)	$PEC_{sw,max}$ [µg/L]	TER (RAC/PEC)
D5/pond		0.093	14.52	0.109	12.39
D5/stream		0.476	2.84	0.434	3.11
D6/ditch		0.46	2.93	0.437	3.09
R1/pond		0.095	14.21	0.17	7.94
R1/stream		2.266	**0.60**	2.723	**0.50**
R2/stream		1.75	**0.77**	2.2	**0.61**
R3/stream		3.498	**0.39**	5.948	**0.23**
R4/stream		10.909	**0.12**	6.863	**0.20**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC)

Table 2.9-24: $FOCUS_{sw}$ step 4 - TERs dimethenamid-P – BAS 656 12 H in soybeans at 1 x 864 g as/ha in pre-emergence

FOCUS Scenarios	Algae SSD-RAC [µg as/L]	FOCUS Step 4 – pre-emergence soybeans	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
5 m Drift mitigation			
R3/stream	1.35	23.084	**0.06**
R4/stream		13.805	**0.10**
10 m Drift mitigation			
R3/stream	1.35	23.084	**0.06**
R4/stream		13.805	**0.10**
20 m Drift mitigation			
R3/stream	1.35	23.084	**0.06**
R4/stream		13.805	**0.10**
10 m Drift + runoff mitigation			
R3/stream	1.35	10.548	**0.13**
R4/stream		6.285	**0.21**
20 m Drift + runoff mitigation			
R3/stream	1.35	5.539	**0.24**
R4/stream		3.295	**0.41**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC).

Based on the TER values above, unacceptable/high risks are identified for all R3-4/stream scenarios ($PEC_{sw;max} > RAC_{sw;ch}$).

Table 2.9-25: FOCUSsw step 4 - TERs dimethenamid-P – BAS 656 12 H in pre-emergence sunflower at 1 x 864 g a.s./ha

FOCUS Scenarios	Algae SSD-RAC [µg a.s./L]	FOCUS Step 4 – pre-emergence sunflower	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
5 m Drift mitigation			
D5/pond	1.35	0.190	7.11
D5/stream		1.584	**0.85**
R1/pond		0.339	3.98
R1/stream		9.407	**0.14**
R3/stream		43.354	**0.03**
R4/stream		37.897	**0.04**

10 m Drift mitigation			
D5/pond	1.35	0.140	9.64
D5/stream		0.845	1.60
R1/pond		0.308	4.38
R1/stream		9.407	**0.14**
R3/stream		43.354	**0.03**
R4/stream		37.897	**0.04**
20 m Drift mitigation			
D5/pond	1.35	0.094	14.36
D5/stream		0.441	3.06
R1/pond		0.279	4.84
R1/stream		9.407	**0.14**
R3/stream		43.354	**0.03**
R4/stream		37.897	**0.04**
10 m Drift + runoff mitigation			
D5/pond	1.35	0.140	9.64
D5/stream		0.845	1.60
R1/pond		0.174	7.76
R1/stream		3.958	**0.34**
R3/stream		19.801	**0.07**
R4/stream		16.627	**0.08**
20 m Drift + runoff mitigation			
D5/pond	1.35	0.094	14.36
D5/stream		0.441	3.06
R1/pond		0.100	13.50
R1/stream		2.014	**0.67**
R3/stream		10.394	**0.13**
R4/stream		8.594	**0.16**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC)

Based on the TER values above, unacceptable/high risks are identified for the R3/stream in sugar beets (post-emergence) and for the R1-3/stream in sunflowers (pre-emergence), respectively, ($PEC_{sw;max}$ > $RAC_{sw;ch}$). However, acceptable risks have been demonstrated for all D scenarios in sugar beets and in sunflowers, considering 10 m drift mitigation, respectively.

Table 2.9-26: TER (FOCUS step 4) calculations considering the algae SSD-RAC in the refined risk assessment for dimethenamid-P following one pre-emergence application [1 x 864 g a.s./ha] in sugar beets and one post-emergence application [1 x 720 g a.s./ha] in sugar beets, respectively.

FOCUS Scenarios	**Algae SSD-RAC [µg a.s./L]**	**FOCUS Step 4 – pre-emergence sugar beet**		**FOCUS Step 4 – post-emergence sugar beet**	
		$PEC_{sw.\ max}$ [µg/L]	**TER (RAC/PEC)**	**$PEC_{sw.\ max}$ [µg/L]**	**TER (RAC/PEC)**
5 m Drift mitigation					
D3/ditch	1.35	1.483	**0.91**	1.237	1.09
D4/pond		0.189	7.14	0.169	7.99
D4/stream		1.578	**0.86**	1.346	1.00
R1/pond		1.948	**0.69**	0.265	5.09
R1/stream		20.477	**0.07**	3.597	**0.38**
R3/stream		38.356	**0.04**	5.7	**0.24**
10 m Drift mitigation					
D3/ditch	1.35	0.787	1.72	0.657	2.05
D4/pond		0.144	9.38	0.125	10.80

D4/stream		0.847	1.59	0.723	1.87
R1/pond		1.912	0.71	0.237	5.70
R1/stream		20.477	0.07	3.597	**0.38**
R3/stream		38.356	0.04	5.7	**0.24**
20 m Drift mitigation					
D3/ditch	1.35	0.409	3.30	0.345	3.91
D4/pond		0.0978	13.80	0.084	16.07
D4/stream		0.445	3.03	0.38	3.55
R1/pond		1.875	**0.72**	0.211	6.40
R1/stream		20.477	**0.07**	3.597	**0.38**
R3/stream		38.356	**0.04**	5.7	**0.24**
10 m Drift + runoff mitigation					
D3/ditch	1.35	0.787	1.72	0.657	2.05
D4/pond		0.144	9.38	0.125	10.80
D4/stream		0.847	1.59	0.723	1.87
R1/pond		0.836	1.61	0.14	9.64
R1/stream		9.34	**0.14**	1.631	**0.83**
R3/stream		17.504	**0.08**	2.603	**0.52**
20 m Drift + runoff mitigation					
D3/ditch	1.35	0.409	3.30	0.345	3.91
D4/pond		0.0978	13.80	0.084	16.07
D4/stream		0.445	3.03	0.38	3.55
R1/pond		0.436	3.10	0.081	16.67
R1/stream		4.898	**0.28**	0.854	1.58
R3/stream		9.188	**0.15**	1.366	**0.99**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC).

Based on the TER values above, unacceptable/high risks are identified for the R3/stream in sugar beets (post-emergence) and for the R1-3/stream in sunflowers (pre-emergence), respectively, ($PEC_{sw;max}$ > $RAC_{sw;ch}$). However, acceptable risks have been demonstrated for all D scenarios in sugar beets and in sunflowers, considering 10 m drift mitigation, respectively.

BAS 830 01 H

Table 2.9-27: Maximum PEC_{SW} values (FOCUS Step 1 and 2) and TER values for dimethenamid-P following one application of BAS 830 01 H in winter oilseed rape [1x 500 g as/ha]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		2600 µg/L	120 µg/L	3200 µg/L	680 µg/L	6.60 µg/L	5.99 µg/L
FOCUS Step 1							
	140.85	18.46	0.85	22.72	4.83	**0.05**	**0.04**
FOCUS Step 2*							
North Europe	56.95	45.65	2.11	56.19	11.94	**0.12**	**0.11**
South Europe	46.29	56.17	2.59	69.13	14.69	**0.14**	**0.13**
FOCUS Step 2+							
North Europe	35.63	72.97	3.37	89.81	19.09	**0.19**	**0.17**
South Europe	29.23	88.95	4.11	109.48	23.26	**0.23**	**0.20**
FOCUS Step 3* pre-emergence							
D2/ditch	8.318	312.58	14.43	384.71	81.75	**0.79**	**0.72**
D2/stream	5.206	499.42	23.05	614.68	130.62	**1.27**	**1.15**
D3/ditch	3.191	814.79	37.61	1002.82	213.10	**2.07**	**1.88**
D4/pond	0.427	6088.99	281.03	7494.15	1592.51	15.46	14.03
D4/stream	2.743	947.87	43.75	1166.61	247.90	**2.41**	**2.18**
D5/pond	0.207	12560.39	579.71	15458.94	3285.02	31.88	28.94
D5/stream	2.959	878.68	40.55	1081.45	229.81	**2.23**	**2.02**
R1/pond	0.122	21311.48	983.61	26229.51	5573.77	54.10	49.10
R1/stream	2.096	1240.46	57.25	1526.72	324.43	**3.15**	**2.86**
R3/stream	6.044	430.18	19.85	529.45	112.51	**1.09**	**0.99**
FOCUS Step 3* post-emergence							
D2/ditch	20.377	127.59	**5.89**	157.04	33.37	**0.32**	**0.29**
D2/stream	12.707	204.61	**9.44**	251.83	53.51	**0.52**	**0.47**

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		2600 µg/L	120 µg/L	3200 µg/L	680 µg/L	6.60 µg/L	5.99 µg/L
D3/ditch	3.181	817.35	37.72	1005.97	213.77	**2.07**	**1.88**
D4/pond	0.787	3303.68	152.48	4066.07	864.04	**8.39**	**7.61**
D4/stream	2.747	946.49	43.68	1164.91	247.54	**2.40**	**2.18**
D5/pond	0.306	8496.73	392.16	10457.52	2222.22	21.57	19.58
D5/stream	2.96	878.38	40.54	1081.08	229.73	**2.23**	**2.02**
R1/pond	0.136	19117.65	882.35	23529.41	5000.00	48.53	44.04
R1/stream	2.096	1240.46	57.25	1526.72	324.43	**3.15**	**2.86**
R3/stream	11.18	232.56	10.73	286.23	60.82	**0.59**	**0.54**
Trigger**		100	10	100	10	10	10

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

TERs shown in **bold** fall below the relevant trigger

* based on a single application in pre-emergence winter oilseed rape (worst case application during Oct-Feb)

+ based on a single application in post-emergence winter oilseed rape (worst case application during Oct-Feb)

Based on FOCUS Step 3, an acceptable risk has been demonstrated for 3 out of 10 FOCUS scenarios in the pre-emergence oilseed rape (OSR) use (D4/pond, D5/pond and R1/pond), whereas only 2 FOCUS scenarios are indicating low risk in the post-emergence OSR use (D5/pond and R1/pond).
The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger value of 10 and 100 based on FOCUS Step 1 and 2 calculations for the remaning FOCUS scenarios in winter OSR, indicating high risk to algae and macrophytes, driving the risk assessment. Therefore, TER-calulations based on FOCUS Step 4 including risk mitigating measures are presented in the tables below.

Table 2.9-26: TER (FOCUS step 4) calculations considering the algae SSD-RAC in the refined risk assessment for dimethenamid-P following one application [BAS 830 01 H, 1 x 500 g as/ha] in pre-emergence and post-emergence winter oilseed rape

FOCUS Scenarios	Algae SSD-RAC [µg as/L]	FOCUS Step 4 – Oil seed rape (pre-emergence)		FOCUS Step 4 – Oil seed rape (post-emergence)	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)	$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
5 m Drift mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.87	1.55	0.876	1.54
D4/pond		0.43	3.14	0.783	1.72
D4/stream		1.01	1.34	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		1.08	1.25	1.089	1.24
R1/pond		0.1	13.50	0.116	11.64
R1/stream		0.77	1.75	0.877	1.54
R3/stream		6.04	**0.22**	11.18	**0.12**
10 m Drift mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.47	2.87	0.876	1.54
D4/pond		0.42	3.21	0.783	1.72
D4/stream		0.71	1.90	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		0.57	2.37	1.089	1.24
R1/pond		0.08	16.88	0.116	11.64
R1/stream		0.41	3.29	0.877	1.54
R3/stream		6.04	**0.22**	11.18	**0.12**
20 m Drift mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.25	5.40	0.258	5.23
D4/pond		0.42	3.21	0.77	1.75
D4/stream		0.71	1.90	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		0.3	4.50	0.342	3.95
R1/pond		0.05	27.00	0.055	24.55
R1/stream		0.21	6.43	0.877	1.54
R3/stream		6.04	**0.22**	11.18	**0.12**
10 m Drift + runoff mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.47	2.87	0.485	2.78
D4/pond		0.42	3.21	0.776	1.74
D4/stream		0.71	1.90	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		0.57	2.37	0.584	2.31
R1/pond		0.08	16.88	0.084	16.07
R1/stream		0.41	3.29	0.406	3.33
R3/stream		2.75	**0.49**	5.095	**0.26**
20 m Drift + runoff mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.25	5.40	0.258	5.23
D4/pond		0.42	3.21	0.77	1.75

FOCUS Scenarios	Algae SSD-RAC [µg as/L]	FOCUS Step 4 – Oil seed rape (pre-emergence)		FOCUS Step 4 – Oil seed rape (post-emergence)	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)	$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
D4/stream		0.71	1.90	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		0.3	4.50	0.342	3.95
R1/pond		0.05	27.00	0.055	24.55
R1/stream		0.21	6.43	0.211	6.40
R3/stream		1.45	**0.93**	2.671	**0.51**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC).

Based on FOCUS step 4 scenarios considering risk mitigating measures and the algae SSD-RAC in the refined risk assessment for dimethenamid-P, TER values for all scenarios indicate an acceptable risk to aquatic organisms except the D2 (ditch/stream) and R3 (stream) scenarios when considering drift mitigation ≥5 m (regardless of runoff mitigation).

Conclusion on the aquatic risk assessment:

BAS 656 12 H

Based on the results above, taking into account SSD analysis for primary producers, no safe use has been identified for the use in soybeans. However, acceptable risk for aquatic organisms ($PEC_{sw;max} < RAC_{sw;ch}$) and therefore safe use has been demonstrated for the proposed uses in maize, sugar beets and sunflowers.

BAS 830 01 H
Based on the results above, taking into account SSD analysis for primary producers, acceptable risk for aquatic organisms has been demonstrated ($PEC_{sw;max} < RAC_{sw;ch}$) and therefore, safe use has been identified for the proposed pre-emergence as well as post-emergence applications in winter oilseed rape.

2.9.9.3 Risk assessment for bees

BAS 656 12 H

Hazard quotients
The acute risk to honeybees from the use of BAS 656 12 H was assessed using the maximum single application rate and the respective LD_{50} values to calculate hazard quotients (HQ) (*EPPO/OEPP, 2003: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145*)) as follows:

$$\text{Hazard Quotient} = \text{maximum application rate [g product/ha]} / LD_{50}\ [\mu g\ \text{product/bee}]$$

HQs for honeybees were calculated for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) to BAS 656 12 H. An HQ < 50 indicates low risk to honeybees in the field. For bumblebees no risk assessment scheme currently exists.

Table 2.9.29: Risk to honeybees and bumblebees from exposure to BAS 656 12 H using the worst-case application rate

Test substance	Application rate [g as/ha]	Endpoint	LD_{50}	Hazard quotient HQ	Trigger
honeybee					
BAS 656 12 H*	864	48 h acute, oral	118.8 µg as/bee	7.3	50
		48 h acute, contact	93.8 µg as/bee	9.2	
bumblebee					
dimethenamid-P (BAS 656 H)	864	48 h oral	> 158 as/bee	-- [1)]	
		48 h contact	> 200 as/bee		

* tested as technical dimethenamid-P (Zenker K., 2011; 2010/1126065)
[1)] HQvalues are not validated for bumblebees.

Due to the results of laboratory tests BAS 656 12 H is considered to be practically non-toxic to bees. All HQs are considerably below the trigger value of 50, indicating that the intended use poses a low risk to bees in the field.

Regarding bumblebees no agreed risk assessment is yet available. However, the endpoints obtained for acute oral and acute contact exposure to BAS 656 H (dimethenamid-P) on bumble bees, compared to the data available for honey bees, do not indicate a higher sensitivity of bumble bees to dimethenamid-P.

Conclusion
The proposed uses of BAS 656 12 H according to good agricultural practice present a low risk to honeybees and bumblebees and will not adversely affect honeybees and honeybee or bumblebee colonies.

BAS 830 01 H

Hazard quotients
The acute risk to honeybees from the use of BAS 830 01 H was assessed using the maximum single application rate and the respective LD_{50} values to calculate hazard quotients (HQ) (*EPPO/OEPP, 2003: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145*)) as follows:

$$\text{Hazard Quotient} = \text{max. application rate [g product/ha]} / LD_{50} \text{ [µg product/bee]}$$

HQs for honeybees were calculated for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) to BAS 830 01 H. An HQ < 50 indicates low risk to honeybees in the field. For bumblebees no risk assessment scheme currently exists.

Table 2.9.30: Risk to honeybees and bumblebees from exposure to dimethenamid-P and BAS 830 01 H using the worst-case application rate

Test substance	Application rate [g/ha]	Endpoint	LD_{50}	Hazard quotient HQ	Trigger
honeybee					
dimethenamid-P (BAS 656 H)	500	48 h acute, oral	118.8 µg as/bee	4.2	50
		48 h acute, contact	93.8 µg as/bee	5.3	
BAS 830 01 H	1702.5 *	48 h acute, oral	233.9 µg product/bee	7.3	
		48 h acute, contact	> 454.0 µg product/bee	< 3.8	

bumblebee				
dimethenamid-P (BAS 656 H)	500	48 h oral	> 158 as/bee	-- [1)]
		48 h contact	> 200 as/bee	

* taking into account the density of BAS 830 01 H of 1.135 g/cm³.
[1)] HQvalues are not validated for bumblebees.

Due to the results of laboratory tests BAS 830 01 H is considered practically non-toxic to honey bees. All HQs are considerably below the trigger value of 50, indicating that the intended use poses a low risk to bees in the field. Additionally, a laboratory honeybee brood toxicity test with the active substance dimethenamid-P showed no indication of increased honeybee brood toxicity.

Regarding bumblebees currently no agreed risk assessment scheme is yet available. However, the endpoints obtained for acute oral and acute contact exposure to BAS 656 H (dimethenamid-P) on bumble bees did not indicate increased sensitivity of bumble bees to dimethenamid-P compared to the toxicity endpoints for honey bees.

Conclusion
The proposed uses of BAS 830 01 H according to good agricultural practice present a low risk to bees and bee colonies.

2.9.9.4 Risk assessment for arthropods

Procedures for risk assessment were in agreement with the recommendations in the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (Working Document Sanco/10329/2002 rev 2 final, 17 October 2002, referring to ESCORT 2).

For detailed risk assessment refer to the RAR, Volume 3 CP, section B.9.6.2.

For the calculation of HQ values for the active substance dimethenamid-P according to ESCORT 2, effect values from the applicant´s submitted limit-test studies were used.

Representative formulation 656 12 H:

Table 2.9-31: First tier risk assessment for BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets at 1.2 L prep./ha (equivalent to 864 g as/ha) [1x; includes splitting]

Test substance	Species	Effect (LR_{50} mL/ha)	HQ in-field	HQ off-field	Trigger
BAS 656 12 H [1]	*Typhlodromus pyri*	>1400	0.86	0.0237 (1 m: 2.77 %)	2
BAS 656 12 H [2]	*Aphidius rhopalosiphi*	66.3	**18**	0.5 (1 m: 2.77 %)	2

HQ values shown in **bold** are above the relevant trigger.
[1] Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H).
[2] Study was carried out with BAS 656 08 H (a similar formulation to BAS 656 12 H).

Table 2.9-32: Higher tier risk assessment for – BAS 656 12 H at 1 x 1.2 L prep./ha (equivalent to 864 g as/ha) g as/ha [includes splitting] based on extended laboratory test

Species	ER_{50} (mL/ha)	In-field rate (mL/ha)	Off-field rate (mL/ha)
Aphidius rhopalosiphi	1400 [1)]	1200	33 (1 m: 2.77 %)

[1] Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H).

For the in–field scenario, calculated HQ values remained below the acceptability criterion for the standard species *Typhlodromus pyri* but not for the standard species *Aphidius rhopalosiphi.* Additionally no effects > 50 % have been observed at the Predicted Environmental Rate in laboratory tests on inert substrate with *T. pyri, P. cupreus, C. carne, A. bilineata*, and *Paradosa sp*., indicating that the risk for additional species is acceptable. The higher tier risk assessment based on an extended laboratory study with *Aphidius rhopalosiphi* indicated an acceptable risk for non-target arthropods due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

For the off-field scenario, all calculated HQ values remained below the acceptability criterion indicating an acceptable risk for non-target arthropods due to the intended use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets according to the label.

Representative formulation BAS 830 01 H:

Table 2.9.33: First tier risk assessment for – BAS 830 01 H at 1.5 L prep./ha (500 g dimethenamid-P/ha + 250 g quinmerac/ha [1x]

Test substance	Species	Effect (LR_{50} mL prep./ha)	HQ in-field [mL prep./ha]	HQ off-field [mL prep./ha]	Trigger
BAS 830 01 H	*Typhlodromus pyri*	> 3 000	0.5	0.01385	2
BAS 830 01 H	*Aphidius rhopalosiphi*	33.6	**44.6**	1.2366	2

Table 2.9-274: Higher tier risk assessment for – BAS 830 01 H at 1.5 L prep. /ha (500 g dimethenamid-p/ha + 250 g quinmerac/ha [1x] based on extended lab tests

Species	ER_{50} (mL prep./ha)	In-field rate	Off-field rate
Aphidius rhopalosiphi	3 000	1 500	415.5 (1 m: 2.77 %)
Aleochara bilineata	3 000	1 500	41.55 (1 m: 2.77 %)

For the in-field scenario, calculated HQ values remained below the acceptability criterion for the standard species *Typhlodromus pyri* but not for the standard species *Aphidius rhopalosiphi.* The higher tier risk assessment based on extended laboratory studies with *Aphidius rhopalosiphi* and *Aleochara bilineata* indicated an acceptable risk for non-target arthropods due to the intended uses of BAS 830 01 H in oilseed rape according to the label.

For the off-field scenario, all calculated HQ values remained below the acceptability criterion indicating an acceptable risk for non-target arthropods due to the intended use of BAS 830 01 H in oilseed rape according to the label.

2.9.9.5 Risk assessment for non-target soil meso- and macrofauna

Procedures for risk assessment were in agreement with the recommendations in the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (Working Document Sanco/10329/2002 rev 2 final, 17 October 2002).

For detailed risk assessment refer to the RAR, Volume 3 CP, section B.9.8.1 (earthworms) and B.9.8.2 (other soil meso- and macrofauna).

Toxicity values are compared with the PEC_{soil} values from section B.8 (maximum concentration after multiple year use: $PEC_{soil,\ accu} = PEC_{s,initial}$ after one application + $PEC_{plateau}$ has been used for M23 and M31).

Representative formulation 656 12 H:

Table 2.9-285: Toxicity/exposure ratios for soil organisms - BAS 656 12 H at 1.2 L prep./ha (equivalent to 864 g as/ha) g as/ha [1x; includes splitting]

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	Dimethenamid-P	Chronic	1.152	22	5
Eisenia fetida	BAS 656 12 H	Chronic	1.152	17	5
Eisenia fetida	M 23	Chronic	0.1533*	54	5
Eisenia fetida	M 27	Chronic	0.179	59	5
Eisenia fetida	M 31	Chronic	0.1534*	652	5
Other soil macroorganisms					
Folsomia candida	Dimethenamid-P	Chronic	1.152	11	5
Hypoaspis aculeifer	Dimethenamid-P	Chronic	1.152	434	5
Folsomia candida	M 23	Chronic	0.1533*	1304	5
Hypoaspis aculeifer	M 23	Chronic	0.1533*	652	5
Folsomia candida	M 27	Chronic	0.179	1117	5
Hypoaspis aculeifer	M 27	Chronic	0.179	1117	5
Folsomia candida	M 31	Chronic	0.1534*	1303	5
Hypoaspis aculeifer	M 31	Chronic	0.1534*	3259	5
Folsomia candida	BAS 656 12 H	Chronic	1.2 L/ha (corresponding to 1.152 mg as/kg dw)	11	5

TER values shown in **bold** are below the relevant trigger.
* PECsoil accu

The TER values in the table above are above the Annex VI 91/414 EEC trigger of 10 and 5 for acute and chronic risk assessment, respectively, showing that the risk is acceptable for the proposed uses.

TER values were calculated for the representative formulation BAS 656 12 H, the active substance dimethenamid-P and its metabolites M23, M27, and M31. For the metabolites M 23 and M 31 a worst-case scenario of annual use with respective accumulation in soil has been used.

Acceptable risks for earthworms and soil mesofauna has been shown for the representative formulation BAS 656 12 H, the active substance dimethenamid-P and its metabolites M23, M27, and M31 for the intended use in maize, soybean, sunflower, and sugar beet.

Representative formulation BAS 830 01 H:

Table 2.9-296: Toxicity/exposure ratios for soil organisms - BAS 830 01 H at 1.5 L prep./ha (500 g dimethenamid-P/ha + 250 g quinmerac/ha [1x]

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	Dimethenamid-P	Chronic	0.667	38	5
Eisenia fetida	BAS 830 01 H	Chronic	1.5 L prep./ha (corresponding to 2.27 mg prep./kg dw)	39	5
Eisenia fetida	M 23	Chronic	0.0884 *	94	5
Eisenia fetida	M 27	Chronic	0.104	102	5
Eisenia fetida	M 31	Chronic	0.0902 *	1109	5
Other soil macroorganisms					
Folsomia candida	Dimethenamid-P	Chronic	0.667	19	5
Hypoaspis aculeifer	Dimethenamid-P	Chronic	0.667	750	5
Folsomia candida	M 23	Chronic	0.0884 *	2262	5
Hypoaspis aculeifer	M 23	Chronic	0.0884 *	1131	5
Folsomia candida	M 27	Chronic	0.104	1923	5
Hypoaspis aculeifer	M 27	Chronic	0.104	1923	5
Folsomia candida	M 31	Chronic	0.0902 *	2217	5
Hypoaspis aculeifer	M 31	Chronic	0.0902 *	5543	5
Folsomia candida	BAS 830 01 H	Chronic	1.5 L prep./ha (corresponding to 2.27 mg prep./kg dw)	33	5
Hypoaspis aculeifer	BAS 830 01 H	Chronic	1.5 L prep./ha (corresponding to 2.27 mg prep./kg dw)	≥ 440	5

TER values shown in **bold** are below the relevant trigger.
* PECsoil accu

TER values were calculated for the representative formulation BAS 830 01 H, the active substance dimethenamid-P and its metabolites M23, M27, and M31. For the metabolites M 23 and M 31 a worst-case scenario of annual use with respective accumulation in soil has been used.

Acceptable risks for earthworms and soil mesofauna has been shown for the representative formulation BAS 830 01 H, the active substance dimethenamid-P and its metabolites M23, M27, and M31 for the intended use in oilseed rape.

2.9.9.6 Risk assessment for soil nitrogen transformation

Procedures for risk assessment were in agreement with the recommendations in the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (Working Document Sanco/10329/2002 rev 2 final, 17 October 2002).

For detailed risk assessment refer to the RAR, Volume 3 CP, section B.9.10.

Representative formulations BAS 656 12 H and BAS 830 01 H:

According to current regulatory requirements the risk is acceptable, if the effect of the recommended

application rate of a compound/product on nitrogen or carbon mineralisation/transformation is < 25 % after 100 days.

In the submitted studies, deviations from the control did not exceed 25 % after 28 days at tested concentrations which were higher than the calculated maximum PEC_{soil} for the proposed uses (see 2.9.9.4.1). No effects on the soil microflora due to dimethenamid-P and its metabolites M23, M27, and M31 were seen up to a concentration of 4.93 kg/ha for the active substance (study conducted with the formulation BAS 656 07 H; 720 g as/L) and 1.0 mg/kg soil for the metabolites. This value exceeds the maximum PEC_{soil} for the use in maize, soybean, sunflower, and sugar beet of 0.864 kg dimethenamid-p/ha by a factor of about 6, the maximum PEC_{soil} of 0.1548 mg M23/kg by a factor of about 6, the maximum PEC_{soil} of 0.1025 mg M27/kg by a factor of about 10 and the maximum PEC_{soil} of 0.1276 mg M31/kg by a factor of about 8, respectively.

Therefore, the risk for effects on soil nitrogen transformation and carbon mineralisation processes is acceptable.

Acceptable risks for earthworms and soil mesofauna has been shown for the representative formulation BAS 656 12 H, the active substance dimethenamid-P and its metabolites M23, M27, and M31 for the intended use in maize, sugar maize, soybean, sunflower, and beets according to the label.

Acceptable risks for earthworms and soil mesofauna has been shown for the representative formulation BAS 830 01 H, the active substance dimethenamid-P and its metabolites M23, M27, and M31 for the intended use in oilseed rape according to the label.

2.9.9.7 Risk assessment for terrestrial non-target higher plants

Procedures for risk assessment were in agreement with the recommendations in the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (Working Document Sanco/10329/2002 rev 2 final, 17 October 2002).

For detailed risk assessment refer to the RAR, Volume 3 CP, section B.9.12.

The calculated exposure for the respective uses and the TER values are given in the following table.

Representative formulation 656 12 H:

Table 2.9-307: Assessment of the risk for non-target plants due to the use of BAS 656 12 H in maize, sugar maize, soybean, sunflower, and beets (uses 1-6 covering also uses 7-9)

Intended use	1-10			
Active substance/product	BAS 656 12 H			
Application rate (g/ha)	1 × 1.2 L prep./ha			
MAF	1			
Test species	**ER_{50} (mL prep./ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER criterion: TER ≥ 5**
Lactuca sativa	No adequate data available	2.77 %	33.24	

TER values shown in **bold** fall below the relevant trigger.
MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

TER values for non-target terrestrial plants could not be calculated due to the lack of adequate toxicity

data for BAS 656 12 H. The risk assessment for the representative formulation BAS 656 12 H could not be finalised.

Representative formulation BAS 830 01 H

Table 2.9-318: Toxicity/exposure ratios for terrestrial non target higher plants - laboratory dose response tests - BAS 830 01 H at 1 x 1.5 L prep./ha (equivalent to 500 g as/ha)

Species	Test substance	ER_{50} (mL prep./ha)[2] vegetative vigour	ER_{50} (mL prep./ha)[2] emergence	Exposure[1] (mL prep./ha)[2]	TER	Trigger
Lolium multiflorum	BAS 830 01 H	527	> 94	41.55 (1 m)	**2.3**	5
Lolium multiflorum	BAS 830 01 H	527	> 94	8.55 (5 m)	11	5
Lolium multiflorum	BAS 830 01 H	527	> 94	4.155 (1 m + 75 % drift reduction)	9	5

TER values shown in **bold** are below the relevant trigger.
[1] exposure has been estimated based on Ganzelmeier drift data
[2] dose is expressed in units of preparation

The tables above show that the TER for the worst case use pattern is above the trigger of 5. Therefore, the risk for non-target plants is acceptable.

In screening for herbicidal efficacy, both in seedling emergence studies and in vegetative vigour tests, the metabolites of the active substance dimethenamid-P, M 23, and M 27 and M 31 showed no or very low herbicidal activity. In a seedling emergence test the metabolite M31 showed inhibitory as well as promoting effects which were well within the effect range of formulation blank, whereas the parent dimethenamid-P showed strong effects. To address the risk from groundwater metabolites a study was conducted (Doc ID 2014/ 1101480). The results indicating a low risk were presented in Document N 4 of the dossier. The study needs to be submitted and evaluated by the RMS.

2.9.9.8 Overall summary of the risk assessment

The risk assessment of dimethenamid-P could not demonstrate for all organisms that the risks are acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of dimethenamid-P products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing dimethenamid-P. Unacceptable acute and reproductive risk remains for the use of BAS 656 12 H in Maize/Sugar Maize at early post emergence (uses 2 and 4). As regards birds, mammals, honey bees, other non-target arthropods, soil organisms and the soil microflora, no need for specific restrictions or risk mitigation measures was identified in the risk assessment. For aquatic organisms, risk mitigation measures, such as a buffer zone of 10 m (BAS 656 12 H) and 5 m (BAS 830 01 H) are needed. For higher terrestrial plants no risk assessment could be performed for the representative formulation BAS 656 12 H; for the representative formulation BAS 830 01 H risk mitigation measures, such as a buffer zone of 5 m, are needed.

2.10 Classification and labelling

Table 2.10-1: Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives				Conclusive but not sufficient for classification
2.2.	Flammable gases				Not relevant
2.3.	Flammable aerosols				Not relevant
2.4.	Oxidising gases				Not relevant
2.5.	Gases under pressure				Not relevant
2.6.	Flammable liquids				Conclusive but not sufficient for classification
2.7.	Flammable solids				Not relevant
2.8.	Self-reactive substances and mixtures				Data/statement lacking
2.9.	Pyrophoric liquids				Data/statement lacking
2.10.	Pyrophoric solids				Not relevant
2.11.	Self-heating substances and mixtures				Data/statement lacking
2.12.	Substances and mixtures which in contact with water emit flammable gases				Conclusive but not sufficient for classification
2.13.	Oxidising liquids				Conclusive but not sufficient for classification
2.14.	Oxidising solids				Not relevant
2.15.	Organic peroxides				Not relevant
2.16.	Substance and mixtures corrosive to metals				Data/statement lacking
3.1.	Acute toxicity - oral	Acute toxicity, cat. 4 (H302)		Acute toxicity, cat. 4 (H302)	
	Acute toxicity - dermal				Conclusive but not sufficient for classification
	Acute toxicity - inhalation				Conclusive but not sufficient for classification
3.2.	Skin corrosion / irritation				Conclusive but not sufficient for classification
3.3.	Serious eye damage / eye irritation				Conclusive but not sufficient for classification

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
3.4.	Respiratory sensitisation				Data lacking
3.4.	Skin sensitisation	Skin sensitisation, cat. 1 (H317)		Skin sensitisation, cat. 1 (H317)	
3.5.	Germ cell mutagenicity				Conclusive but not sufficient for classification
3.6.	Carcinogenicity				Conclusive but not sufficient for classification
3.7.	Reproductive toxicity				Conclusive but not sufficient for classification
3.8.	Specific target organ toxicity - single exposure				Conclusive but not sufficient for classification
3.9.	Specific target organ toxicity - repeated exposure				Conclusive but not sufficient for classification
3.10.	Aspiration hazard				Data lacking
4.1.	Hazardous to the aquatic environment	GHS09, H400, H410	M-acute: 10 M-chronic: 10		
5.1.	Hazardous to the ozone layer				Data lacking

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive or conclusive but not sufficient for classification

Labelling: Signal word: Warning
Hazard statements: H302 Harmful if swallowed.
H317 May cause an allergic skin reaction
Precautionary statements: -

Labelling: Signal word: warning
Hazard statements: H400, H410
Precautionary statements: P273, P391, P501

Proposed notes assigned to an entry:
Notes in accordance with CLP Regulation, Annex VI, Section 1.1.3

Table 2.10-2: Proposed classification according to Dangerous Substances Directive (Directive 67/548/EEC)

Hazardous property	Proposed classification	Proposed SCLs	Current classification [1)]	Reason for no classification [2)]
Explosiveness				Conclusive but not sufficient for classification
Oxidising properties				Conclusive but not sufficient for classification
Flammability				Conclusive but not sufficient for classification
Other physico-chemical properties *[Add rows when relevant]*				Not relevant
Thermal stability				Conclusive but not sufficient for classification
Acute toxicity	Xn; R 22		Xn; R 22	
Acute toxicity - irreversible damage after single exposure				Conclusive but not sufficient for classification
Repeated dose toxicity				Conclusive but not sufficient for classification
Irritation / Corrosion				Conclusive but not sufficient for classification
Sensitisation	Xi; R 43		Xi; R 43	
Carcinogenicity				Conclusive but not sufficient for classification
Mutagenicity - Genetic toxicity				Conclusive but not sufficient for classification
Toxicity to reproduction - fertility				Conclusive but not sufficient for classification
Toxicity to reproduction - development				Conclusive but not sufficient for classification
Toxicity to reproduction - breastfed babies. Effects on or via lactation				Conclusive but not sufficient for classification
Environment				

[1)] Including SCLs
[2)] Data lacking, inconclusive or conclusive but not sufficient for classification

Labelling:	Indication of danger:	Xn Harmful
	R-phrases:	R 22 Harmful if swallowed.
		R 43 May cause sensitisation by skin contact.
	S-phrases:	-

BAS 656 12 H:
In accordance with Directives 67/548/EEC and 1999/45/EC the following classification is proposed for the preparation:
Hazard symbol: Xn
Indication of danger: Harmful
Risk phrase: 22-36-37-38-43
Labelling:
'Contains dimethenamid-P. May produce allergic reactions.'

According to Regulation (EC) No. 1272/2008 the following classification is proposed for the preparation:
Signal word: Warning
Hazard class, category: Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3
Hazard statement: 302-315-317-319-335
Labelling:
'Contains dimethenamid-P. May produce allergic reactions.' [EUH208]

BAS 830 01 H
In accordance with Directives 67/548/EEC and 1999/45/EC the following classification is proposed for the preparation:
Hazard symbol: Xi
Indication of danger: Harmful
Risk phrase: 36-43
Labelling:
'Contains dimethenamid-P. May produce allergic reactions.'

According to Regulation (EC) No. 1272/2008 the following classification is proposed for the preparation:
Signal word: Warning
Hazard class, category: Eye Irrit. 2, Skin Sens. 1
Hazard statement: 317-319
Labelling
'Contains dimethenamid-P. May produce allergic reactions.' [EUH208]

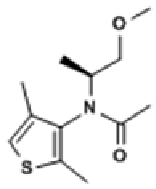
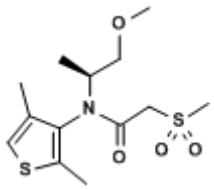
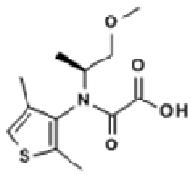
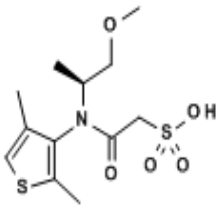
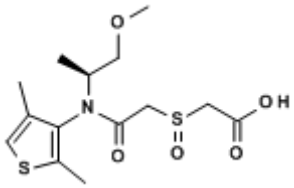
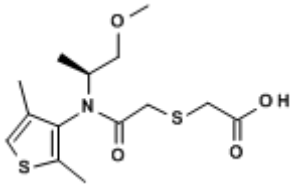
2.11 Relevance of metabolites in groundwater

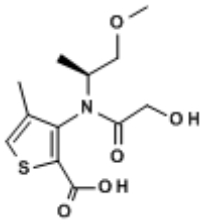
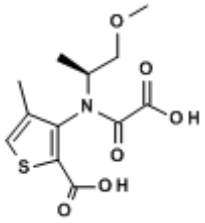
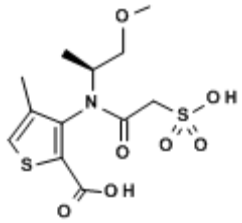
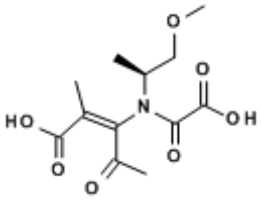
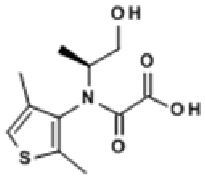
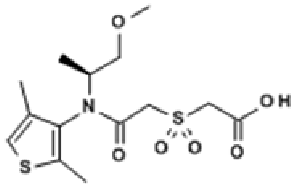
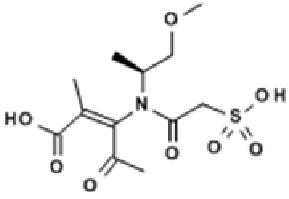
2.11.1 STEP 1: Exclusion of degradation products of no concern

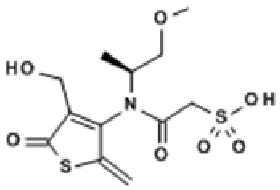
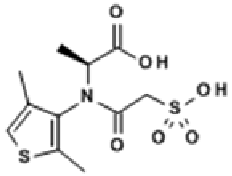
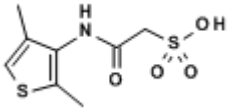
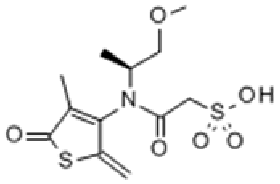
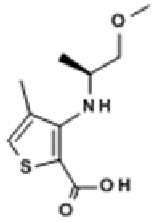
Except for CO_2, soil and lysimeter metabolites of dimethenamid-P do not meet the criteria for "a degradation product of no concern" as defined in SANCO/221/2000 – rev.10 – final (Guidance document on the assessment of the relevance of metabolites in groundwater).

The dimethenamid-P metabolites listed in Table **2.11-1** were identified as potentially relevant for groundwater.

Table 2.11-1: Metabolites detected in soil degradation studies which fulfill the criteria according to SANCO/221/2000- rev.10-final (2003)

Metabolite	Stucture formula	Molecular weight (g/mol)	Max. occurrence in soil after n days and max. annual average conc. in lysimeter leachate
M656PH003 N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)acetamide		241.3	Lysimeter: 0.1 µg/L
M656PH010 N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)-2-(methyl-sulfonyl)acetamide		319	Lysimeter: 0.07 µg/L * * M656PH010 is not relevant according to SANCO/221/2000-rev.10-final (2003) since its maximum annual average concentrations in the lysimeter leachate did not exceed 0.1 µg/L, however Step 2 groundwater modelling was performed for this metabolite leading to modelled concentrations ≥0.1 µg/L
M656PH023 N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)- oxalamic acid		271.34	Soil, lab, aerobic: max. 12,2 % after 28 d Lysimeter: 1.0 µg/L
M656PH027 2-[(2,4-dimethyl-3-thienyl)-(2-methoxy-1-methyl-ethyl)amino]-2-oxo-ethanesulfonic acid		321.41	Soil, lab, aerobic: max. 13,32 % after 28 d Lysimeter: 4.0 µg/L
M656PH031 2-[2-[(2,4-dimethyl-3-thienyl)-[(1S)-2-methoxy-1-methyl-ethyl]amino]-2-oxo-ethyl]sulfinylacetic acid		347.46	Soil, lab, aerobic: max. 10.34 % after 28 d
M656PH032 2-[2-[(2,4-dimethyl-3-thienyl)-[(1S)-2-methoxy-1-methyl-ethyl]amino]-2-oxo-ethyl]sulfanylacetic acid		331	Lysimeter: 1.5 µg/L

Metabolite	**Stucture formula**	**Molecular weight (g/mol)**	**Max. occurrence in soil after n days and max. annual average conc. in lysimeter leachate**
M656PH043 3-[(2-hydroxyacetyl)-(2-methoxy-1-methyl-ethyl)amino]-4-methyl-thiophene-2-carboxylic acid		287	Lysimeter: 1.2 µg/L
M656PH045 3-[(2-methoxy-1-methyl-ethyl)-oxalo-amino]-4-methyl-thiophene-2-carboxylic acid		301	Lysimeter: 2.0 µg/L
M656PH047 3-[(2-methoxy-1-methyl-ethyl)-(2-sulfoacetyl)amino]-4-methyl-thiophene-2-carboxylic acid		351	Lysimeter: 1.2 µg/L
M656PH049 (E)-3-[(2-methoxy-1-methyl-ethyl)-oxalo-amino]-2-methyl-4-oxo-pent-2-enoic acid		287	Lysimeter: 1.0 µg/L
M656PH050 2-[(2,4-dimethyl-3-thienyl)-(2-hydroxy-1-methyl-ethyl)amino]-2-oxo-acetic acid		257	Lysimeter: 0.5 µg/L
M656PH051 2-[2-[(2,4-dimethyl-3-thienyl)-(2-methoxy-1-methyl-ethyl)amino]-2-oxo-ethyl]sulfonylacetic acid		363	Lysimeter: 1.1 µg/L
M656PH052 (E)-3-[(2-methoxy-1-methyl-ethyl)-(2-sulfoacetyl)amino]-2-methyl-4-oxo-pent-2-enoic acid		337	Lysimeter: 0.9 µg/L

Metabolite	Stucture formula	Molecular weight (g/mol)	Max. occurrence in soil after n days and max. annual average conc. in lysimeter leachate
M656PH053 2-[[4-(hydroxymethyl)-2-methylene-5-oxo-3-thienyl]-(2-methoxy-1-methyl-ethyl)amino]-2-oxo-ethanesulfonic acid		351	Lysimeter: isomere 1: 0.8 µg/L isomere 2: 2.00 µg/L
M656PH054 2-[(2,4-dimethyl-3-thienyl)-(2-sulfoacetyl)amino]propanoic acid		321	Lysimeter: 3.3 µg/L
M656H055 2-[(2,4-dimethyl-3-thienyl)amino]-2-oxo-ethanesulfonic acid		249	Lysimeter: 0.7 µg/L
M656PH059 2-[(2-methoxy-1-methyl-ethyl)-(4-methyl-2-methylene-5-oxo-3-thienyl)amino]-2-oxo-ethanesulfonic acid		335	Lysimeter: isomere 1: 0.8 µg/L isomere 2: 0.40 µg/L Isomer 3: 1.6 µg/L
M656PH062 3-[(2-methoxy-1-methyl-ethyl)amino]-4-methyl-thiophene-2-carboxylic acid		229	Lysimeter: 2.0 µg/L

The metabolites listed in Table 2.11-1 do not fulfil the criteria for being excluded as a degradation product of no concern (inorganic compound not containing a heavy metal; short aliphatic chain without alerting chemical moieties; non-toxic natural product). Hence, the metabolites have to be considered further in Step 2 of the tiered relevance assessment.

2.11.2 STEP 2: Quantification of potential groundwater contamination

Based on groundwater modelling with FOCUS PELMO 5.5.3, groundwater in concentrations > 0.1 µg/L cannot be excluded for any of the metabolites listed in Table 2.11-1.

Maxima of the 80th percentile of the annual leachate concentrations of the metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031 M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 for all representative uses of BAS 656 12 H and BAS 830 01 H are summarised in Table 2.11-2 and Table 2.11-3.

Table 2.11-2: Maxima of the 80th percentile annual leachate concentrations of the dimethenamid-P metabolites relevant according to Step 1 for all representative uses of BAS 656 12 H calculated with FOCUS-PELMO 5.5.3

Metabolite	Maximum concentrations [µg L^{-1}]	FOCUS scenario	Crop and application scenario
M656PH003	0.2	Jokoinen	Pre-emergence application to sugar beet
M656PH010	0.1		
M656PH023	1.3	Hamburg	Pre-emergence application to maize
M656PH027	7.4	Jokoinen	Pre-emergence application to sugar beet
M656PH031	25.0		
M656PH032	2.8		
M656PH043	2.2		
M656PH045	3.7		
M656PH047	2.2		
M656PH049	1.8		
M656PH050	0.9		
M656PH051	2.0		
M656PH052	1.7		
M656PH053 (iso 1)	2.9		
M656PH053 (iso 2)	3.7		
M656PH054	6.1		
M656H055	1.3		
M656PH059 (iso 1)	1.5		
M656PH059 (iso 2)	0.7		
M656PH059 (iso 3)	2.9		
M656PH062	3.7		

Table 2.11-3: Maxima of the 80th percentile annual leachate concentrations of the dimethenamid-P metabolites relevant according to Step 1 for all representative uses of BAS 830 01 H calculated with FOCUS-PELMO 5.5.3

Metabolite	Maximum concentrations [µg L^{-1}]	FOCUS scenario	Crop and application scenario
M656PH003	0.2	Hamburg	Pre-emergence application to winter oilseed rape
M656PH010	0.1		
M656PH023	1.6		
M656PH027	6.4		
M656PH031	12.3		
M656PH032	2.4		
M656PH043	1.9		
M656PH045	3.2		
M656PH047	1.9		
M656PH049	1.6		
M656PH050	0.8		
M656PH051	1.7		
M656PH052	1.4		
M656PH053 (iso 1)	2.5		
M656PH053 (iso 2)	3.2		
M656PH054	5.2		
M656H055	1.1		
M656PH059 (iso 1)	1.3		
M656PH059 (iso 2)	0.6		
M656PH059 (iso 3)	2.5		
M656PH062	3.2		

2.11.3 STEP 3: Hazard assessment - identification of relevant metabolites

2.11.3.1 STEP 3, Stage 1: Screening for biological activity

Since the metabolites M656PH003, M656PH010, M656PH023, M656PH027, M656PH031 M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053, M656PH054, M656H055, M656PH059 and M656PH062 exceed groundwater concentrations of 0.1 µg/L at Step 2, Step 3 a hazard assessment is required.
For the metabolites M656PH003, M656PH010 and M656PH023, at least one scenario is below the groundwater trigger of 0.1 µg/L in all intended uses, except for M656PH023 in pre-emergence applications to soybeans and sugar beet. For the remaining metabolites, all PEC_{GW} values exceed the groundwater trigger of 0.1 µg/L in all intended uses (for further details, please refer to chapter 2.8.6).
A screening test for the soil metabolites M656PH023, M656PH030, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH054, M656H055, the Na-salt of M656PH027 and the ethylester derivative for M656PH062 was conducted resulting in no herbicidal effects (visual observation) according to Document N4 of the dossier.
For M23, M27 (Doc ID 1995/11317) and M31 (Doc ID 2008/1068011; seedling emergence tests for pesticidal activity were submitted and these metabolites show less phytotoxic effects than the parent in these studies.
Data gaps were proposed for all those metabolites were no study is available. The study Doc ID 2014/1101480 mentioned by the applicant in Document N4 has not been submitted yet. Reporting of the study DocID 2014/1101480 was not conducted by the applicant because of following reasons: The study is not conducted under GLP and not according to OECD guidelines for addressing the risk for non-target terrestrial plants. The study deviates from these OECD guidelines since no clear dose response with a NOEC, EC_{25} and EC_{50} estimation was recorded and a higher peat content (> 1.5 %)

and less pot area /rye grass plant < 5.1 cm^2 were used.
In the view of RMS the non-GLP and non-OECD study DocID 2014/1101480 seems to be well-documented and the design seems to be common for herbicidal screening tests. It is therefore not clear why the test conditions should hinder reporting and submission of the study.
The metabolites tested so far (M23, M27, M31) showed less phytotoxic effects than the parent, and they are all missing the toxophore (chloracetamid-moiety) of dimethenamid-P. According to the applicant the chloracetamid-moiety is required for the herbicidal effects. The assumption that other metabolites lacking the toxophore are as well not of relevance and covered in the risk assessment should be confirmed by the above mentioned study Doc ID 2014/ 1101480 or by a comparable study.

2.11.3.2 STEP 3, Stage 2: Screening for genotoxicity

M31-group

Of the group members, M656PH030 being a plant metabolite with exposure via edible commodities, M656PH031 and M656PH032 were selected as key structures for genotoxicity testing.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3.
The selected key metabolites of the M31-group M656PH030, M656PH031 and M656PH032 by weight of evidence did not show genotoxicity in the performed tests and thus the M31-group members are considered to pass stage 2 of step 3.

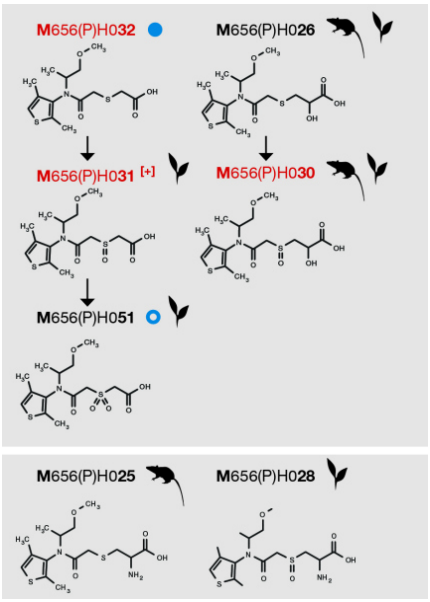


Figure 2.11-1: M31-group

M11-group

The members of M11-group include the metabolites M656PH003, M656PH011, M656PH043 and M656PH087. Of the group members, the groundwater metabolite M656PH043 was selected as key structure for genotoxicity testing.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3.
The selected key metabolite of the M11-group M656PH043 by weight of evidence did not show genotoxicity in the performed tests and thus the M11-group members are considered to pass stage 2 of step 3.

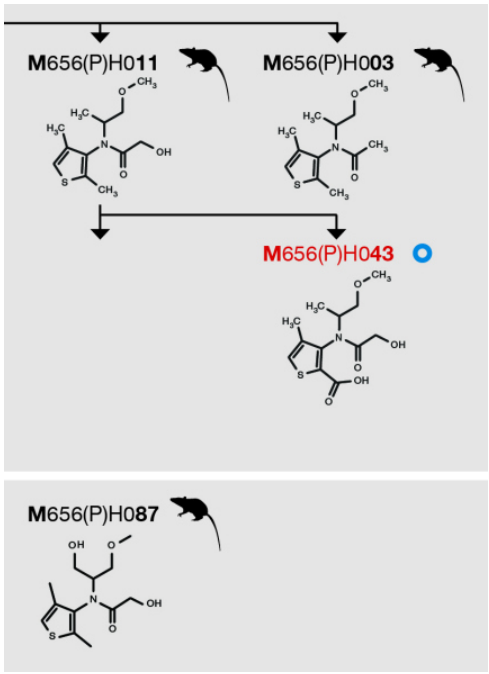


Figure 2.11-2: M11-group

M19-group

Of the group members, M656PH054 and M656PH055 were selected as key structures for genotoxicity testing.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3 of this dossier.
The selected key metabolites of the M19-group M656PH054 and M656PH055 by weight of evidence did not show genotoxicity in the performed tests and thus the M19-group members are considered to pass stage 2 of step 3.

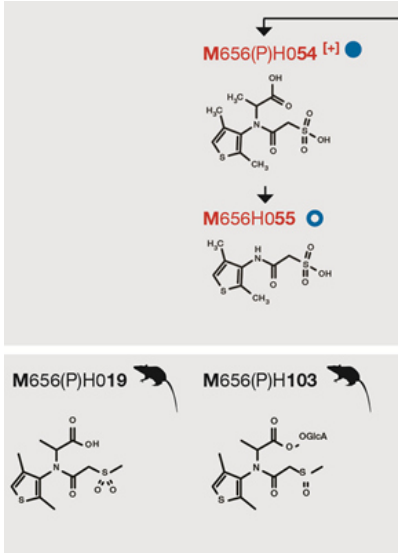


Figure 2.11-3: M19-group

M62-group

Of the group members, the ethylester derivative of M656PH062 was selected as key structure for genotoxicity testing because M656PH062 itself could not be stably synthetised.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9

and in Vol. 3.

The selected key metabolite of the M62-group the ethylester derivative of M656PH062 by weight of evidence did not show genotoxicity in the performed tests and thus the M62-group members are considered to pass stage 2 of step 3.

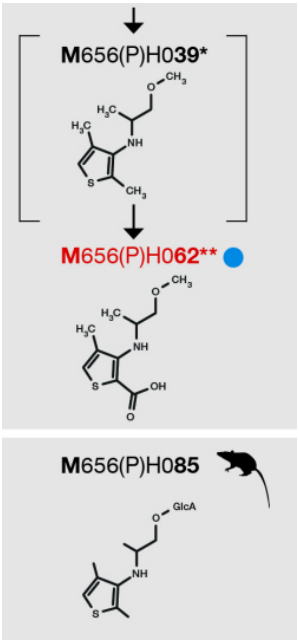


Figure 2.11-4: M62-group

M23-group

Of the group members, M656PH023 and M656PH045 were selected as key structure for genotoxicity testing. For M656PH023 the toxicologically equivalent surrogate of the racemic dimethenamid metabolism pathway M656H023 was tested.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3 of this dossier.
The selected key metabolite of the M23-group the M656PH023 and M656PH045 did not show genotoxicity in the performed tests and thus the M23-group members are considered to pass stage 2 of step 3.

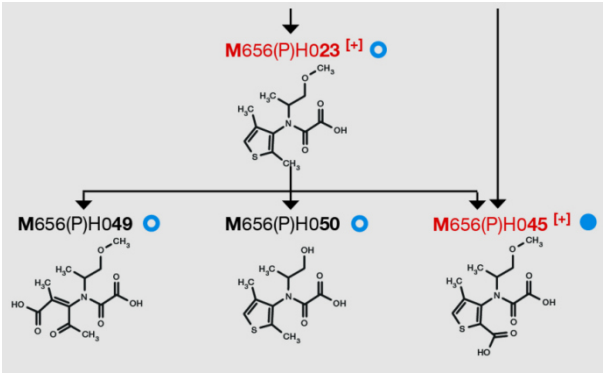


Figure 2.11-5: M23-group

M27-group

Of the group members, M656PH027 and M656PH047 were selected as key structure for genotoxicity testing. For M656PH027 the sodium salt of M656H027 representing the stable and toxicologically

equivalent surrogate of the racemic dimethenamid metabolism pathway was chosen.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3.
The selected key metabolite of the 27-group the M656PH027 and M656PH047 did not show genotoxicity in the performed tests and thus the M27-group members are considered to pass stage 2 of step 3.

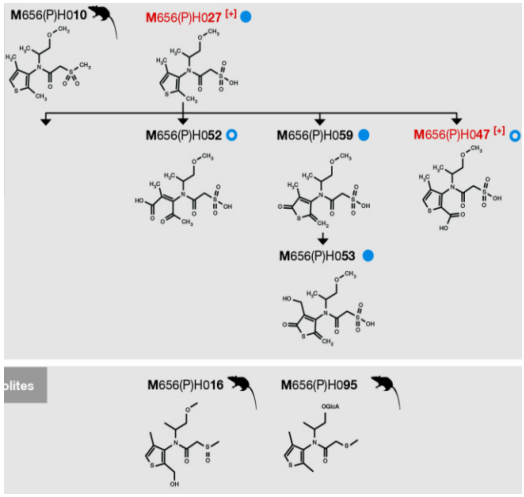


Figure 2.11-6: M27-group

2.11.3.3 STEP 3, Stage 3: Screening for toxicity

The starting point for the consideration of toxicity of the metabolites is the toxicity of the parent molecule dimethenamid-P. Dimethenamid-P is not classified as acutely or chronically toxic or very toxic (Acute Tox. Cat. 1 or 2, STOT Re 1 or STOT SE according to the CLP regulation 1272/2008). Dimethenamid is also not classified for reproductive toxicity (Repr. Cat 1 or 2). Also it is not classified in any category for carcinogens. Therefore no further investigations to classify the metabolites are needed.

However, given the extended range of metabolites determined, based on the grouping proposal made selected key structures were considered for screening of the toxicological profile by conducting a repeated dose feeding study.

M31-group

Of the group members, M656PH031 was selected as key structure for toxicological screening.
M656PH031 is considered to be less toxic than dimethenamid-P.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3.
Based on the studies conducted the selected key metabolites of the M31-group, M656PH030, M656PH031 and M656PH032 were not considered to be toxicologically relevant. Thus, in conclusion there is no evidence for toxicological relevance of the M31-group members to be considered i.e. M656PH026, M656PH030, M656PH032 and M656PH051.
By weight of evidence no evidence of genotoxicity and on the basis of low mammalian short-term toxicity the group members to be considered M656PH026, M656PH030, M656PH032 and M656PH051 are not considered as toxicologically “relevant” metabolites and they pass step 3.

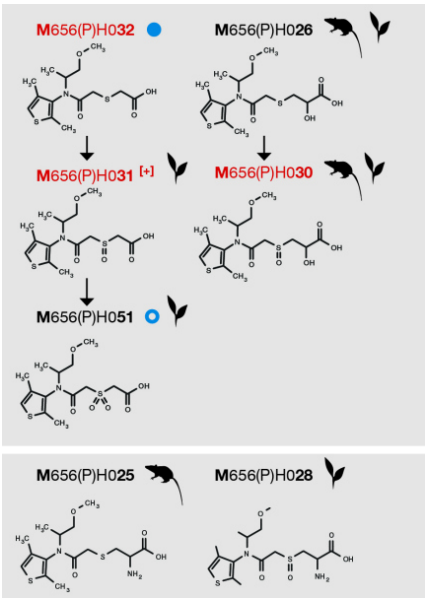


Figure 2.11-7: M31-group

M11-group

Of the group members, the groundwater metabolite M656PH043 was below the trigger for toxicological screening according to the applicant.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3.
As the exposure level for the relevant group member M656PH043 was predicted below 0.75 µg/L by the applicant toxicological screening was not considered necessary and thus not conducted. Based on the studies conducted the selected key metabolite of the M43-group, M656PH043, the only group member to be considered was not considered to be toxicologically relevant.
On this basis and by weight of evidence no evidence of genotoxicity the group member to be considered M656PH043, is not considered as toxicological “relevant” metabolite and passes step 3.

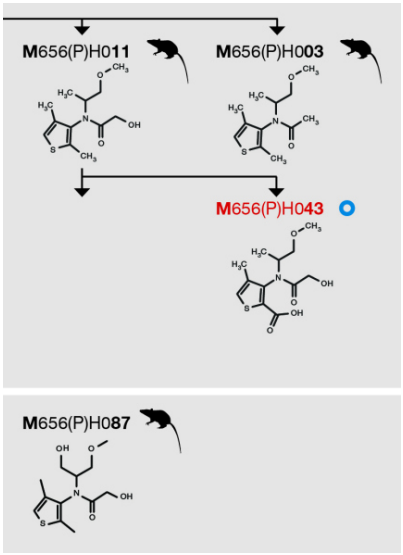


Figure 2.11-8: M11-group

M19-group

Of the group members, M656PH054 was selected as key structure for toxicological screening.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9

and in Vol. 3.
M656PH054 is considered to be less toxic than dimethenamid-P.
Based on the studies conducted the selected key metabolites of the M19-group, M656PH054, and M656PH055 were not considered to be toxicologically relevant. Thus, in conclusion there is no evidence for toxicological relevance of the M11-group members to be considered i.e. M656PH054 and M656PH055.
Thus by weight of evidence no evidence of genotoxicity and low mammalian short-term toxicity the group members to be considered M656PH054 and M656PH054 are not considered as toxicological "relevant" metabolites and they pass step 3.

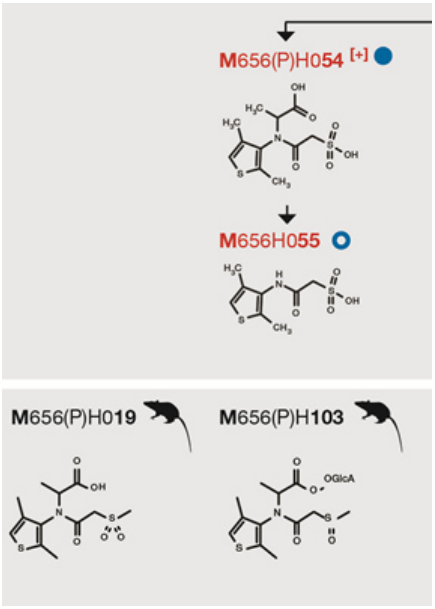


Figure 2.11-9: M19-group

M62-group

Of the group members, the ethylester derivative of M656PH062 was selected as key structure for toxicological screening because M656PH062 itself could not be stably synthetised.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3 of this dossier.
The ethylester derivative of M656PH062 is considered to be less toxic than dimethenamid-P.
Based on the studies conducted with the ethylester derivative of M656PH062 the selected key metabolite of the M62-group, M656PH062 was not considered to be toxicologically relevant. Thus, in conclusion there is no evidence for toxicological relevance of the M62-group members to be considered i.e. M656PH062.
By weight of evidence no evidence of genotoxicity and low mammalian short-term toxicity the group member to be considered M656PH062 is not considered as toxicological "relevant" metabolite and passes step 3.

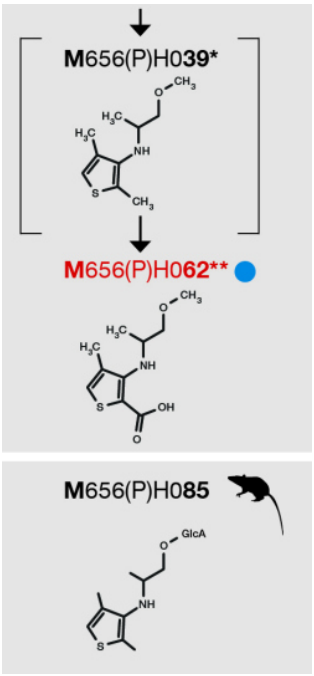


Figure 2.11-10: M62-group

M23-group

Of the group members, M656PH023 and M656PH045 were selected as key structure for toxicological screening. For M656PH023 the toxicologically equivalent surrogate of the racemic dimethenamid metabolism pathway M656H023 was tested in the acute toxicity study while M656PH023 was used in the 28-day study.
Further details to the grouping approach and to the study results are presented in Vol. 1, section 2.6.9 and in Vol. 3.
M656PH023 is considered to be less toxic than dimethenamid-P. M656PH045 is considered to be less toxic than dimethenamid-P.
Based on the studies conducted the selected key metabolites of the M23-group, M656PH023 and M656PH045 were not considered to be toxicologically relevant. Thus, in conclusion there is no evidence for toxicological relevance of the M23-group members to be considered i.e. M656PH023, M656PH045, M656PH049 and M656PH050.
By weight of evidence no evidence of genotoxicity and low mammalian short-term toxicity the group members to be considered M656PH023, M656PH045, M656PH049 and M656PH050 are not considered as toxicological “relevant” metabolites and they pass step 3.

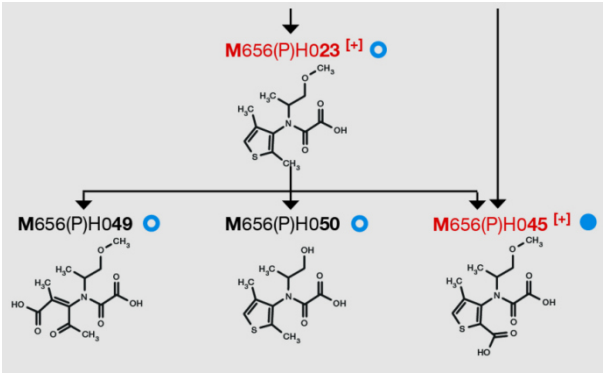


Figure 2.11-11: M23-group

M27-group

Of the group members, M656PH027 and M656PH047 were selected as key structure for toxicological screening. For M656PH027 the sodium salt of M656H027 representing the stable and toxicologically equivalent surrogate of the racemic dimethenamid metabolism pathway was chosen.
Further details to the grouping approach and to the study results are presented in Volume 1, section 2.6.9 (Summary of toxicological data on impurities and metabolites) and more detailed in Volume 3.
M656PH027 and M656PH047 are considered to be less toxic than dimethenamid-P.
Based on the studies conducted the selected key metabolites of the M27-group, M656PH027 and M656PH047 were not considered to be toxicologically relevant. Thus, in conclusion there is no evidence for toxicological relevance of the M27-group members to be considered i.e. M656PH027, M656PH047, M656PH052, M656PH053 and M656PH059.
By weight of evidence no evidence of genotoxicity and low mammalian short-term toxicity the group members to be considered M656PH027, M656PH047, M656PH052, M656PH053 and M656PH059 are not considered as toxicological “relevant” metabolites and they pass step 3.

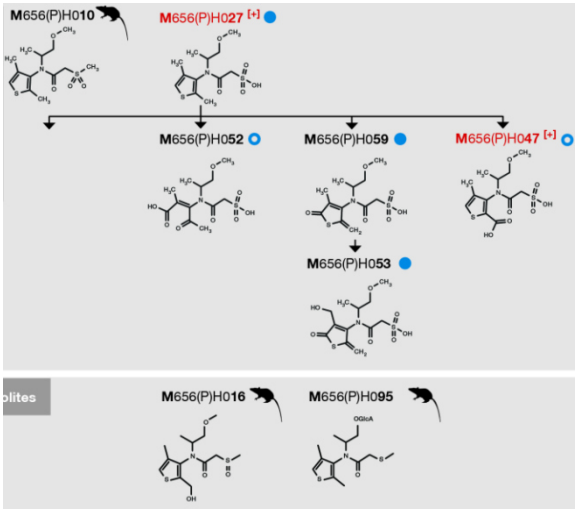


Figure 2.11-12: M27-group

2.11.4 STEP 4: Exposure assessment – threshold of concern approach

As defined in SANCO/221/2000 – rev.10 – final (Guidance document on the assessment of the relevance of metabolites in groundwater), metabolites which have not been identified as being relevant according to the hazard screening outlined in Step 3, should be further tested in an exposure assessment to make sure that any contamination of groundwater will not lead to unacceptable exposure

of consumers via their drinking water. As a pragmatic alternative in cases where a full quantitative risk assessment cannot be provided, an approach following a "threshold of concern" should be followed. Such an acceptable exposure level relates to an acceptable estimated upper limit for the concentration of a metabolite of 0.75 µg/L.
Thus, in conclusion all metabolites of the presented groups (M31-group, M11-group, M19-group, M62-group, M23-group and M27-group) fulfil the criteria of step 4 and can be accepted up to a concentration of 0.75 µg/L in groundwater.

2.11.5 STEP 5: Refined risk assessment

According to SANCO/221/2000 – rev.10 – final (Guidance document on the assessment of the relevance of metabolites in groundwater) metabolites which have passed steps 1 to 3 and for which levels of estimated concentrations of metabolites in groundwater (as defined in Step 2) lie between 0.75 µg/L (from Step 4) and 10 µg/L will require a refined assessment of their potential toxicological significance for consumers.
Considering the toxicological data presented it can be concluded that there is generated enough information to allow a comparison with the toxicology profile of the active substance dimethenamid-P. Based on the studies conducted with the selected key metabolites it can be concluded that the groundwater metabolites evaluated by the grouping approach are expected to be less toxic than dimethenamid-P. Therefore, a refined risk assessment of the presented groundwater metabolites can be made based on the ADI of dimethenamid-P.
Using this approach, an ADI of 0.04 mg/kg bw/day can be derived for these metabolites. From this value, an acceptable safe value for groundwater of 140 µg/L can be derived, assuming water intake of 2 litres/day by a 70 kg person, and permissible exposure in water being 10 % of the ADI.
However, according to SANCO/221/2000 – rev.10 – final (Guidance document on the assessment of the relevance of metabolites in groundwater) a limit value of 10 µg/L is selected for pragmatic reasons. This limit value can be accepted as maximum concentration in the groundwater. It presents an extremely low risk via exposure in groundwater.

2.11.6 Overall conclusion

The degradation pathway of dimethenamid-P is extensive and leads to a complex array of observed metabolites. A grouping strategy was defined and representative structures for the groups were selected. The representative structures M656PH023, M656PH027, M656PH030, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH054, M656H055, and M656PH062 have been shown to be of no toxicological relevance in groundwater.
According to the grouping strategy the toxicological relevance of all the other group members can be evaluated according to SANCO/221/2000 – rev.10 – final (Guidance document on the assessment of the relevance of metabolites in groundwater).
The following tables summarise the toxicological relevance assessment of potential groundwater metabolites.

Table 2.11-4: Dimethenamid-P metabolites of M31-group considered for potential toxicological relevance

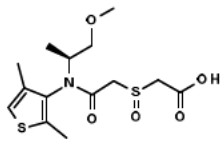
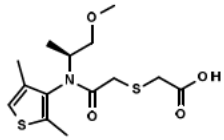
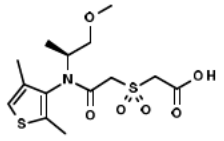
Metabolite	Structure	Reason for relevance assessment	Toxicity data	Relevance assessment
M31-group				
M656PH031 identified in maize and soybean, soil, surface water and groundwater		Groundwater metabolite Human exposure: M656PH031 ≤0.1 µg/L	Structural alerts: no Bacterial mutagenicity, gene mutation assay, micronucleus *in vitro* test: negative; 28-day, rat: no adverse signs of toxicity NOAEL: 12000 ppm (1068 mg/kg bw/d)	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH031 ≤10 µg/L
M656PH032 identified in hen and groundwater		Groundwater metabolite Human exposure: 0.75 µg/L< M656PH032 ≤4.5 µg/L	Structural alerts: positive chromosomal aberration *in vitro* Bacterial mutagenicity: negative	No toxicological relevance Covered by the toxicological testing of M656PH030 and M656PH031 Acceptable groundwater concentration: 0.1 µg/L< M656PH032 ≤10 µg/L
M656PH051 identified in groundwater, soybean and rotational crop		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH051 ≤0.75 µg/L	Structural alerts: positive chromosomal aberration *in vitro*	No toxicological relevance Covered by the toxicological testing of M656PH030 and M656PH031 Acceptable groundwater concentration: 0.1 µg/L< M656PH051 ≤10 µg/L

Table 2.11-5: Dimethenamid-P metabolites of M11-group considered for potential toxicological relevance

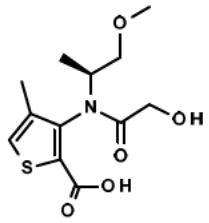
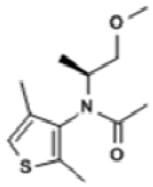
Metabolite	Structure	Reason for relevance assessment	Toxicity data	Relevance assessment
M11-group				
M656PH043 identified in groundwater		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH043 ≤0.75 µg/L	Structural alerts: no; Bacterial mutagenicity, gene mutation assay, micronucleus *in vitro* test: positive, micronucleus *in vivo* test: negative;	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH043 ≤0.75 µg/L
M656PH003 identified in groundwater		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH003 ≤0.75 µg/L	Structural alerts: no	No toxicological relevance Covered by the toxicological testing of M656PH043 Acceptable groundwater concentration: 0.1 µg/L< M656PH003 ≤0.75 µg/L

Table 2.11-6: Dimethenamid-P metabolites of M19-group considered for potential toxicological relevance

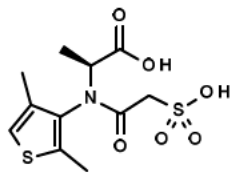
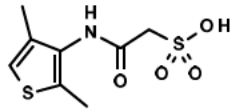
Metabolite	Structure	Reason for relevance assessment	Toxicity data	Relevance assessment
M19-group				
M656PH054 identified in groundwater		Groundwater metabolite Human exposure: 0.75 µg/L< M656PH054 ≤4.5 µg/L	Structural alerts: positive chromosomal aberration *in vitro*; Bacterial mutagenicity, gene mutation assay: negative Micronucleus *in vitro* test: positive Micronucleus *in vivo* test: negative 28-day, rat: food consumption in males ↓, bw development in male and female ↓ NOAEL 4000 ppm (346 mg/kg bw/d)	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH054 ≤10 µg/L
M656H055 identified in groundwater		Groundwater metabolite Human exposure: 0.1 µg/L< M656H055 ≤0.75 µg/L	Structural alerts: positive chromosomal aberration *in vitro* for presumed degradates Bacterial mutagenicity, gene mutation assay, micronucleus *in vivo* test: negative	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH055 ≤10 µg/L

Table 2.11-7: Dimethenamid-P metabolites of M62-group considered for potential toxicological relevance

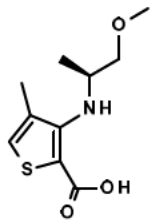
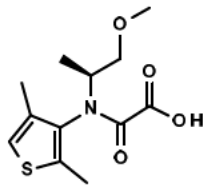
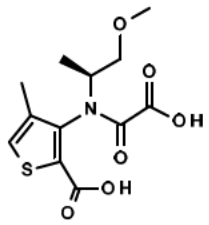
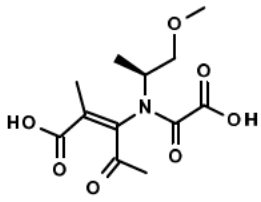
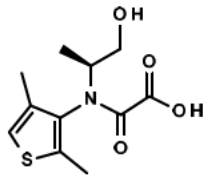
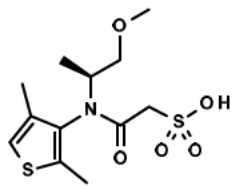
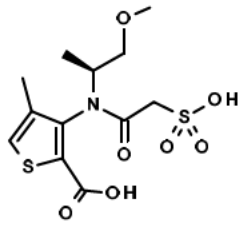
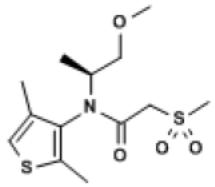
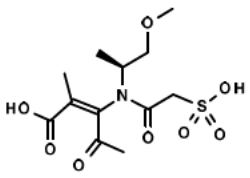
Metabolite	Structure	Reason for relevance assessment	Toxicity data	Relevance assessment
M62-group				
M656PH062 identified in groundwater		Groundwater metabolite Human exposure: 0.75 µg/L< M656PH062 ≤4.5 µg/L	Structural alerts: no; Bacterial mutagenicity, gene mutation assay: negative Micronucleus *in vitro* test: positive Micronucleus *in vivo* test: negative; 28-day, rat: 12000/8000 ppm: bw gain ↓, food consumption ↓ altered clinical chemistry parameters, absolute and relative liver weights ↑, moderate centrilobular liver cell hypertrophy in females, follicular hypertrophy/hyperplasia of the thyroid, 4000 ppm: bw gain ↓, absolute and relative liver weight ↑, low incidence of minimal centrilobular liver cell hypertrophy in females NOAEL: 4000 ppm (323 mg/kg bw/d)	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH062 ≤10 µg/L

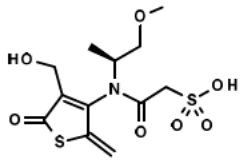
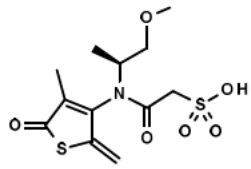
Table 2.11-8: Dimethenamid-P metabolites of M23-group considered for potential toxicological relevance

Metabolite	Structure	Reason for relevance assessment	Toxicity data	Relevance assessment
M23-group				
M656PH023 identified in soil, surface water, groundwater and plants		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH023 ≤0.75 µg/L	Structural alerts: positive chromosomal aberration *in vitro*; LD_{50} oral, rat: 5000 mg/kg bw; Bacterial mutagenicity, gene mutation assay, micronucleus *in vivo* test: negative; 28-day, rat: no adverse effects NOEAL: 12000 ppm (1057 mg/kg/bw/d)	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH023 ≤10 µg/L
M656PH045 identified in groundwater		Groundwater metabolite Human exposure: 0.75 µg/L< M656PH045 ≤4.5 µg/L	Structural alerts: no; Bacterial mutagenicity, gene mutation assay, micronucleus *in vivo* test: negative; 28-day, rat: No adverse signs of toxicity NOAEL: 12000 ppm (1174 mg/kg bw/d)	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH045 ≤10 µg/L
M656PH049 identified in groundwater No successful efforts to synthestise		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH049 ≤0.75 µg/L	Structural alerts: positive chromosomal aberration *in vitro*	No toxicological relevance Covered by the toxicological testing of dimethenamid-P, M656PH023 and M656PH054 Acceptable groundwater concentration: 0.1 µg/L< M656PH049 ≤10 µg/L
M656PH050 identified in groundwater and soybean		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH050 ≤0.75 µg/L	Structural alerts: no	No toxicological relevance Covered by the toxicological testing of M656PH023 and M656PH054 Acceptable groundwater

Metabolite	Structure	Reason for relevance assessment	Toxicity data	Relevance assessment
				concentration: 0.1 µg/L< M656PH050 ≤10 µg/L

Table 2.11-9: Dimethenamid-P metabolites of M27-group considered for potential toxicological relevance

Metabolite	Structure	Reason for relevance assessment	Toxicity data	Relevance assessment
M27-group				
M656PH027 identified in rat, hen, goat, mice, plant and groundwater and surface water		Groundwater metabolite Human exposure: 0.75 µg/L< M656PH027 ≤4.5 µg/L	Structural alerts: positive chromosomal aberration *in vitro*; Bacterial mutagenicity, gene mutation assay, micronucleus *in vivo* test: negative; 28-day, rat: No adverse signs of toxicity NOAEL: 12000 ppm (1064 mg/kg bw/d)	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH027 ≤10 µg/L
M656PH047 identified in groundwater		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH047 ≤0.75 µg/L	Structural alerts: no Bacterial mutagenicity, gene mutation assay, micronucleus *in vivo* test: negative; 28-day, rat: No adverse signs of toxicity NOAEL: 13200 ppm (967 mg/kg bw/d)	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH047 ≤10 µg/L
M656PH010 identified in groundwater		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH010 ≤0.75 µg/L	Structural alerts: positive chromosomal aberration *in vitro*	No toxicological relevance Covered by the toxicological testing conducted with M656PH027, M656H031 and M656PH054 Acceptable groundwater concentration: 0.1 µg/L< M656PH010 ≤10 µg/L
M656PH052 identified in groundwater		Groundwater metabolite Human exposure: 0.1 µg/L< M656PH052 ≤0.75 µg/L	Structural alerts: positive chromosomal aberration *in vitro*	No toxicological relevance Covered by the toxicological testing conducted with M656PH027, M656H031 and M656PH054 Acceptable

Metabolite	Structure	Reason for relevance assessment	Toxicity data	Relevance assessment
				groundwater concentration: 0.1 µg/L< M656PH052 ≤10 µg/L
M656PH053 identified in groundwater		Groundwater metabolite Human exposure: 0.75 µg/L< M656PH053 (2 isomers) ≤4.5 µg/L	Structural alerts: no	No toxicological relevance Covered by the toxicological testing conducted with M656PH027 and M656PH047 Acceptable groundwater concentration: 0.1 µg/L< M656PH053 ≤10 µg/L
M656PH059 identified in groundwater		Groundwater metabolite Human exposure: 0.1 µg/L < M656PH059 (2 isomers) ≤0.75 µg/L< M656PH059 (1 isomer) ≤ 4.5 µg/L	Structural alerts: no	No toxicological relevance Covered by the toxicological testing conducted with M656PH027 and M656PH047 Acceptable groundwater concentration: 0.1 µg/L< M656PH053 ≤10 µg/L

2.12 Consideration of isomeric composition in the risk assessment

2.12.1 Identity and physical chemical properties

Dimethenamid-P ((*S*)-2-chloro-*N*-(2,4-dimethyl-3-thienyl)-*N*-(2-methoxy-1-methylethyl)acetamide) is a single enantiomer with a minimum purity of 930 g/kg. The evaluation of the physical and chemical properties of dimethenamid-P is regarded as independent of the isomeric ratio.

2.12.2 Methods of analysis

Validated enantioselective analytical methods for the determination of individual isomers in the technical active substance and for the determination of dimethenamid-P in the representative

formulations are available.

2.12.3 Mammalian toxicity

The mammalian toxicology database was built up for dimethenamid-P based on a bridging concept employing the database developed for racemic dimethenamid and key studies for dimethenamid-P. A comparative *in vitro* metabolism in rat liver slices demonstrated that the metabolic pathway of both racemic and S-enantiomer (dimethenamid-P) is comparable qualitatively and quantitatively. All in all, the available bridging studies of acute toxicity, short-term toxicity, genotoxicity and developmental toxicity share the same toxicological profile and the effects established are observed at comparable dose levels. This bridging concept was already evaluated during Annex I inclusion of dimethenamid-P and the conclusion drawn was that racemic dimethenamid and dimethenamid-P are equivalent entities with regard to their behaviour in mammals and the toxicological profile. Consequently, all studies available for racemic dimethenamid should be considered in the toxicological evaluation of dimethenamid-P. The results justify a toxicological evaluation without considering the isomers separately.

2.12.4 Operator, worker, bystander and resident exposure

No guidance currently available. Not necessary.

2.12.5 Residues and consumer risk assessment

Not necessary.

2.12.6 Environmental fate

Metabolism and degradation rate of racemic dimethenamid and dimethenamid-P under aerobic conditions in soil are similar. Besides, the ratio between the S-enantiomer (~97 %) and the R-enantiomer (~3 %) of dimethenamid-P remained constant during aerobic degradation in soil.
There was also no significant difference in the degradation rate and pattern of racemic dimethenamid and dimethenamid-P in the soil photolysis study. Thus, no change in the isomeric composition of dimethenamid-P and its metabolites is expected under natural conditions in soil.

An adsorption study for first Annex 1 approval determined slightly smaller K_{oc} values for racemic dimethenamid-P (K_{oc}: 40 – 233, 1/n: 0.73 – 1.00) compared to dimethenamid-P (K_{oc}: 90 – 474, 1/n: 0.92 – 1.05). From these results, it can be assumed that the adsorption of the R-enantiomer (~3 %) of dimethenamid-P to soil is slightly weaker than the adsorption of the S-entantiomer (~97 %). This might lead to a small change in the ratio of S-enantiomer and the R-enantiomer of the metabolites formed by dimethenamid-P and reaching the groundwater in concentrations >0.1 µg/L. Since dimethenamid-P itself does not reach the groundwater < 0.1 µg/L, no effect on the active substance is expected.

Metabolism and degradation rate of racemic dimethenamid and dimethenamid-P under aerobic conditions in water/sediment studies.

The degradation and dissipation rates of racemic dimethenamid and dimethenamid-P in the investigated water sediment systems and in the water and sediment phases were in the same range. Besides, no change in the ratio of the R- and S-enantiomer of dimethenamid-P was observed during degradation in the water/sediment system. No difference in aqueous photolysis of dimethenamid and dimethenamid-P could be determined. Thus, no change in the isomeric composition of dimethenamid-P is expected under natural conditions in water and sediment systems.

The degradation route dimethenamid and dimethenamid-P in the investigated water sediment systems appeared slightly different with different metabolites being formed in concentrations >5 %. However, all metabolites of the study performed in the water sediment systems with racemic dimethenamid and in the water/sediment system with dimethenamid-P were considered for environmental exposure assessment. No additional metabolites are expected to be formed in surface water systems under natural conditions. It cannot be concluded for certain if a change of isomeric composition is expected during formation and degradation of the metabolites, however since dimethenamid-P contains only 3 % R-enantiomer, any possible changes are expected to remain small.

2.12.7 Ecotoxicology

The studies submitted for the active substance and listed accordingly under “dimethenamid-P” (see Table 2.9-3 in chapter 2.9.2 Summary of effects on aquatic organisms) comprise data on both the racemic mixture (SAN 582 H) and the P isomer (dimethenamid-P; SAN 1289). For the same reasons as explained above in chapter 2.9.1 data for these substances were considered equally since there was no significant difference in toxicity among these isomeric compounds. Thus, the lowest endpoints (most sensitive studies) from all available studies were considered for the risk assessment, regardless of the isomeric properties.

2.13 Residue definitions

2.13.1 Definition of residues for exposure/risk assessment

Food of plant origin:
Sum of dimethenamid-P + metabolite M26, and M30, expressed as dimethenamid-P (provisional)

Food of animal origin:
Sum of metabolites M26 and M30, expressed as dimethenamid-P (provisional)

Soil:
Dimethenamid-P, M656PH023, M656PH027 and M656PH031

Groundwater:
Dimethenamid-P, M656PH003, M656PH010, M656PH023, M656PH027 and M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053 (isomer 1 und 2), M656PH054, M656H055, M656PH059 (isomer 1, 2 und 3) and M656PH062

Surface water:
Dimethenamid-P, M656PH003, M656PH023, M656PH027 and M656PH031

Sediment:
Dimethenamid-P and M656PH003

Air:
Dimethenamid-P

2.13.2 Definition of residues for monitoring

Food of plant origin:
Sum of stereoisomers of dimethenamid + metabolite M30, expressed as dimethenamid-P

Food of animal origin:
Sum of stereoisomers of metabolite M30, expressed as dimethenamid-P (provisional)

Soil:
Sum of stereoisomers of dimethenamid

Groundwater:
Sum of stereoisomers of dimethenamid

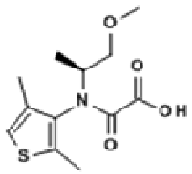
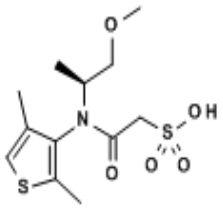
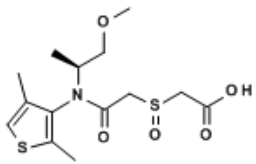
Surface water:
Sum of stereoisomers of dimethenamid

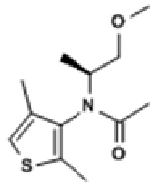
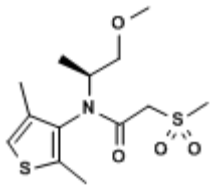
Sediment:
Not required

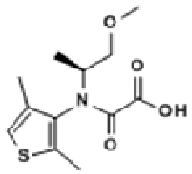
Air:
Sum of stereoisomers of dimethenamid

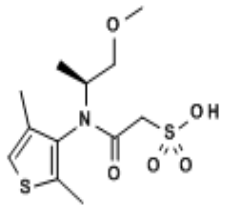
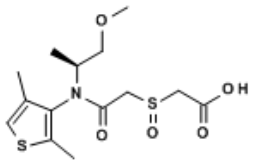
Tissues and body fluids:
Sum of stereoisomers of dimethenamid

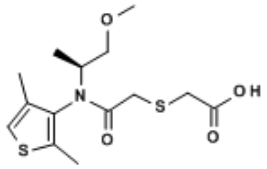
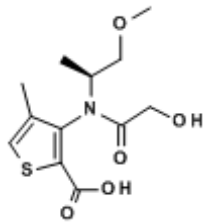
Table 2.13-1: Overview about metabolites

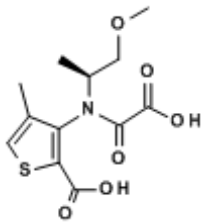
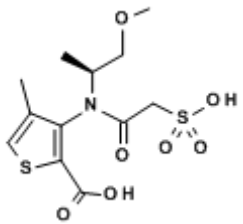
Code	Active substance *Dimethenamid-P*	Soil		
Metabolites		**Occurrence**	**Risk Assessment**	
Code	**Structural formula**		**Persistence, succeeding crops**	**Ecotoxicology**
M656PH023		aerob, laboratory: 12.2 % max. after 28 d aerob, field studies: 13.32 % max. after 28 d $DT_{50,lab}$: 63.9 days (maximum, laboratory data, not normalised) $DT_{50,field}$: not available anaerob: not available soil photolysis: not available	• $PEC_{soil,\ max}$ after multiple pre-emergence applications of BAS 656 12 H to maize: 0.1533 mg/kg • $PEC_{soil,\ max}$ after multiple pre-emergence applications of BAS 830 01 H to winter oilseed rape: 0.0893 mg/kg	Soil: not relevant (earthworms, soil mesofauna and microflora; non-target terrestrial plants: consideration of worst-case exposure and effect estimates)
M656PH027		aerob, laboratory: 13.32 % max. after 32 d aerob, field studies: 7.64 % max. after 59 d $DT_{50,lab}$: 149.2 d (maximum, laboratory data, not normalised) $DT_{50,field}$: 31.3 days (maximum, field data, not normalised) – used for PEC_{soil} calculations anaerob: not available soil photolysis: not available	• $PEC_{soil,\ max}$ after multiple pre-emergence applications of BAS 656 12 H to maize: 0.1025 mg/kg • $PEC_{soil,\ max}$ after multiple pre-emergence applications of BAS 830 01 H to winter oilseed rape: 0.0593 mg/kg	Soil: not relevant (earthworms, soil mesofauna and microflora; non-target terrestrial plants: consideration of worst-case exposure and effect estimates)
M656PH031		aerob, laboratory: 10.34 % max. after 28 d aerob, field studies: 8.56 % max. after 28 d $DT_{50,lab}$103.3 d (maximum, laboratory data, not normalised) $DT_{50,field}$: *value* anaerob: not available soil photolysis: not available	• $PEC_{soil,\ max}$ after multiple pre-emergence applications of BAS 656 12 H to maize: 0.1276 mg/kg • $PEC_{soil,\ max}$ after multiple pre-emergence applications of BAS 830 01 H to winter oilseed rape: 0.0738 mg/kg	Soil: not relevant (earthworms, soil mesofauna and microflora; non-target terrestrial plants: consideration of worst-case exposure and effect estimates)

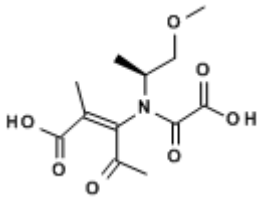
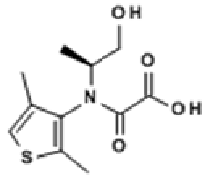
Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
M656PH003		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 0.1 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} <0.1 µg/L in all scenarios after pre-emergence applications of BAS 656 12 H to soybeans and sunflowers • PEC_{GW} ≥0.1 µg/L in some scenarios after pre and post-emergence applications of BAS 656 12 H to maize and sugar beet, maximum modelled concentration: 0.2 µg/L • PEC_{GW} ≥0.1 µg/L in some scenarios after pre and post-emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 0.2 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing of M656PH043 Acceptable groundwater concentration: 0.1 µg/L< M656PH003 ≤0.75 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**
M656PH010		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 0.07 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} <0.1 µg/L in all scenarios after pre-emergence application of BAS 656 12 H to maize, soybeans and sunflowers and after post-emergence application to maize and sugar beet • PEC_{GW} ≥0.1 µg/L in one scenario after pre-emergence of BAS 656 12 H to sugar beet, maximum modelled concentration:	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing conducted with M656PH027, M656H031 and M656PH054 Acceptable groundwater concentration: 0.1 µg/L< M656PH010 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**

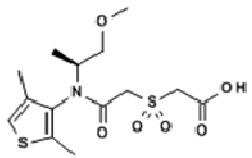
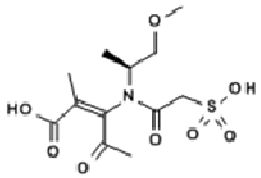
Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
		0.1 µg/L • PEC_{GW} <0.1 µg/L in all scenarios after post-emergence application of BAS 830 01 H to winter oilseed rape • PEC_{GW} ≥0.1 µg/L in one scenarios after pre -emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 0.1 µg/L			
M656PH023		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 1.0 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} ≥ 0.1 µg/L in all scenarios after pre-emergence of BAS 656 12 H to sugar beet and in most scenarios after pre-emergence of BAS 656 12 H to maize, soybeans, sunflowers and after post-emergence applicationn of BAS 656 12 H to sugar beet, maximum modelled concentration: 2.6 µg/L • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 2.69 µg/L	No pesticidal activity on non-target terrestrial plants.	No toxicological relevance Acceptable grondwater concentration: 0.1 µg/L< M656PH023 ≤10 µg/L	Not relevant (earthworms, soil mesofauna and microflora: non-target terrestrial plants consideration of worst-case exposure and effect estimates)

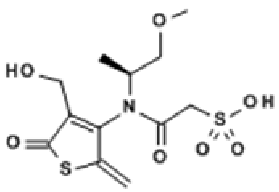
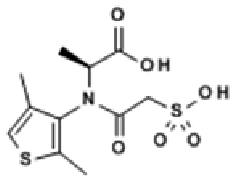
Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
M656PH027		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 4.0 µg/L FOCUS PELMO 5.5.3 modelling: • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 7.37 µg/L • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 6.34 µg/L		No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH027 ≤10 µg/L	
M656PH031		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): < LOD FOCUS PELMO 5.5.3 modelling: • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 25.0 µg/L • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 12.27 µg/L		No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH031 ≤10 µg/L	

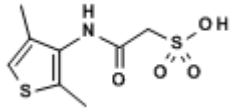
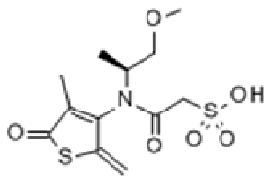
Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
M656PH032		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 1.5 µg/L FOCUS PELMO 5.5.3 modelling: • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 2.8 µg/L • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 2.4 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing of M656PH030 and M656PH031 Acceptable groundwater concentration: 0.1 µg/L< M656PH032 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**
M656PH043		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 1.2 µg/L FOCUS PELMO 5.5.3 modelling: • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 2.2 µg/L • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH043 ≤0.75 µg/L **Data gap: Step 5: Refined risk assessment for concentrations >0.75 µg/L**	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**

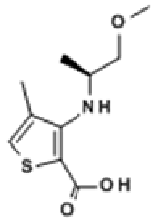
Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
		winter oilseed rape, maximum modelled concentration: 1.9 µg/L			
M656PH045		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 2.0 µg/L FOCUS PELMO 5.5.3 modelling: • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 3.7 µg/L • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 3.2 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH045 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**
M656PH047		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 1.2 µg/L FOCUS PELMO 5.5.3 modelling: • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 2.2 µg/L • $PEC_{GW} \geq 0.1$ µg/L in all scenarios	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH047 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**

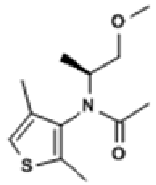
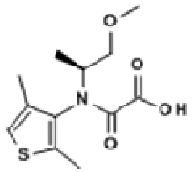
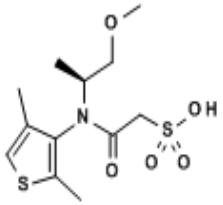
Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
		after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 1.9 µg/L			
M656PH049		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 1.0 µg/L FOCUS PELMO 5.5.3 modelling: • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 1.8 µg/L • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 1.6 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing of dimethenamid-P, M656PH023 and M656PH054 Acceptable groundwater concentration: 0.1 µg/L< M656PH049 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**
M656PH050		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize) 0.5 µg/L FOCUS PELMO 5.5.3 modelling: • $PEC_{GW} \geq 0.1$ µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing of M656PH023 and M656PH054 Acceptable groundwater concentration: 0.1 µg/L< M656PH050 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**

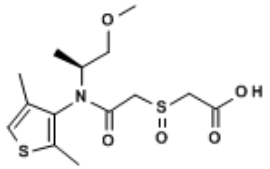
Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
		concentration: 0.9 µg/L • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 0.8 µg/L			
M656PH051		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 1.1 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} ≥ 0.1 µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 2.0 µg/L • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 1.7 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing of M656PH030 and M656PH031 Acceptable groundwater concentration: 0.1 µg/L< M656PH051 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**
M656PH052		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 0.9 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} ≥ 0.1 µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing conducted with M656PH027, M656H031 and M656PH054 Acceptable groundwater concentration: 0.1 µg/L< M656PH052	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**

Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
		concentration: 1.7 µg/L • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 1.4 µg/L		≤10 µg/L	
M656PH053		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize) isomer1: 0.8 µg/L, isomer 2: 2.0 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} ≥ 0.1 µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 2.9 µg/L (isomere 1) & 3.7 µg/L (isomere 2) • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 2.5 µg/L (isomer 1) & 3.2 µg/L (isomer 2)	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing conducted with M656PH027 and M656PH047 Acceptable groundwater concentration: 0.1 µg/L< M656PH053 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**
M656PH054		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 3.3 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} ≥ 0.1 µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH054 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**

Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
		maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 6.1 µg/L • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 5.2 µg/L			
M656H055		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 0.7 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} ≥ 0.1 µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 1.3 µg/L • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 1.1 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH055 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**
M656PH059		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): isomer 1: 0.8 µg/L isomer 2: 0.4 µg/L isomer 3: 1.6 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} ≥ 0.1 µg/L in all scenarios	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Covered by the toxicological testing conducted with M656PH027 and M656PH047	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**

Code	Active substance Dimethenamid-P	Ground water			
Metabolites		**Occurrence**	**Risk Assessment**		
Code	**Structural formula**		**Pesticidal activity**	**Toxicology**	**Ecotoxicology**
		after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 1.5 µg/L (isomer 1), 0.7 µg/L (isomer 2) and 2.9 µg/L (isomer 3) • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 1.3 µg/L (isomer 1), 0.6 µg/L (isomer 2) and 2.5 µg/L (isomer 3)		Acceptable groundwater concentration: 0.1 µg/L< M656PH059 ≤10 µg/L	
M656PH062		Lysimeter (pre-emergence application of 1440 g/ha dimethenamid to maize): 2.0 µg/L FOCUS PELMO 5.5.3 modelling: • PEC_{GW} ≥ 0.1 µg/L in all scenarios after pre- and post-emergence of BAS 656 12 H to sugar beet and maize and after pre-emergence of BAS 656 12 H application soybeans and sunflowers, maximum modelled concentration: 3.7 µg/L • PEC_{GW} ≥0.1 µg/L in all scenarios after pre – and post- emergence application of BAS 830 01 H to winter oilseed rape, maximum modelled concentration: 3.2 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**	No toxicological relevance Acceptable groundwater concentration: 0.1 µg/L< M656PH062 ≤10 µg/L	**Data gap: Study to show that there is no pesticidal activity on non-target terrestrial plants has to be submitted.**

Code	**Active substance** **Dimethenamid-P**	**Surface water and sediment**	
Metabolites		**Occurrence**	**Risk Assessment**
Code	**Structural formula**		**Ecotoxicology**
M656PH003		hydrolysis: dimethenamid-P is stable to hydrolysis photolysis: not formed ≥ 5 % w/s-study: water: max. 9.1 % on d 105 (end of study) sediment: max. 5.3 % on d 105 (end of study) → additional entry path after formation in soil and run-off/ drainage	Not relevant (fish, *Daphnia*, and algae: consideration of worst-case exposure and effect estimates)
M656PH023		hydrolysis: dimethenamid-P is stable to hydrolysis photolysis: not formed in conc. ≥ 5 % w/s-study: water: max. 9.6 % on d 100 (end of study) sediment: not found in conc. ≥ 5 % → additional entry path after formation in soil and run-off/ drainage	Not relevant (fish, *Daphnia*, and algae: consideration of worst-case exposure and effect estimates)
M656PH027		hydrolysis: dimethenamid-P is stable to hydrolysis photolysis: not formed in conc. ≥ 5 % w/s-study: water: 6.3 % AR at the end of the experiment sediment: not found in conc. ≥ 5 % → additional entry path after formation in soil and run-off/ drainage	Not relevant (fish, *Daphnia*, and algae: consideration of worst-case exposure and effect estimates)

Code	**Active substance** **Dimethenamid-P**	**Surface water and sediment**	
Metabolites		**Occurrence**	**Risk Assessment**
Code	**Structural formula**		**Ecotoxicology**
M656PH031		hydrolysis: dimethenamid-P is stable to hydrolysis photolysis: not formed in conc. ≥ 5 % w/s-study: water: not formed in conc. ≥ 5 % sediment: not formed in conc. ≥ 5 % → entry path after formation in soil and run-off/ drainage	Not relevant (*Daphnia*, algae and aquatic plants: consideration of worst-case exposure and effect estimates)

Level 3

Dimethenamid-P

3 Proposed decision with respect to the application

3.1 Background to the proposed decision

3.1.1 Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009

3.1.1.1 Article 4

		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.		X	*Brief summary – name of active and assessed uses formulation considered. [Identify the representative uses/products that are considered to comply with Article 4 and those that are not]* All uses.

3.1.1.2 Submission of further information

		Yes	No	
i)	It is considered that a complete dossier has been submitted		X	*[If no go to ii immediately below]*
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.		X	*[If yes – specify here the rationale i.e. whether (a) or (b) applies and cross reference to section xx detailing the information still to be submitted* *If no – explain the further information to be submitted and its relevance to the decision on approval* *Explain if some of the information to be submitted relates only to specified products/uses/use scenarios]* - Data on higher tier refinement of voles are necessary to suspend the

				scenario common vole from higher tier risk assessment for maize early post emergence. Otherwise uses 2 and 4 (BAS 656 12 H) cannot be considered safe. - Data according to current guideline on the toxicity of the representative formulation BAS 656 12 to non-target terrestrial plants. The new studies submitted are not acceptable for risk assessment. - The original study to show that there is no herbicidal activity of several groundwater metabolites on non-target terrestrial plants has to be submitted. It was only presented as summary. (b) To ensure that the provisional residue definition for risk assessment is correct and M81 can be left out of it, the applicant needs to carry out a grouping approach of metabolite M14, a QSAR evaluation should also be performed (see also 3.1.5)

3.1.1.3 Restrictions on approval

		Yes	No	
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.	X		*[If yes –clearly specify the nature of the proposed restriction(s) i.e.* (a) the minimum degree of purity of the active substance; ≥ 930 g/kg (b) the nature and maximum content of certain impurities; 1,1,1,2-tetrachloroethane: < 1.0 g/kg 2,4-dimethylthiophene-3-ol: ≤ 1.5 g/kg (c) restrictions arising from the evaluation of the information referred to in Article 8 of 1107/2009 taking account of the agricultural, plant health and environmental, including climatic, conditions in question; - (d) type of preparation; Emulsifiable concentrate (EC)

				Suspo-emulsion (SE) (e) manner and conditions of application; - (f) submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority, (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge; (g) designation of categories of users, such as professional and non-professional; - (h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under specific conditions; - Member States should pay particular attention to the potential of the metabolites of dimethenamid-P for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions, (i) the need to impose risk mitigation measures and monitoring after use; - Risk mitigation measures should be considered to protect aquatic ecosystems, especially algae and aquatic plants. (j) any other particular conditions that result from the evaluation of information made available in the context of Regulation 1107/2009. Explain if some of the information to be submitted relates only to specified products/uses/use scenarios] -

3.1.1.4 Criteria for the approval of an active substance

		Yes	No	
Dossier				
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	X		
	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals; (e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.	X		*[Insert brief overall summary of consideration of residues & consumer assessment here]* *[Explain if this applies to all or some of the representative uses/use scenarios/products]* The dossier contains the information to carry out a risk assessment and to set residue definitions for enforcement. However the residue definition for risk assessment could not be finalised due to missing information on metabolite M81. Metabolite M81 was detected in edible plant parts (radish tops are considered a surrogate for leafy brassica) during a rotating crop study. M81 is the glycosylated metabolite of M14, which was also identified in the rat metabolism. However, M14 occured in very small amounts only and cannot be considered as toxicologically covered by the parent substance. Consequently, a decision on the inclusion of M81 into the residue definition cannot be made until the applicant has provided a toxicological characterisation of M14.
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.		X	*[Explain if this applies to all or some of the representative uses/use scenarios/products]* Data for higher tier risk assessment for voles are missing. A study according to current guideline on the toxicity of the representative formulation BAS 656 12 to non-target terrestrial plants is missing. The full study regarding herbicidal activity of groundwater metabolites on non-target terrestrial plants has to be submitted.
Efficacy				

		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, considering an application in accordance with good agricultural practice and having regard to realistic conditions of use is sufficiently effective.	X		Please refer to level 2 point 2.3
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.		X	*[Explain if this applies to all or some of the representative uses/use scenarios/products]* The assessment of pesticidal activity for the soil metabolites M656PH023, M656PH030, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH054, M656H055, the Na salt of M656PH027 and the ethylester derivative for M656PH062 could not be finalised. The non-relevance of the metabolites for groundwater still needs to be clarified.
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.	X		*[Insert brief overall summary on identify here. Cross refer to level 2 as necessary]* An acceptable specification was proposed by the RMS.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.			There is no FAO specification for dimethenamid-P.
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted.			not relevant
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater	X		*[Insert brief overall summary here. Cross refer to level 2 as necessary]* Adequate analytical methods are available for the determination of dimethenamid-P in the technical active substance and in the

	than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.			representative formulations. Adequate analytical methods are available for the determination of significant and relevant impurities in the technical active substance. However, analytical methods for the determination of the relevant impurities in one representative formulation (BAS 830 01 H) are missing.
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.	X		The overview Table 2.5-3 shows that sufficiently validated analytical methods are available for all required matrices. For matrices of animal origin, an independent laboratory validation for metabolite M30 is missing. However, as no residues of M30 are expected, the ILV is not required until potential future uses relevant for animal feed further trigger the dietary burden.
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		
Impact on human health				
Impact on human health – ADI, AOEL, ArfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ArfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		An ADI of 0.04 mg/kg bw based on the 'overall NOAEL' of the 13-week and the 52-week dog studies is proposed. The proposed ARfD is 0.25 mg/kg bw/day. An AOEL of 0.04 mg/kg bw based on an 'overall NOAEL' obtained from the 13-week and 1 year dog studies is proposed.
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as mutagen category 1A or 1B.**		X	Overall, the results do not indicate that dimethenamid-P possesses a genotoxic potential.
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the		X	In summary, long-term feeding studies with racemic dimethenamid in

	carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**			rats and mice showed no evidence of a carcinogenic potential.
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.	-	-	Not applicable.
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or 1B.**		X	There was no evidence of reproductive and developmental toxicity investigated in a two-generation reproduction study with racemic dimethenamid in rats, in prenatal toxicity studies in rats with both dimethenamid-P and racemic dimethenamid, and in a prenatal toxicity study in rabbits with racemic dimethenamid.
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.	-	-	Not applicable.

Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties**		X	There is no evidence that dimethenamid-P has a human relevant endocrine related effect.
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2 and** in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**		X	There is no evidence that dimethenamid-P has a human relevant endocrine related effect.
iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.	-	-	Not applicable.
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		X	On consideration of all available data on the characteristics of dimethenamid-P, the substance does not fulfil the criteria of a persistent organic pollutant (POP). The assessment of the POP criteria is described in more detail below: <u>Persistence criteria:</u> The DT_{50} values (SFO or SFO recalculated) at 20 °C and pF2 in soil under aerobic conditions measured in the laboratory range from 4.8 to 30.6 d. The DT_{50} values (SFO or SFO recalculated) at 20 °C and pF2 in soil under aerobic conditions measured in field degradation studies range from 10.2 to 20.4 d. None of the DT_{50} values exceed the trigger

				value for soil of 6 month (180 days). The DT_{50} values of dimethenamid-P in the water/sediment total systems at 20 °C under aerobic conditions measured in the laboratory range from 19.8 to 35.1 d. They do not exceed the trigger values of 2 month (60 days) for water and of 6 month (180 days) for sediment (see 2.8.1 and 2.8.2) Potential for long-range transport criteria: Dimethenamid-P has a vapour pressure of 3.47×10^{-3} Pa (20 °C) and is thus regarded as semivolatile (volatilisation from soil and plant surfaces). However, the photochemical oxidative degradation half life of dimethenamid-P was calculated as 0.2 d for a 12 h day and a OH radicals concentration of 1.5×10^{6} cm^{-3}. Distribution of the active substance via long range transport through the atmosphere is therefore not expected (see 2.8.3). Due to its short DT_{50} values in water/sediment systems, it also has a low potential for long-range transport through water. Bioaccumulation criteria: Dimethenamid-P has a $logP_{o/w}$ of 1.89 and therefore a study on bioaccumulation is not triggered. The potential for bioaccumulation of dimethenamid-P is considered to be low.
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		X	On consideration of all available data on the characteristics of dimethenamid-P, the active substance does not fulfil the criteria of a PBT substance. The assessment of the PBT criteria is described in more detail below: Persistence criteria: The DT_{50} values (SFO or SFO recalculated) at 20 °C and pF2 in soil under aerobic conditions measured in the laboratory range from 4.8 to 30.6 d. The DT_{50} values (SFO or SFO recalculated) at 20 °C and pF2 in soil under aerobic conditions measured in field degradation studies range from 10.2 to 20.4 d. They do not exceed the trigger value for soil of 120 days. The DT_{50} values in the water/sediment total systems at 20 °C under aerobic conditions measured in the laboratory range from 19.8 to 35.1 d. They do not exceed the trigger values of 40 days for water and of 120 days for sediment (see 2.8.1 and 2.8.2)

				Bioaccumulation criteria: Dimethenamid-P has a $logP_{o/w}$ of 1.89 and therefore a study on bioaccumulation is not triggered. The potential for bioaccumulation of dimethenamid-P is considered to be low. Toxicity criteria: Dimethenamid-P is considered to be toxic. The lowest endpoint for aquatic organisms is E_yC_{50} = 0.00599 mg as/L for the species *Lemna gibba*.
Very persistent and very bioaccumulative substance (vPvB)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	On consideration of all available data on the characteristics of dimethenamid-P, the active substance does not fulfil the criteria of a vPvB substance. The assessment of the vPvB criteria is described in more detail below: Persistence criteria: The DT_{50} values (SFO or SFO recalculated) at 20 °C and pF2 in soil under aerobic conditions measured in the laboratory range from 4.8 to 30.6 d. The DT_{50} values (SFO or SFO recalculated) at 20 °C and pF2 in soil under aerobic conditions measured in field degradation studies range from 10.2 to 20.4 d. None of the DT_{50} values exceed the trigger value for soil of 180 days. The DT_{50} values in the water/sediment total systems at 20 °C under aerobic conditions measured in the laboratory range from 19.8 to 35.1 d. They do not exceed the trigger values of 60 days for water and of 180 days for sediment (see 2.8.1 and 2.8.2) Bioaccumulation criteria: Dimethenamid-P has a $logP_{o/w}$ of 1.89 and therefore a study on bioaccumulation is not triggered. The potential for bioaccumulation of dimethenamid-P is considered to be low.
Ecotoxicology				
		Yes	No	
	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product		X	The risk to **birds** has been assessed as acceptable for the intended use on the Tier 1-level. The risk to mammals has been assessed as acceptable for the intended use of BAS 830 01 H and for the intended uses 1, 3 and 5-10 of BAS 656 12 H. For these uses no use restrictions for risk mitigation are required. In contrast, the risk to

	containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.			mammals has been assessed as **not acceptable for the intended uses 2 and 4 of BAS 656 12 H** (see 2.9.1). The risk to **aquatic organisms** has been assessed as acceptable for the intended uses in maize, sugar beets and sunflowers of BAS 656 12 H, when applying risk mitigation measures such as 10 m drift mitigation. The risk has been assessed as unacceptable for the intended use in soybeans. The risk to **aquatic organisms** has been assessed as acceptable for the intended use in winter oilseed rape of BAS 830 01 H when applying risk mitigation measures such as drift mitigation ≥ 5 m. The risk to **non-target arthropods (NTA)** has been assessed based on standard studies and extended laboratory studies. An acceptable risk for off-field NTA as well as on in-field NTA has been identified. No need for risk mitigation measures has been identified (see 2.9.9.4). The risk to soil organisms has been assessed using PEC_{soil} values considering also accumulation of the dimethenamid-P metabolites M23 and M31 over several years of consecutive use. An acceptable risk for **earthworms** could be demonstrated for the active substance and the metabolites M23, M27 and M31. TER values calculated for collembolans and no-effect concentrations for **soil micro-organisms** are above the respective acceptability values. No use restrictions for risk mitigation are required (see 2.9.5 and 2.9.6). The risk assessment for **terrestrial plants** for BAS 656 12 H could not be finalised because no dose-response tests fulfilling the data requirements have been submitted (see 2.9.6). A risk to **biological sewage treatment** is not expected (see 2.9.8).
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine disrupting properties that may cause adverse effects on non-target organisms.		X	There are currently no indications from the available toxicity and ecotoxicity data (mammalian and avian reproduction, fish early life stage (ELS) and *Daphnia* chronic studies) to conclude on an endocrine disrupting potential of dimethenamid-P.
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.		X	The intended use is a spray application in the field, therefore the exposure of non-target organisms cannot be considered as negligible.
	It is considered following an appropriate risk assessment on the	X		Due to the results of laboratory tests BAS 656 12 H and BAS 830 01

	basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use and according to good agricultural practice of plant protection products containing dimethenamid-P present a low risk to honeybees and bumblebees and will not adversely affect honeybees or honeybee colonies as well as bumblebee colonies.			H are considered to be practically non-toxic to bees. The endpoints obtained for bumble bees, compared to the data available for honey bees, do not indicate a higher sensitivity of bumble bees to dimethenamid-P. The proposed uses of BAS 656 12 H according to good agricultural practice present a low risk to honeybees and bumblebees and will not adversely affect honeybees or honeybee colonies as well as bumblebee colonies.
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X		<u>Plant Matrices:</u> Risk assessment: Sum of dimethenamid-P + metabolite M26, and M30, expressed as dimethenamid-P (provisional) Monitoring: Sum of stereoisomers of dimethenamid + metabolite M30, expressed as dimethenamid-P <u>Animal Matrices:</u> Risk assessment: Sum of metabolites M26 and M30, expressed as dimethenamid-P (provisional) Monitoring: Sum of stereoisomers of metabolite M30, expressed as dimethenamid-P (provisional) <u>Soil:</u> Relevant residues requiring further risk assessment in soil are dimethenamid-P and the metabolites M656PH023, M656PH027 and M656PH031 (see 2.8.1). Relevant residues for monitoring is dimethenamid-P. <u>Groundwater:</u> Relevant residues requiring further risk assessment are dimethenamid-P and the metabolites M656PH003, M656PH010, M656PH023, M656PH027 and M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053 (isomer 1 and 2),

				M656PH054, M656H055, M656PH059 (isomer 1, 2 and 3) and M656PH062 (see 2.8.1). Relevant residue for monitoring is dimethenamid-P. Surface water: Relevant compounds requiring further assessment in surface water are dimethenamid-P and the metabolites M656PH003, M656PH023, M656PH027 and M656PH031 (see 2.8.1 and 2.8.2). Relevant residue for monitoring is dimethenamid-P. Sediment: Relevant compounds requiring further assessment in the sediment are dimethenamid-P and the metabolite M656PH003 (see 2.8.2). Relevant residue for monitoring is dimethenamid-P. Air: No criteria for definition of a relevant residue in air are available. By default, the relevant residue for monitoring is the active substance dimethenamid-P. Tissue and body fluids: Sum of stereoisomers of dimethenamid.
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.		X	For details please refer to 2.8.6. Dimethenamid-P: The modelled concentration in groundwater is < 0.1 µg L^{-1} in all FOCUS scenarios for all representative uses. Degradation products In all FOCUS scenarios and for all representative uses some of the degradation products exceed the limit of 0.1 µg/L. As the non-relevance of the metabolites M656PH003, M656PH010, M656PH032, M656PH043, M656PH045, M656PH047, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053 (isomer 1 and 2),

				M656PH054, M656H055, M656PH059 (isomer 1, 2 and 3) and M656PH062 has not been verified, no safe use could be specified. <u>M656PH003 & M656PH010:</u> PEC_{GW} <0.1 µg/L in all scenarios of some representative uses of BAS 656 12 H PEC_{GW} ≥0.1 µg/L in some scenarios of some representative uses of BAS 656 12 H and BAS 830 01 H • maximum modelled PEC_{GW} of M656PH010: 0.1 µg/L • maximum modelled PEC_{GW} of M656PH003: 0.2 µg/L <u>M656PH059-isomer 2:</u> PEC_{GW} ≥0.1 µg/L in all scenarios of all representative uses of BAS 656 12 H and BAS 830 01 H PEC_{GW} <0.75 µg/L in all scenarios of all representative uses of BAS 656 12 H and BAS 830 01 H • maximum modelled PEC_{GW} of M656PH059- isomere 2: 0.7 µg/L <u>M656PH043, M656PH049, M656PH050, M656PH051, M656PH052, M656PH053-isomer 1, M656H055, M656PH059- isomer 1:</u> PEC_{GW} ≥0.1 µg/L in all scenarios of all representative uses of BAS 656 12 H and BAS 830 01 H PEC_{GW} ≥0.75 µg/L in some scenarios of some representative uses of BAS 656 12 H and BAS 830 01 H • maximum modelled PEC_{GW} of M656PH050: 0.9 µg/L • maximum modelled PEC_{GW} of M656H055: 1.3 µg/L • maximum modelled PEC_{GW} of M656PH059-isomer 1: 1.5 µg/L • maximum modelled PEC_{GW} of M656PH052: 1.7 µg/L • maximum modelled PEC_{GW} of M656PH049: 1.8 µg/L • maximum modelled PEC_{GW} of M656PH051: 2.0 µg/L • maximum modelled PEC_{GW} of M656PH043: 2.2 µg/L • maximum modelled PEC_{GW} of M656PH053-isomer 1: 2.9 µg/L • maximum modelled PEC_{GW} of M656PH059-isomer 3: 2.9 µg/L

				M656PH023, M656PH027, M656PH032, M656PH045, M656PH047, M656PH053-isomer 2, M656PH054: PEC_{GW} ≥0.1 µg/L in all scenarios of all representative uses of BAS 656 12 H and BAS 830 01 H PEC_{GW} ≥0.75 µg/L in some or all scenarios of all representative uses of BAS 656 12 H and BAS 830 01 H • maximum modelled PEC_{GW} of M656PH047: 2.2 µg/L • maximum modelled PEC_{GW} of M656PH023: 2.6 µg/L • maximum modelled PEC_{GW} of M656PH032: 2.8 µg/L • maximum modelled PEC_{GW} of M656PH045: 3.7 µg/L • maximum modelled PEC_{GW} of M656PH053- isomer 2: 3.7 µg/L • maximum modelled PEC_{GW} of M656PH054: 6.1 µg/L • maximum modelled PEC_{GW} of M656PH027: 7.4 µg/L M656PH031: PEC_{GW} ≥0.1 µg/L and ≥0.75 µg/L in all scenarios for all representative uses of BAS 656 12 H and BAS 830 01 H PEC_{GW} ≥10 µg/L in some scenarios of some representative uses of BAS 656 12 H and BAS 830 01 H • maximum modelled PEC_{GW} of M656PH031: 25.0 µg/L

3.1.2 Proposal – Candidate for substitution

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution		X	Based on ADI, ARfD and AOEL dimethenamid-P is not considered as a candidate for substitution. On consideration of all available data, dimethenamid-P does not fulfill the criteria of a PBT substance. In particular, dimethenamid-P does not fulfill the criteria for persistence[1)] nor for bioaccumulation[2)] but for (eco)toxicity[3)]. Persistence criteria:

				The DT_{50} values (SFO or SFO recalculated) at 20 °C and pF2 in soil under aerobic conditions measured in the laboratory range from 4.8 to 30.6 d. They do not exceed the trigger value for soil of 120 days. The DT_{50} values of picolinafen in the water/sediment total systems at 20 °C under aerobic conditions measured in the laboratory range from 19.8 to 35.1 d. They do not exceed the trigger values of 40 days for water and of 120 days for sediment (see 2.8.1 and 2.8.2) Bioaccumulation criteria: Dimethenamid-P has a $logP_{o/w}$ of 1.89 and therefore a study on bioaccumulation is not triggered. The potential for bioaccumulation of dimethenamid-P is considered to be low. Toxicity criteria: Dimethenamid-P is considered to be toxic. The lowest endpoint for aquatic organisms is E_yC_{50} = 0.00599 mg as/L for the species *Lemna gibba*. ECHA´s RAC concluded that no classification and labelling for dimethenamid-P for Repr. Cat 1A or 1B is warranted. Endocrine properties There are currently no indications from the available toxicity and ecotoxicity data (mammalian and avian reproduction, fish early life stage (ELS) and *Daphnia* chronic studies) to conclude on an endocrine disrupting potential of dimethenamid-P.

3.1.3 Proposal – Low risk active substance

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** In particular it is considered that the substance **should NOT be classified or proposed for classification** in accordance with		X	Dimethenamid-P is not considered as a low risk active substance as it is a sensitising chemical (harmonised classification according to Regulation (EC) No 1272/2008: Skin Sens. 1, H317: May cause an allergic skin reaction).

	Regulation (EC) No 1272/2008 as at least one of the following: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**: — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.			

3.1.4 List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.1 Identity of the active substance or formulation				

3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
Spectra of relevant impurities are missing.	relevant for all uses		March 2016	
2-year shelf life studies for formulations BAS 656 12 H and BAS 830 01 H are required.	relevant for all uses		X	
The n-octanol/water partition coefficient (log Pow) of metabolites included in the residue definition for risk assessment are missing.	relevant for all uses	X		
3.1.4.3 Data on uses and efficacy				
3.1.4.4 Data on handling, storage, transport, packaging and labelling				
3.1.4.5 Methods of analysis				
Analytical methods for the determination of the relevant impurities in one representative formulation (BAS 830 01 H) are missing.	relevant for all uses of BAS 830 01 H		June 2016	

An independent laboratory validation of metabolite M30 in animal matrices. However, the ILV is not required until potential future uses relevant for animal feed further trigger the dietary burden.	relevant for all uses	X		
A method for the determination of isomers of dimethenamid in body fluids.	relevant for all uses	X		
3.1.4.6 Toxicology and metabolism				
Report of the analysis of the impurity profile of the toxicological batch L81-46	relevant for all uses		X	
3.1.4.7 Residue data				
As proposed by the applicant, a grouping approach of metabolite M14, as well as a QSAR evaluation should be performed.	relevant for all uses	X		
Further storage time points in the ongoing storage stability study by Oppinger (2014)	Sunflower		X	
A storage stability study for metabolite M26 in high water content materials	High water content commodities	X		
Within the MRL application 8 field trials with carrots (4 trials if residues < 0.01 mg/kg per analyte) are missing for each N+SEU.	Carrot	X		
Within the MRL application at least 8 field trials (4 trials if residues < 0.01 mg/kg per analyte) are missing in SEU.	Cucurbits with edible peel	X		

Within the MRL application at least 8 field (4 trials if residues < 0.01 mg/kg per analyte) trials are missing for melon in SEU.	Cucurbits with inedible peel	X		
Within the MRL application 4 field trials are missing for Brussels sprouts in SEU.	Brussels sprouts	X		
Within the MRL application at least 8 field trials (4 trials if residues < 0.01 mg/kg per analyte) are missing for green beans and vicia beans in SEU.	Green beans and vicia beans	X		
3.1.4.8 Environmental fate and behaviour				
3.1.4.9 Ecotoxicology				
Data on higher tier refinement of voles.	BAS 656 12: Maize BBCH 09 - 19 (use 2 + 4)	X		
Data according to current guideline on the toxicity of the representative formulation to non-target terrestrial plants	BAS 656 12: all uses	X		
Study to show that there is no herbicidal activity of groundwater metabolites on non-target terrestrial plants has to be submitted.	All uses			X (study BASF RegDoc#2014/ 1101480 needs to be submitted)

3.1.5 Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	**Relevance in relation to representative use(s)**
Proposed residue definition for plants	In plants, residue definition for risk assessment could not be finalised due to missing information on metabolite M81. Metabolite M81 was detected in edible plant parts (radish tops are considered a surrogate for leafy brassica) during a rotating crop study. M81 is the glycosylated metabolite of M14, which was also identified in the rat metabolism. However, M14 did occur in very small amounts only and cannot be considered as toxicologically covered by parent substance. Consequently, a decision on the inclusion of M81 into the residue definition cannot be made until the applicant has provided a toxicological characterisation of M14.
Risk to mammals	According to the Guidance Document EFSA/2009/1438 the common vole (*Microtus arvalis)* is the representative species for the small herbivorous mammal. The applicant proposed to exclude the common vole from risk assessment. Overall, the RMS came to the conclusion that this scenario cannot be excluded from higher tier risk assessment for maize early post emergence and therefore unacceptable acute and chronic risks remain for the uses 2 and 4 for BAS 656 12 H.
Risk to Non-target terrestrial plants	TER values for non-target terrestrial plants could not be calculated due to lack of adequate toxicity data for BAS 656 12 H. The risk assessment for the representative formulation BAS 656 12 H could not be finalised for all uses.
Assessment of relevance of groundwater metabolites	The PEC_{GW}-calculations provided by the applicant are only partly acceptable. According to re-calculations by the RMS, the

	metabolites M23, M27 and M31 were mostly modelled in groundwater concentrations > 0.1 µg L^{-1}. The metabolite M31 also exceeded the 10 µg L^{-1} threshold in some FOCUS scenarios. None of the metabolites is of ecotoxicological relevance. Toxicity to terrestrial vertebrates, aquatic organisms and soil fauna is much lower than for the parent. Preliminary results of screening tests also show that the tested metabolites of BAS 656 H, applied pre- and post-emergence, have no biological activity comparable to the parent. To finalise this assessment the full study has to be submitted. Still it is not clear, if really all vulnerable regions in Europe are covered by the lysimeter study. Thus, the RMS believes that the results of the lysimeter study should not overwrite the results of the groundwater modelling but should be considered as additional information providing important information on the expected metabolite pattern in groundwater under natural conditions. The groundwater monitoring performed by the applicant is considered not acceptable by the RMS for higher tier groundwater assessment. The RMS believes that the higher tier leaching data based on lysimeter or groundwater monitoring should be discussed among the European experts, since the use of these approaches for EU approval are uncommon and there is not much experience on the evaluation of such studies.

3.1.6 Critical areas of concern

An issue is listed as a critical area of concern:
(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	**Relevance in relation to representative use(s)**
	[specify if concern relates to all or specific representative use/use scenario/product or to all uses/products]
Risk to mammals	*BAS 656 12: uses 2 and 4:* Since the proposal of the applicant for the assessment of risk to mammals cannot be followed, unacceptable acute and chronic risks remain for the uses 2 and 4 for BAS 656 12 H.
Risk to Non-target terrestrial plants	*BAS 656 12: all uses:* TER values for non-target terrestrial plants could not be calculated due to lack of adequate toxicity data for BAS 656 12 H. The risk assessment for the representative formulation BAS 656 12 H could not be finalised.
Assessment of relevance of groundwater metabolites	*BAS 656 12 H and BAS 830 01 H: all uses* The relevance assessment for all metabolites except M23, M27 and M31 could not be finalised. Results of a non-GLP screening study show that the tested metabolites, applied pre- and post-emergence, show no biological activity comparable to the parent, but the study was not submitted. The PEC_{GW}-calculations provided by the applicant are only partly acceptable. According to re-calculations by the RMS, the metabolites M23, M27 and M31 were mostly modelled in groundwater concentrations $> 0.1\ \mu g\ L^{-1}$. The metabolite M31 also exceeded the $10\ \mu g\ L^{-1}$ threshold in some FOCUS scenarios. Still it is not clear, if really all vulnerable regions in Europe are covered by the lysimeter study. Thus, the RMS believes that the results of the lysimeter study should not overwrite the results of the groundwater modelling but should be considered as additional information providing important

Critical area of concern identified	Relevance in relation to representative use(s)
	information on the expected metabolite pattern in groundwater under natural conditions. The groundwater monitoring performed by the applicant is considered not acceptable by the RMS for higher tier groundwater assessment. The RMS believes that the higher tier leaching based on lysimeter or groundwater monitoring data should be discussed among the European experts, since the use of these approaches for EU approval are uncommon and there is not much experience on the evaluation of such studies.

3.1.7 Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		Use "A" (X[1]) BAS 830 01 H	Use "B" (X[1]) BAS 656 12 H
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		X (use 2 + 4)
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		X (terrestrial plants)
Risk to aquatic organisms	Risk identified		X (use 5)
	Assessment not finalised		
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached	X	X
	Parametric value of 10 µg/L(a) breached		X
	Assessment not finalised	X	X
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.
(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8 Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	Justification
Environmental fate and behaviour – groundwater	The RMS believes that the higher tier leaching based on lysimeter or groundwater monitoring data should be discussed among the European experts, since the use of these approaches for EU approval are uncommon and there is not much experience on the evaluation of such studies.

3.1.9 Critical issues on which the Co RMS did not agree with the assessment by the RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	Opinion of Co-RMS	Opinion of RMS
none		

3.2 Proposed decision

[redacted]

[redacted]

3.3 Rational for the conditions and restrictions to be associated with the approval or authorisation(s), as appropriate

3.3.1 Particular conditions proposed to be taken into account to manage the risk identified

[redacted]

[redacted]	[redacted]

3.4 Appendices

3.4.1 Guidance documents used in this assessment

[List of Guidance documents used in the conduct of the evaluation and risk assessment.]

European Commission, Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC, Sanco/221/2000 –rev.10-final 25 February 2003

European Commisssion, Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Regulation (EC) No 1107/2009, SANCO/10597/2003 –rev. 9 17 June 2011

3.4.2 Reference list

List [in the conventional format] any references specifically cited in Volume 1 (i.e references to underpinning documents such as PPR-Panel Opinions, EFSA conclusions, national documents etc.).

Committee for Risk Assessment RAC Opinion of Dimethenamid-P, adopted 4 June 2013; CLH-O-0000003037-80-03/F.

European Commission, Review report for the active substance dimethenamid-P, dimethenamid-P, SANCO/1402/2001-Final 3 July 2003.

World Health Organisation and Food and Agriculture Organisation of the United Nations Rome, 2004, FAO Plant Production and Protection Paper, 178 Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004.