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Department of Food, Nutrition, and Veterinary Public Health
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ITALY**

**Monograph prepared in the context of the inclusion of the following
active substance in Annex I of the Council Directive 91/414/EEC**

Bensulfuron Methyl

Volume 1

Report and Proposed Decision

May 2006

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

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LEVEL 1

**Statement of the subject matter and
purpose of the monograph**

Bensulfuron Methyl

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Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

1. Statement of subject matter and purpose for which the monograph was prepared

1.1 Purpose for which the monograph was prepared

The technical dossier is being submitted in the context of the first inclusion of the existing active substance Bensulfuron methyl in Annex I of Directive 91/414/EEC.

1.2 Summary and assessment of information relating to the collective provision of dossiers

This requirement does not apply to bensulfuron methyl since DuPont de Nemours (France) S.A. was the sole notifier for this active substance under Article 8 (2) of Directive 91/414/EEC.

1.3 Identity of the active substance (Annex IIA 1)

1.3.1 Name and address of applicant(s) for inclusion of the active in Annex (Annex IIA 1.1)

1.3.1.1 Applicant (name, address, etc.)

Applicant:

DuPont de Nemours (France) S.A.S.

Address

137, Rue de l'Université

75334 Paris Cédex 07, France

[illegible]

1.3.2 Common name and synonyms (Annex IIA 1.3)

Bensulfuron methyl (BSI and ISO approved)

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1.3.3 Chemical name (Annex IIA 1.4)IUPAC: Methyl α -(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-o-toluate

CAS: Methyl 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]methyl]benzoate

1.3.4 Manufacturer's development code number (Annex IIA 1.5)

DPX-F5384

F5384

1.3.5 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS Registry No.: 83055-99-6

EEC No.: 401-340-6

EINECS, ELINCS: See EEC number above

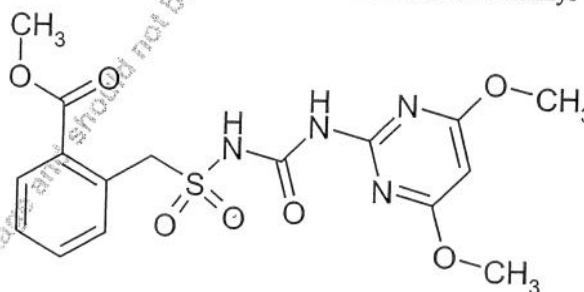
1.3.6 Molecular and structural formulae, molecular mass (Annex IIA 1.7)

a. Empirical Formula:



b. Structural Formula:

Figure 1. 1: Structural formula of bensulfuron methyl



c. Molecular Mass:

410.4 g/mol

1.3.7 Manufacturer or manufacturers of the active substance (Annex IIA 1.2)

a. Present Manufacturer:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

b. Location of Plant(s):

[REDACTED]

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c. Future manufacturer (name and address): Same as above.

1.3.8 Method or methods of manufacture (Annex IIA 1.8)

Details of the method of manufacture of the active substance are given in confidential Document J-Part 1 (DuPont-6172 EU). The applicant points out that information pertaining to the process description is highly confidential and requests it to be treated as such according to Article 14 of Council Directive 91/414/EEC.

1.3.9 Specification of purity of the active substance (Annex IIA 1.9)

Production scale: Minimum purity of bensulfuron methyl is 975 g/kg. Information is provided in confidential Document J – Part 1, DuPont-6172 EU.

1.3.10 Identity of isomer, impurities and additives (Annex IIA 1.10)

There are neither additives nor isomers in bensulfuron methyl technical. A list of impurities with their maximum values is provided in confidential Bensulfuron methyl EU Dossier, Document J-Part 1, DuPont-6172 EU.

1.3.11 Analytical profile of batches (Annex IIA 1.11)⁽⁶⁾

Analytical profiles of commercial production batches together with those for the samples used in the main toxicological studies can be found in confidential Document J, - Part I, DuPont-6172 EU.

1.4 Identity of the plan protection product (Annex IIA 3.1; IIIA 1)

1.4.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

Bensulfuron methyl 60WG is registered in Europe under the trade names Londax®, Sector®, Testar®. For consistency the formulated product is referred to as Bensulfuron methyl 60WG.

It has been referred in reports submitted in support of this application as Bensulfuron 60WG, DPX-F5384 60WG.

1.4.2 Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)

a. Present Manufacturer:

[REDACTED]

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179, Magowar Road , Girraween, NSW, 2145, Australia

b. Location of Plant(s): Same address as above

c. Future manufacturer Same address as above

(name and address):

Present Manufacturer

Manufacturing site for the active
substance bensulfuron methyl:

Future Manufacturer

Manufacturing site for the active
substance, bensulfuron methyl:**1.4.3 Type of the preparation and code (Annex IIIA 1.5)**

Water Dispersible Granule (WG).

1.4.4 Function (Annex IIA 3.1; Annex IIIA 1.6)

Postemergence, selective herbicide acting primarily through foliar uptake with little soil activity.

1.4.4.1 Use category (herbicide, insecticide, etc.) (IIIA 1.6)

Selective herbicide.

1.4.5 Composition of the preparation (III 1.4)

Identity of the active substance:

Common name: Bensulfuron methyl

CAS Registry No: 83055-99-6

Bensulfuron methyl 60WG contains 600 grams of bensulfuron methyl active substance per kilogram.

Detailed information on the composition of the preparation is provided in Bensulfuron methyl EU Dossier, Document J–Part 3, DuPont-6174 EU which contains industrial and commercial data for which confidentiality is requested in accordance with Article 14 of Directive 91/414/EEC.

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1.5 Uses of the plant protection product (Annex IIA 3.2 to 3.4; Annex IIIA 3.1 to 3.7, 3.9 and 12.1)

1.5.1 Field of use (Annex IIA 3.3; Annex IIIA 3.1)

Bensulfuron methyl is to be used in agriculture under field conditions only.

Bensulfuron methyl 60WG is to be used in agricultural situations and under field conditions only. Bensulfuron methyl 60WG is a selective herbicide which controls broadleaved weeds and *Cyperaceae* in rice crop.

1.5.2 Effects on harmful organisms (Annex IIA 3.2; Annex IIIA 3.2)

1.5.2.1 Nature of the effects on harmful organisms (IIA 3.2)

Bensulfuron methyl affects sensitive weeds through inhibition of the enzyme acetolactate synthase (ALS). Inhibition of ALS leads to the cessation of cell division and subsequent growth processes in plants. Symptoms of chlorosis appear in affected weeds in a matter of days with necrosis and subsequent death occurring within 10 to 25 days under optimal conditions for herbicidal activity.

1.5.2.2 Translocation in plants

When applied into paddy water, bensulfuron methyl rapidly disperses and is subsequently absorbed by the plants. Bensulfuron methyl can be absorbed through both foliage/shoots and roots with the former being most dominant.

Sulfonylureas have a systemic phloem translocation in plants. When sulfonylurea molecules reach the acid cell wall environment either *via* foliar or root uptake, some of the molecules are in the neutral, highly permeable form, and are able to cross the phloem tube/companion cell plasma membrane and enter the phloem. Upon entering the alkaline phloem environment, the molecule dissociates and becomes "trapped" in its anionic form. Once "trapped" the sulfonylurea will move systemically by "mass flow" action with sucrose and other phloem solutes.

1.5.2.3 Effects on harmful organisms (IIIA 3.2)

Bensulfuron methyl 60WG contains bensulfuron methyl, a herbicide from the sulfonylurea class. These herbicides are effective inhibitors of plant root and shoot growth.

Bensulfuron methyl affects sensitive weeds through inhibition of the enzyme acetolactate synthase (ALS). This enzyme is needed to make the essential amino acids isoleucine, leucine and valine. Inhibition of ALS leads to the cessation of cell division and subsequent growth processes in plants. Visual symptoms such as chlorosis, discolouration and leaf malformation appear in affected weeds few days after the herbicide application; necrosis and subsequent death occurring within 10 to 25 days. During this time sensitive weeds do not take up any water or nutrients from the soil, thus removing the competitive effect from the crop.

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1.5.3 Summary of intended uses (Annex IIA 3.4; Annex 3.3 to 3.7, 3.9)

1.5.3.1 Harmful organisms controlled and crops or products protected or treated (IIA 3.4)

1.5.3.1.1 Intended crop uses

Bensulfuron methyl is intended for control of broadleaved weeds (*Dicotyledonous*), aquatic broadleaved weeds (*Monocotyledonous* not *Graminae*) and *Cyperaceae* in rice.

1.5.3.1.2 Harmful organisms controlled

Bensulfuron methyl, when used according to label recommendations, provides selective control or suppression of key annual weeds in rice crop, including *Alisma plantago aquatica*, *Alisma lanceolata*, *Ammania coccinea*, *Bergia spp.*, *Bolboschenus (Scirpus) maritimus*, *Schoenoplectus (Scirpus) mucronatus*, *Scirpus supinus*, *Butomus umbellatus.*, *Cyperus spp.*, *Lindernia spp.*, *Heteranthera reniformis*, *Heteranthera rotundifolia*, *Sparganium erectum*, and *Typha spp.*

1.5.3.1.3 Effects achieved

Sensitive plant species – Within 1-2 hours after the application of bensulfuron methyl, there is a cessation of shoot and root cell division and general plant growth. Secondary plant responses appear a few days after treatment. These visual symptoms include; chlorosis, necrosis, leaf malformation, terminal bud death, enhanced anthocyanin formation and vein discolouration. Plant death generally occurs within 10 to 25 days after the appearance of visual symptoms. During this period they do not take up any water or nutrients from the soil, thus removing the competitive effect from the rice crop.

1.5.3.2 Details of intended use (IIIA 3.3)

Bensulfuron methyl 60WG is intended to be used against broadleaved weeds and *Cyperaceae* in rice crop.

Bensulfuron methyl 60WG can be applied in flooded rice (with 5-10 centimetres of water) or in dry land rice (saturated with 0-1 centimetres of water). In flooded rice the application can occur in pre-sowing of the crop (from 2 to 5 days before sowing) or in post-emergence between 20 to 45 days after sowing (depending on locale this may be between BBCH 12 two leaves and BBCH 29 maximum tillers). In dry land rice the application can only occur in post-emergence between 20 to 50 days after sowing (again depending on locale this may be between BBCH 12 two leaves and BBCH 29 maximum tillers). In any case, according to Good Agricultural Practice, Table 1. 2, only 1 application per year is requested.

Bensulfuron methyl 60WG, when used according to label recommendations, provides selective control or suppression of key annual weeds in rice crop, including *Alisma plantago aquatica*, *Alisma lanceolata*, *Ammania coccinea*, *Bergia spp.*, *Bolboschenus (Scirpus) maritimus*, *Schoenoplectus (Scirpus) mucronatus*, *Scirpus supinus*, *Butomus umbellatus.*, *Cyperus spp.*, *Lindernia spp.*, *Heteranthera reniformis*, *Heteranthera rotundifolia*, *Sparganium erectum*, *Typha spp.*

Within the above recommended growth stage of the crop, application should be targeted at the growth stage of weed species to be controlled. Best control is achieved when weeds are treated at an early growth stage.

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Application timing for weeds is generally from the two leaf stage to maximum tillers, depending on the locale practice and the sensitivity of the weeds to bensulfuron methyl.

1.5.3.3 Application rate (IIIA 3.4)

The maximum recommended dose rate is shown in Table 1. 1.

Table 1. 1: Maximum recommended dose rates of Bensulfuron methyl 60WG

Crop	Rate of plant protection product	Rate of active substance	Maximum number of applications per year
Rice	Bensulfuron methyl 60WG	Bensulfuron methyl	1
	100 g/ha	60 g/ha	

1.5.3.4 Concentration of active substance in material used (e.g., in the diluted spray, baits or treated seed) (IIIA 3.5)

Bensulfuron methyl 60WG is typically applied using spray volumes between 200 and 400 L/ha. The suggested application rate of 60 grams bensulfuron methyl per hectare results in an active substance concentrations in the spray tank between 0.3 g/L (as maximum) and 0.15 g/L (as minimum).

1.5.3.5 Method of application (IIIA 3.6)

Bensulfuron methyl 60WG is diluted in water and applied using tractor-mounted hydraulic field sprayers with ground-directed booms.

1.5.3.6 Number and timing of applications (III 3.7)

Bensulfuron methyl 60WG is applied once per year at the recommended application rate of 100 g/ha. Bensulfuron methyl 60WG can be applied in flooded rice (with 5-10 centimetres of water) or in dry land rice (saturated with 0-1 centimetres of water). In flooded rice the application can occur in pre-sowing of the crop (from 2 to 5 days before sowing) or in postemergence between 20 to 45 days after sowing (depending on locale this may be between BBCH 12 two leaves and BBCH 29 maximum tillers). In dry land rice the application can only occur in postemergence between 20 to 50 days after sowing (again depending on locale this may be between BBCH 12 two leaves and BBCH 29 maximum tillers). In any case, according to Good Agricultural Practice (Table 1. 2), only 1 application per year is requested.

1.5.3.7 Proposed instructions for use (IIIA 3.9)

A European label proposal is included in Bensulfuron methyl EU Dossier, Document C, DuPont-6162 EU.

1.5.4 Information on authorizations in EU Member State (Annex IIIA 12.1)

The active substance Bensulfuron methyl is currently authorized in the following EU member states: Italy, Spain, France, Greece, Portugal.

Approved uses are detailed in Document D-2, DuPont document DuPont-6164 EU.

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Table 1. 2: Good Agricultural Practice (GAP) for the 60WG product containing bensulfuron methyl

Crop and/ or situation (a)	Member State, Country or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL (l) min – max	water L/ha min – max	g as/ha (l) min – max		
Rice	Italy Spain France (South) Greece Portugal Hungary	Londax® Sectar® Testar®	F	Broadleaved weeds and Cyperaceae	WG	600 a.s.g/kg	Flooded Rice Broadcast terrestrial	Pre-sowing application 5-2 days before sowing. Post- emergence Application to be made between 20 to 45 days after sowing. (Depending on locale, this may be between BBCH12 two leaves and BBCH 29 maximum tillers)	1	N/A	N/A	200- 400	0.048- 0.060	Normal Matur ity (BBC H 89)	Flooded: (5-10 cm) water Do not apply within 60 days of harvest.

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Crop and/ or situation (a)	Member State, Country or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL (l) min – max	water L/ha min – max	g as/ha (l) min – max		
Rice	Italy Spain France (South) Greece Portugal Hungary	Londax® Sectar® Testar®	F	Broadleaved weeds and Cyperaceae	WG	600 a.s.g/kg	Saturated soil with 0-1 cm of water Broadcast terrestrial	Post-emergence Application to be made between 20 to 50 days after sowing. (Depending on locale, this may be between BBCH 12 two leaves and BBCH 29 maximum tillers)	1	NA	N/A	200- 400	0.048- 0.060	Normal Maturity (BBCH H 89)	Soil will be flooded with 5-10 cm of water from 2 to 5 days after the treatment and water will be kept in rice paddy for at least 15 days. Do not apply within 60 days of harvest.

[1] The risk assessment has revealed a risk in section 4.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s). (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalecarb-isopropyl). (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha) (m) PHI - minimum pre-harvest interval
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Level 1 – Appendix 1

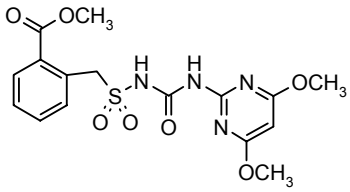
Appendix 1: Chemical names and code numbers for bensulfuron methyl and its degradation products

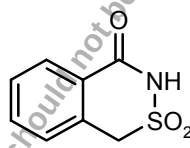
The compounds shown below were found in one or more studies involving the metabolism and/or environmental fate of bensulfuron methyl (DPX-F5384). The parent compound structure of bensulfuron methyl is shown first in this list and is followed by metabolite or related compounds organised by ascending order of IN-Code number which is given in the upper left-hand corner for each molecule in the description form.

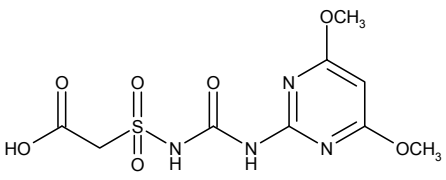
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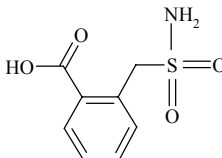
DPX-F5384	CAS name:	methyl 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]methyl]benzoate bensulfuron methyl		
	Common name:			
				
CAS registry number:	83055-99-6	Molecular weight:	410.41	
Structural formula:	C₁₆H₁₈N₄O₇S	Observed in:	active substance	

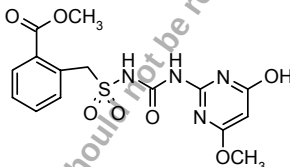
IN-B6895	CAS name:	1H-2,3-benzothiazin-4(3H)-one 2,2-dioxide		
	Common name:	homosaccharin		
				
CAS registry number:	21784-53-2	Molecular weight:	197.21	
Structural formula:	C₈H₇NO₃S	Observed in:	rice foliage, goat, rat, aqueous hydrolysis	

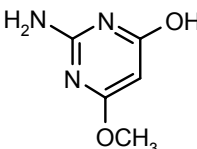
IN-DAT97	CAS name:	[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-acetic acid		
	Common name:	None		
				
CAS registry number:	Not available	Molecular weight:	320.8	
Structural formula:	C₉H₁₂N₄O₇S	Observed in:	water/sediment	

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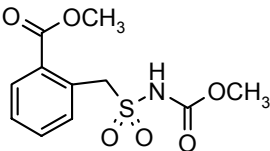
IN-D1R84	CAS name:	2-[(aminosulfonyl)methyl]benzoic acid	
	Common name:	Acid sulphonamide	
			
CAS registry number:	Not available	Molecular weight:	215.23
Structural formula:	C₈H₉NO₄S	Observed in:	soil, water

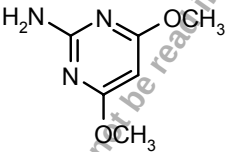
IN-F7880	CAS name:	methyl 2-[[[(4-hydroxy-6-methoxy-2-pyrimidinyl)amino]carbonyl]amino[sulfonyl]methyl]benzoate		
	Common name:	ODM-DPX-F5384, O-desmethyl bensulfuron methyl		
				
CAS registry number:	106985-29-9	Molecular weight:	396.38	
Structural formula:	C₁₅H₁₆N₄O₇S	Observed in:	rice foliage, goat, hen, rat, soil, water	

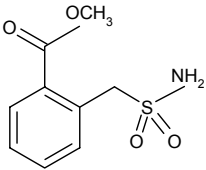
IN-H9235	CAS name:	2-amino-6-methoxy-4-pyrimidinol		
	Common name:	ODM-pyrimidine amine		
				
CAS registry number:	59081-28-6	Molecular weight:	141.13	
Structural formula:	C₅H₇N₃O₂	Observed in:	rat	

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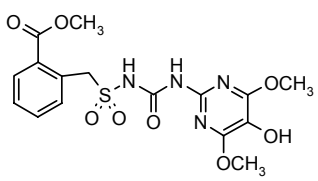
IN-JF987	CAS name:	methyl 2-[[[methoxycarbonyl]amino]sulfonyl]methyl]benzoate
	Common name:	sulfonylurethan
		
CAS registry number:	140618-16-2	Molecular weight: 287.29
Structural formula:	C₁₁H₁₃NO₆S	Observed in: rat

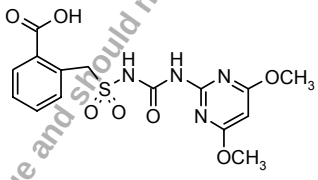
IN-J290	CAS name:	2-amino-4,6-dimethoxypyrimidine
(IN-J0290)	Common name:	pyrimidine amine
		
CAS registry number:	36315-01-2	Molecular weight: 155.16
Structural formula:	C₆H₇N₃O₂	Observed in: rice foliage, goat, rat, soil, water

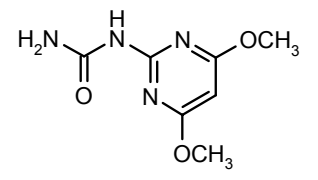
IN-N5297	CAS name:	methyl 2-[(amino)sulfonyl]methyl]benzoate
	Common name:	sulphonamide
		
CAS registry number:	112941-26-1	Molecular weight: 229.26
Structural formula:	C₉H₁₁NO₄S	Observed in: rice foliage, goat, rat, soil, water

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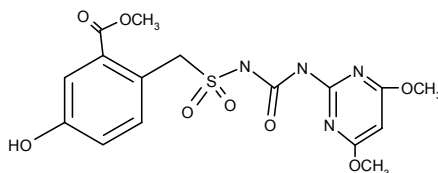
IN-N8989	CAS name:	methyl 2-[[[(5-hydroxy-4,6-pyrimidinyl)amino]carbonyl]amino]sulfonyl]methyl]benzoate		
	Common name:	HPY-DPX-F5384		
				
CAS registry number:	Not available	Molecular weight:	426.41	
Structural formula:	C₁₆H₁₈N₄O₈S	Observed in:	goat, rat, soil/water sediment	

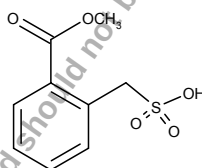
IN-R9419	CAS name:	2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]methyl]benzoic acid		
	Common name:	FA-DPX-F5384, bensulfuron, free acid bensulfuron methyl		
				
CAS registry number:	99283-01-9	Molecular weight:	396.38	
Structural formula:	C₁₅H₁₆N₄O₇S	Observed in:	rat, soil, water	

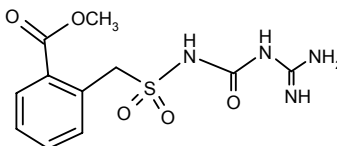
IN-T5831	CAS name:	(4,6-dimethoxy-2-pyrimidinyl) urea		
	Common name:	pyrimidine urea		
				
CAS registry number:	151331-81-6	Molecular weight:	198.18	
Structural formula:	C₇H₁₀N₄O₃	Observed in:	soil photolysis	

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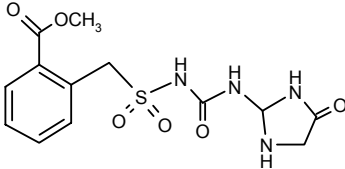
IN-W8956	CAS name:	methyl 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]methyl] hydroxybenzoate		
	Common name:	hydroxylated bensulfuron methyl		
				
CAS registry number:	Not available	Molecular weight:	428.42	
Structural formula:	C₁₆H₂₀N₄O₈S	Observed in:	immature rice foliage, hen, water/sediment	

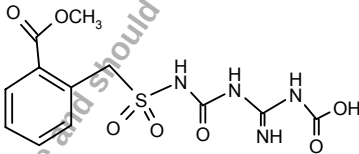
IN-68991	CAS name:	methyl 2-(sulfomethyl)benzoate sodium salt		
	Common name:	sulfonic acid		
				
CAS registry number:	180313-02-4	Molecular weight:	230.24	
Structural formula:	C₉H₁₀O₅S	Observed in:	water/sediment	

IN-78184	CAS name:	methyl 2-[[[(aminoiminomethyl)amino]carbonyl]amino]-sulfonyl]methyl]benzoate	
	Common name:	metabolite III	
			
CAS registry number:	59081-28-6	Molecular weight:	314.32
Structural formula:	C₁₁H₁₄N₄O₅S	Observed in:	hen

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Not assigned	CAS name:	methyl 2-[[[[[4,5-dihydro-5-oxo-1H-imidazol-2-yl]amino]carbonyl]amino]sulfonyl]methyl]benzoate	
	Common name:	dehydrate metabolite II	
			
CAS registry number:	Not available	Molecular weight:	356.36
Structural formula:	C₁₃H₁₆N₄O₆S	Observed in:	hen

Not assigned	CAS name:	methyl 2-[[[[[N-hydroxyacetyl]amino]iminomethyl]amino]carbonyl]amino]sulfonyl]methyl]benzoate	
	Common name:	metabolite II	
			
CAS registry number:	Not available	Molecular weight:	372.36
Structural formula:	C₁₃H₁₆N₄O₇S	Observed in:	hen

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

LEVEL 2

**Reasoned statement of the overall conclusions drawn by
the Rapporteur Member State**

Bensulfuron Methyl

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Level 2

2. Reasoned statement of the overall conclusions drawn by the Rapporteur Member State

The technical dossier includes an Annex II dossier for the active substance Bensulfuron methyl (DPX-F5384) and an Annex III dossier for a Plant Protection Product formulated as Water Dispersible Granules (WG) containing 60% of Bensulfuron methyl. The Plant Protection Product will be referred to in this document as Bensulfuron methyl 60WG (DPX-F5384 60WG).

2.1.1 Identity

All points of Annex IIA points and Annex IIIA Section 1 have been addressed and the information supplied is generally acceptable. Analytical profile of batches was submitted (Confidential information in Volume 4 Annex C).

2.1.2 Physical and chemical properties

Bensulfuron methyl is a sulfonylurea herbicide. The pure active substance is an odourless, white solid with very low vapour pressure and an octanol:water partition coefficient indicating (together with its major metabolites) a low potential for bio-accumulation. Bensulfuron methyl is a weak acid with a pKa of 5.2, existing in water in its anionic form at pH levels above the pKa. pH both affects its water solubility (range: 2 mg/L at pH 5 to 3100 mg/L at pH 9) and hydrolysis rate (hydrolytic half lives: 6d at pH 4, essentially stable at pH 7 and 141d at pH 9). The proposed hydrolytic degradation pathway is shown in Figure ... together with the major metabolites formed. Indirect rather than direct photolysis (low absorption at $\lambda > 290$ nm) may contribute significantly to the degradation of bensulfuron methyl in natural water under sunlight.

Bensulfuron methyl is formulated as water dispersible granules (WG) with an active substance content of 60.1% and essentially inert formulant ingredients. All physical properties and chemical stability specifications, as defined by “The Manual on the Development and Use of FAO Specifications for Plant Protection Products” were met both prior to and after completion of accelerated storage.

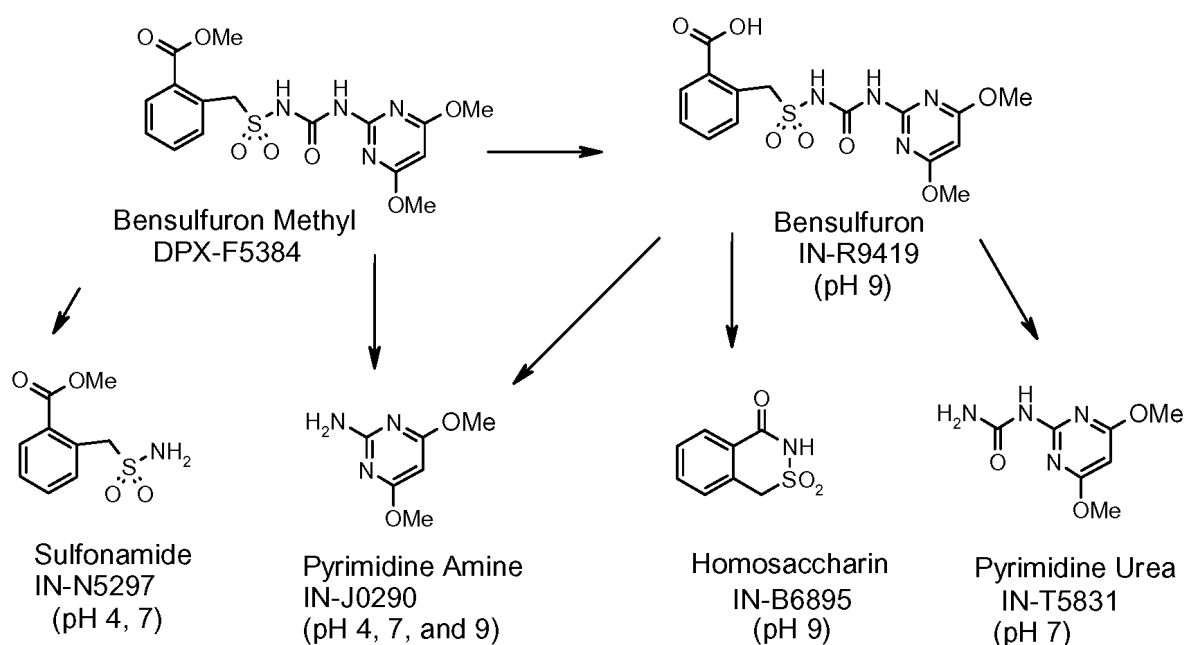
Both the technical material and the formulation are not classified for explosive, oxidising or flammable properties.

In conclusion, the data submitted for bensulfuron methyl active substance show no evidence of adverse physical and chemical properties; also, the plant protection product bensulfuron methyl 60WG shows no adverse properties which could impact user's safety and possesses favourable characteristics with regard to spray tank behaviour and application.

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Figure 2. 1: Proposed degradation pathway of Bensulfuron methyl in aqueous buffers at pH 4, pH 7 and pH 9



2.1.3 Details of uses and further information

All the Annex IIA and Annex IIIA points concerned have been addressed in the Tier II Section 1 summaries.

Bensulfuron methyl is intended for use in rice culture for the control of a range of broadleaved weeds (Dicotyledonous), aquatic broadleaved weeds (Monocotyledonous not Graminae) like Alismataceae, Butomaceae, Pontederiaceae, Typhaceae, and Cyperaceae weeds. It acts mainly through foliar uptake and to a lesser extent by root uptake.

Bensulfuron methyl is applied once per cropping season at a maximum seasonal rate of 60 g a.s./ha. The product can be applied in pre-sowing to the crop (typically from 2 to 5 days before sowing) in flooded rice or in postemergence to the crop both in flooded or dry land conditions (typically from 20 to 45 days and from 20 to 50 days after sowing, respectively). The application is made to the ground using equipment as tractor-mounted, ground-directed broadcast sprayers with water volumes ranging between 200 and 400 L/ha. Depending on the local cultivation practice, application may be performed between two leaves (growth stage BBCH 12) and maximum tillering of the crop (growth stage BBCH 29). Typical seasonal application timing is between mid April and the end of June.

2.1.4 Classification and labelling

Bensulfuron methyl is currently included in Annex I of the Directive 67/548 (16th adaptation to technical progress). The corresponding classification/labelling is as follows:

Symbols:

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Xi (Irritant) – N (Dangerous for the environment)

Risk phrases :

R43 (May cause sensitisation by skin contact)

R51/53 (Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment)

Safety phrases:

S2 (Keep out of the reach of children)

S24 (Avoid contact with skin)

S37 (Wear suitable gloves)

S61 (Avoid release to the environment. Refer to special instructions/Safety data sheets)

The proposed classification and labelling of the active substance according to the provisions of Directive 67/548/EEC are shown in Table 2. 1 and Table 2. 2 below:

Table 2. 1: Proposed classification of bensulfuron methyl according to Directive 67/548/EEC

Hazard	N	Dangerous for the environment
Risk Phrases	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Risk Phrases	R63	Possible risk of harm to the unborn child

Table 2. 2: Proposed labelling of bensulfuron methyl according to Directive 67/548/EEC

Hazard	N	Dangerous for the environment
Risk Phrases	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety Phrases	S35	This material and container must be disposed of in a safe way.
	S57	Use appropriate containment to avoid environmental contamination
Risk Phrases	R63	Possible risk of harm to the unborn child

Justifications for the proposal:

Mammal toxicity

Bensulfuron methyl, according to Directive 67/548/EEC and its 16th adaptation to technical progress, is classified as skin sensitizer, since when evaluated for dermal sensitisation potential by Closed-patch repeated insult (Maximization method) produced an insignificant weak hypersensitivity response in Guinea pigs. However all subsequent testing of bensulfuron methyl showed that the technical ingredient and formulations were negative for dermal sensitisation using Buehler and Magnusson-Kligman Maximisation testing methodologies. In addition, no incidence of skin sensitisation has been noted in the large population of bensulfuron methyl users, who have been in regular contact with bensulfuron methyl for several years. RMS agrees with the notifier about the proposal that bensulfuron methyl should not be classified under R43 (skin sensitizer).

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Bensulfuron methyl is of low acute toxicity by the oral, dermal and inhalation routes of exposure with oral LD₅₀ greater than 5000 mg/kg, dermal LD₅₀ greater than 2000 mg/kg and an inhalation LC₅₀ greater than 5 mg/L. According to the provisions of Directive 67/548/EEC, classification for acute oral, dermal, and inhalation toxicity should not apply.

In the developmental toxicity study in rats, the NOAEL for maternal effects was 2000 mg/kg/day based on the absence of maternal toxicity at 2000 mg/kg bw/day. The foetal NOAEL was 500 mg/kg/day, based on the adverse effects on pup weight, and the presence of variations in pups at 2000 mg/kg/day.

In light of these findings the RMS proposes that bensulfuron methyl should be classified under R 63 (possible risk of harm to the unborn child)

Environmental toxicity

Environmental classification of bensulfuron methyl is based on the acute aquatic toxicity to algae (72-hour EC₅₀ on *Selenastrum capricornutum* is 0.020 mg/L) and to aquatic weeds (14-day EC₅₀ on *Lemna gibba* is 0.0008 mg/L). Bensulfuron methyl is not considered readily biodegradable under OECD protocol 301.

Physical and chemical hazards

Bensulfuron methyl should not be classified for physical and chemical hazards, according to Directive 67/548/EEC and according to available information.

2.1.5 Proposals for the classification and labelling of preparations (Annex IIIA 12.3 and 12.4)

Bensulfuron methyl 60WG is classified as follows according to Directive 1999/45/EC:

Symbol: N

Hazard: Dangerous for the environment

This classification is based on the following properties of the plant protection product:

R50: Acute aquatic toxicity to algae, 72-hour E_rC₅₀ on *Selenastrum capricornutum* = 0.020 mg/L and acute aquatic toxicity to aquatic weeds, 14-day E_rC₅₀ on *Lemna gibba* = 0.0008 mg/L

R53: Contains 60% w/w of bensulfuron methyl assigned

R53: Bensulfuron methyl being not readily biodegradable.

See Table 2.3 and Table 2.4.

2.1.6 Proposals for risk and safety phrases

The proposed classification and labelling for Bensulfuron methyl 60WG according to the provisions of Directive 1999/45/EC are shown risk and safety phrases are given in Tables below:

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Table 2. 3: Proposed classification for Bensulfuron methyl 60WG according to Directive 1999/45/EC

Component	Abbr.	Full text	Justification
Symbol of danger	N	Dangerous for the environment	Related to R50
Risk phrases	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	R50: 72-h E_rC_{50} on <i>Selenastrum capricornutum</i> = 0.020 mg/L and 14-day E_rC_{50} on <i>Lemna gibba</i> = 0.0008 mg/L R53: product contains 60% w/w of Bensulfuron methyl, active substance with assigned R53.
Risk phrases	R63	Possible risk of harm to the unborn child	Developmental toxicity study in rats: NOAEL maternal > 2000 mg/kg/day NOAEL foetal=500mg/kg/day

Table 2. 4: Proposed labeling for Bensulfuron methyl 60WG according to Directive 1999/45/EC

Component	Abbr.	Full text	Justification
Symbols	N	Dangerous for the environment	See classification
Risk phrases	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	See classification
Risk phrases	R63	Possible risk of harm to the unborn child	See classification
Safety phrases	S35	This material and its container must be disposed in a safe way	Appropriate for substances and preparations assigned the symbol N and not likely to be used by the general public
	S57	Use appropriate containment to avoid environmental contamination.	
Hazardous components		Contains bensulfuron methyl: May produce an allergic reaction	According to the provisions of Directive 1999/45/EC (article 10) label disclosure is required since bensulfuron methyl content is 60% (600 g/kg)

Note: Bensulfuron methyl 60WG is restricted to agricultural uses. Therefore the product is not destined to be sold or to be used by the general public. The strict application of labelling criteria according to Annex VI of Directive 67/548/EEC (which Directive 1999/45/EC refers to) does not require more safety phrases than those mentioned above.

2.2 Methods of analysis

All recently developed and validated analytical methods are considered adequate for the determination of bensulfuron methyl (DPX-F5384) in the technical material, plant protection product, rice grain and rice straw, soil, water and air. Given the revised definition of residue in soil (AE F082671/parent, IN-J0290, IN-N5297, IN-D1R84, IN-R9419), in surface water (AE F082671/parent, IN-J0290, IN-N5297, IN-R9419) and in drinking/groundwater (AE F082671/parent, IN-N5297, IN-T5831, IN-DAT97) a request will follow for the submission of suitable analytical methods for the determination of these metabolites. Adequate methods exist for the quantitation of impurities (process residual solvents, water, and inorganic ions) in the active substance as

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manufactured. The inert ingredients contained in the plant protection product (bensulfuron methyl 60WG) are not expected to interfere with the extraction and analysis of bensulfuron methyl residues in any matrix.

Methods for the determination of bensulfuron methyl in foodstuffs of animal origin were not submitted due to the absence of residues in feedingstuffs. Also, no method for the determination of bensulfuron methyl or metabolites in body fluids and tissues were submitted since no of them has been classified as highly toxic or toxic to humans and is not expected to accumulate in human tissues in case of accidental contact or ingestion.

Analytical methods considered suitable for use by regulatory agencies for monitoring, confirmatory and enforcement purposes are resumed in Table 2.5.

Table 2. 5: Proposed analytical methods for monitoring bensulfuron methyl residues

Matrix	Reference and report	Separation / Quantitation	Limit of determination	Comments
Technical material	Du Pont-7095 Morgan E.A., 2002	LC/UV GC/FID	Active substance and impurities >1g/kg	Method validated for quantitative analysis by LC/UV at 236nm (a.s.) and 230nm (impurities) GC/FID for the determination of solvents (Confidential Attachment)
Plant Protection Product	Du Pont-7095 Morgan E.A., 2002	LC/UV	Active substance	No specific method developed since inert ingredients contained in p.p.p. not expected to interfere with extraction and analysis of the a.s..
Rice Grain Rice Straw	Du Pont-4510: Amoo and Jones, 2001	LC/UV LC/MS LC/MS/MS	0.010 mg/kg 0.050 mg/kg	Method validated for quantitative analysis by LC/UV with column switching, LC/MS, or LC/MS/MS
Animal Products				No method required since residues are not expected in food from animal origin
Soil	Du Pont-5082 Rev. No. 1: Hill and Stry, 2001	LC/MS/MS	0.050 µg/kg	Multiple sulfonylurea herbicides analysis method.
Water	Du Pont-5491 Revision No. 1: Devine and Jin, 2004	LC/MS/MS	0.050 µg/L	Multiple sulfonylurea herbicides analysis method.
Air	Du Pont-4560 Amended Report: Bacher, 2001	LC/MS/MS	0.30 µg/m ³	Multiple sulfonylurea herbicides analysis method.
Body fluids and tissues				No method required (low acute toxicity of a.s. and metabolites, accumulation in tissues not expected)

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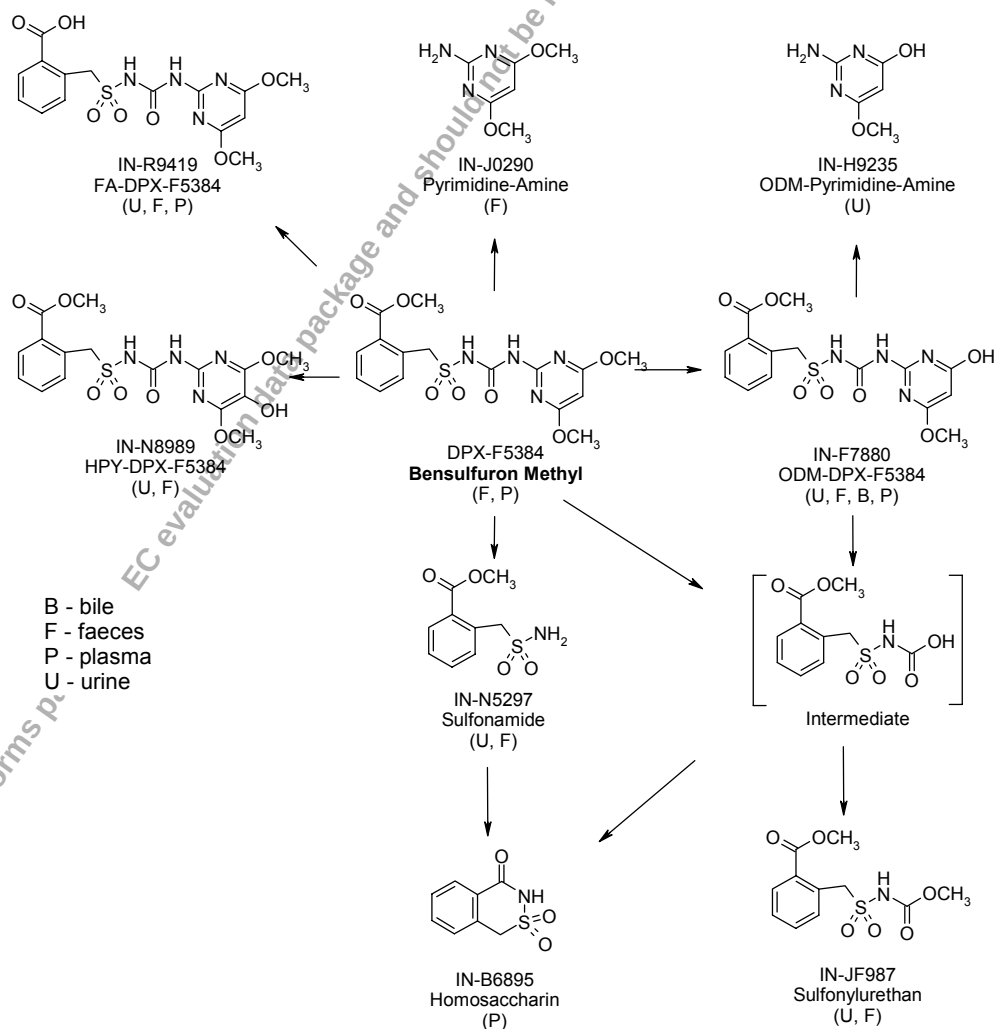
2.3 Impact on human and animal health

2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

2.3.1.1 Metabolism

At doses relevant to human exposure, bensulfuron methyl was rapidly and extensively absorbed from the gastrointestinal tract (e.g., >83% and >90% absorbed for female and male rats, respectively). It was extensively metabolised in rats; primarily by *O*-demethylation and hydroxylation of the pyrimidine ring as well as sulfonamide bond cleavage. Although urine was the predominant route of elimination, significant amounts were also eliminated through the bile and to a lesser extent through the faeces. Elimination was rapid, with plasma elimination half-lives ranging from approximately 5 to 9-hours. Excretion in the urine, bile and faeces was essentially complete within 48- to 72-hours. Tissue clearance was also rapid and there was no evidence of accumulation, e.g., ≤0.3% of ¹⁴C-residues remained in tissues after 96 hours. A proposed metabolic pathway for bensulfuron methyl in rat is given in Figure 2. 2.

Figure 2. 2: Metabolic Pathways for bensulfuron methyl in rat



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2.3.1.2 Acute toxicity

Results of acute toxicity studies in rats and rabbits indicate that bensulfuron methyl has no significant acute toxicity via the oral, dermal, or inhalation routes of exposure. The oral LD₅₀ was greater than 5000 mg/kg for female and male rats. The dermal LD₅₀ in rabbits was greater than 2000 mg/kg and the inhalation LC₅₀ in male and female rats was greater than 5 mg/L.

Bensulfuron methyl is not an eye or skin irritant. Following dermal application neither oedema nor erythema was observed in rabbits. Following ocular instillation, bensulfuron methyl produced no ocular irritation in any of treated eyes (washed or unwashed). The dermal sensitisation potential of bensulfuron methyl was evaluated in albino guinea pigs by Closed-patch repeated insult dermal sensitisation study (Maximisation method). Bensulfuron methyl was not a dermal sensitizer by this method.

Bensulfuron methyl 60WG has low acute toxicity *via* the oral and dermal routes of exposure. There were no mortalities at the highest dose/concentration tested. There were no target organs identified by gross pathological evaluations. Clinical signs were generally non-specific and reversible. The inhalation LC₅₀ for the technical bensulfuron methyl was greater than 5 mg/L and there were no compound-related mortalities and no target organs were identified by gross pathological evaluation. Based on the low toxicity of the active substance, Bensulfuron methyl 60WG would not be expected to produce significant acute toxicity by the inhalation route of exposure. Bensulfuron methyl 60WG is neither a skin nor eye irritant and when tested for skin sensitisation through both Magnusson-Kligman maximisation method and Buelher method did not cause skin sensitisation.

2.3.1.3 Subchronic toxicity

In subchronic (90-day) feeding study in rats, the NOAEL was 1500 ppm (93 mg/kg/day) in males and 7500 ppm (567 mg/kg/day) in females based on mild haematology effects in males. The haematology effects typically consisted of decreases in number of erythrocytes, haemoglobin concentration, and haematocrit.

The NOAEL in the 90-day study with bensulfuron methyl in dogs was 1000 ppm (32 mg/kg/day in males and 37 mg/kg/day in females) based on elevations in the activities of alkaline phosphatase and alanine aminotransferase that were consistent with gross and microscopic liver changes at the 10,000 ppm dietary concentration. Body weight and food efficiency were also lower in 10,000 ppm dietary concentration for males and females. However, in the one-year study in dogs, the NOEL was 750 ppm (21.4 and 19.9 mg/kg/day for males and females, respectively) based on liver enlargement.

Mice were less sensitive to the subchronic toxicity of bensulfuron methyl relative to the rat and dog, with NOAELs of 1272 and 1401 mg/kg/day in males and females, respectively. These NOAELs were based on the absence of adverse effects at dietary concentrations up to 10,000 ppm.

2.3.1.4 Chronic toxicity

Chronic studies with bensulfuron methyl were conducted in rats and mice to determine the carcinogenic potential and/or chronic toxicity of the compound. Effects generally similar to those seen in the 90-day studies were seen in the chronic studies. Bensulfuron methyl was not carcinogenic in the rat or mouse.

The chronic NOAEL in rats was 750 ppm for both males and females, equivalent to 30 and 40 mg/kg/day, respectively. In male rats, the NOAEL was based on body weight, nutritional effects, decreased haemoglobin,

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and histological changes in the liver at 7500 ppm. In females, the NOAEL was based on body weight and nutritional effects, and histological changes in the liver at 7500 ppm. The chronic NOAEL in mice was 5000 ppm for both males and females, equivalent to 455 and 460 mg/kg/day, respectively, based on the absence of persistent, adverse effects at any dietary concentration in either males or females. The NOAEL in both male and female dogs fed bensulfuron methyl at the end of 1-year-dog study was 750 ppm (21.4 mg/kg/day in males and 19.9 mg/kg/day in females) based on increases in alanine aminotransferase activity, alkaline phosphatase activity, liver weight, and liver to body weight ratio at 7500 ppm.

2.3.1.5 Genetic toxicity

Most genetic toxicity studies, including a rat *in vivo* bone marrow study, were negative. However, bensulfuron methyl was positive in an *in vitro* Sister Chromatid Exchange assay without metabolic activation. However, the sister chromatid exchange assay is considered to be less than ideal for detecting effects due directly to a chemical (Preston, R.J. "Chromosomal Changes" in The Use of Short- and Medium-term Tests for Carcinogens and Data on Genetic Effects in Carcinogenic Hazard Evaluation, Ed. by D.B. McGregor, J.M. Rice, and S. Venitt, IARC Scientific Publications No. 146.) Based on these studies, the weight of evidence indicates that bensulfuron methyl is not genotoxic.

Reproductive and developmental toxicity

In the two-generation reproduction toxicity study with bensulfuron methyl the NOAEL for parental toxicity was 250 ppm (19.5–22.3 mg/kg bw/day) based on slight reductions in body weight in F₁ adult males at 7500 ppm and above. The NOAEL for reproductive and fertility effects was 20,000 ppm (1404.5–1874.0 mg/kg bw/day), based on the absence of any effects at any dietary concentration. The NOAEL for effects on pup growth and development was 250 ppm (22.3 mg/kg bw/day for F₁ dams), based on a reduction in the body weight of F₁ pups at 7500 ppm and above. Developmental toxicity studies were conducted with bensulfuron methyl in rats and rabbits. Bensulfuron methyl was not teratogenic. In the developmental toxicity study in rats, the NOAEL for maternal effects was ≥2000 mg/kg/day based on the absence of maternal toxicity at 2000 mg/kg bw/day. The foetal NOAEL was 500 mg/kg/day, based on the adverse effects on pup weight, and the presence of variations in pups at 2000 mg/kg/day. In the developmental study conducted in rabbits, both the maternal and foetal NOAEL was 300 mg/kg/day based on death of females dosed with 1500 mg/kg/day and on the decreased maternal body weight and food consumption, and on total resorptions and decreased pup body weight at 1500 mg/kg bw/day.

2.3.1.6 Neurotoxicity

Bensulfuron methyl was evaluated for its potential to produce neurotoxicity in laboratory animals administered sub lethal doses. For this evaluation, existing acute, subchronic, reproduction, developmental, and chronic toxicity studies in rodents and non-rodents were considered. Clinical observations indicative of potential effects on the central and peripheral nervous system were evaluated, and no observations suggestive of neurotoxicity were noted. This evaluation was further supported by the absence of gross and microscopic effects on nervous system tissues. Bensulfuron methyl is not structurally related to a known neurotoxin or class of neurotoxins. It is

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an herbicide; and therefore, its pesticide mode of action is designed to interact with plants, not the mammalian nervous system.

2.3.1.7 Conclusions - mammalian toxicology

Bensulfuron methyl has no significant acute toxicity *via* the oral, dermal, and inhalation routes of exposure. It is not an eye or skin irritant and does not cause skin sensitisation. Bensulfuron methyl is not genotoxic, carcinogenic, or teratogenic. In the developmental toxicity study in rats, the NOAEL for maternal effects was ≥ 2000 mg/kg/day based on the absence of maternal toxicity at 2000 mg/kg bw/day. The foetal NOAEL was 500 mg/kg/day, based on the adverse effects on pup weight, and the presence of variations in pups at 2000 mg/kg/day. In the developmental study conducted in rabbits, both the maternal and foetal NOAEL was 300 mg/kg/day based on death of females dosed with 1500 mg/kg/day and on the decreased maternal body weight and food consumption, and on total resorptions and decreased pup body weight at 1500 mg/kg bw/day. The lowest effect levels following exposure to bensulfuron methyl are based on increases in alanine aminotransferase activity, alkaline phosphatase activity, liver weight, and liver to body weight ratio at 7500 ppm in male and female dogs.

The lowest NOAEL is 19.9 mg/kg/day, based on clinical chemistry and organ weight changes in the 1-year study in dogs.

2.3.1.8 Summary of medical data

DuPont has produced bensulfuron methyl on a commercial scale for more than 17 years. The Manati, Puerto Rico manufacturing site has produced bensulfuron methyl for the vast majority of this time. The medical records of randomly selected employees, who work at Manati in the manufacturing, formulation or packaging areas for bensulfuron methyl were reviewed. An evaluation of these records indicated the parameters measured were within the normal published ranges or were normal with respect to the opinion of the examining physician. Therefore, there were no occupational illnesses or symptoms associated with this product.

There have been no reported accidental poisonings and there are no known specific human effects. Therefore, no specific intervention or antidote is indicated and in case of poisoning, the patient should be treated symptomatically.

2.3.1.9 Metabolite toxicity

IN-B6895 (homosaccharin), IN-N5297 (sulphonamide), IN-R9419 (free acid bensulfuron methyl), IN-F7880 (*O*-desmethyl bensulfuron methyl), and IN-N8989 (hydroxypyrimidinyl bensulfuron methyl) are the metabolites that were often observed in rice foliage, goat, rat, soil and water. Because several of these metabolites were either synthesis intermediates or were common to metabolites from other active substances, limited toxicology data were available.

The following metabolites were tested and exhibited low acute oral toxicity, with an oral LD₅₀ of 1200 mg/kg bw for IN-J290 and Approximate Lethal Doses (ALD) ranging from 7500 to 11000 mg/kg body weight: IN-B6895, IN-N5297, IN-R9419 and IN-J290. Note: in addition to the ALD, a 10-dose oral range finding study

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was also conducted on metabolite IN-J290 to further characterize any potential oral toxicity from repeated dosing. This also resulted in low toxicity and exhibited a NOAEL ≥ 450 mg/kg bw/day.

For each of these four metabolites (IN-B6895, IN-N5297, IN-R9419 and IN-J290), negative results were obtained from *in vitro* bacterial gene mutation assays in *Salmonella typhimurium*.

Based on the low acute oral toxicity, the lack of genotoxicity and the fact that all of these metabolites were present during mammalian toxicology testing, additional testing was considered unnecessary.

2.3.2 ADI

The chronic studies in rats and mice and 1-year dog study were considered the appropriate studies as a basis for the ADI. Of these three studies the lowest NOAEL was observed in the 1-year dog study (19.9 mg/kg bw/day, female). This NOAEL was based on liver weight increases and changes in clinical parameters (alanine aminotransferase and alkaline phosphatase). Therefore, the proposed ADI is 0.2 mg/kg/day, based on the NOAEL of 19.9 mg/kg/day applying a default 100 fold safety factor.

Table 2. 6: ADI derivation: Summary of bensulfuron methyl long-term toxicity studies

Study / doses (mg/kg bwt /day)	NOAEL (mg/kg bwt /day)	LOAEL (mg/kg bwt /day)	Effects at the LOAEL	Reference
2-Year Rat M: 2, 30, 309 F: 2.7, 40, 405	30 (M) 40 (F)	309 (M) 405 (F)	Reduced body weights Reduced red blood cell mass Liver histopathological changes	Stadler, 1986
2-Year Mouse M: 0.87, 13.4, 226, 455 F: 0.93, 13.6, 227, 460	455 (M) 460 (F)	> 455 (M) > 460 (F)	No adverse effects at the highest dose tested.	Maita, 1985
1-Year Dog M: 1.4, 21.4, 237.3 F: 1.4, 19.9, 222.6	21.7 (M) 19.9 (F)	237.3 (M) 222.6 (F)	Increased liver weight. Increased liver leakage enzymes (ALT, ALP)	Bolte, 1986

2.3.3 ARfD (acute reference dose)

No Acute Reference Dose (ARfD) has been established because toxicological end points are not relevant for acute oral dietary exposure. Consequently no acute dietary exposure has been estimated.

2.3.4 AOEL

Results of the bensulfuron methyl 90-day feeding studies, 1 year dog study, and the developmental and reproductive toxicity studies are considered appropriate for determination of the AOEL, according to the EU document 7531/VI/95-rev 6, adopted by the Scientific Committee on Plants on 23 October 2002, "Guidance for the setting of AOELs".

The 1-year dog study has the lowest relevant NOAEL (19.9 mg/kg bw/day) for establishing the AOEL. The dog's response to bensulfuron methyl administration results in more significant systemic toxicity, e.g., effects on liver enzymes and liver histopathology. The 1-year dog study NOAEL was based on clinical chemistry and organ weight effects indicative of liver toxicity.

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Even if in developmental study in rat there is a foetal effect (reduced pup weight and abnormal ossification) at doses lower than those eliciting parental toxicity, the NOAEL is higher (22 fold) than the 1-year dog study NOAEL; furthermore in the rat reproduction study the parental systemic toxicity NOAEL is pretty near (19.5 mg/kg bw/day). That's why choosing the 1-year dog study NOAEL will prevent embryotoxic effects, which may be induced by a single exposure during the critical phase.

Using the NOAEL of 19.9 mg/kg bw/day and applying a default safety factor of 100 results in an AOEL of 0.2 mg/kg/day (absorbed dose). The metabolism study conducted in rats indicates that bensulfuron methyl is almost completely absorbed from the gastrointestinal tract, thus no correction for oral absorption is applied. The proposed AOEL is 0.2 mg/kg bw/day.

2.3.5 Drinking water limit

In absence of suitable data from human or animal studies of bensulfuron methyl in drinking water, it is appropriate to follow the International Programme on Chemical Safety (WHO, 1994) approach to the Maximum Allowable Concentration (MAC) in water allocating one tenth of the ADI to water and then this allocation is converted to a concentration in water as follows:

$$\frac{\text{ADI} \times \text{body weight} \times \text{P}}{\text{C}}$$

Where:

Body weight = body weight (60 kg) for adults

P = fraction of the ADI allocated to drinking water (*i.e.*, 1/10)

C = daily consumption of water (2 litres)

Therefore the MAC for bensulfuron methyl is 0.6 mg/L

2.3.6 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it

2.3.6.1 Operators, bystanders, and workers

Estimation of operator exposure using the German Model

Operator exposure was estimated according to the German model as published in *Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection): Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Berlin-Dahlem, no. 277, 1992*. A summary of the estimated exposures is presented in Table 2. 7. Details of the estimated exposure calculations are presented in Appendix.2.

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Table 2. 7: German model operator exposure estimation for Bensulfuron methyl 60WG

Crop	Application method	Exposure (mg a.s./kg bw/day)		% of AOEL	
		No PPE	PPE ^a	No PPE	PPE ^a
Field crop 200 L/ha	Tractor mounted equipment 0.06 kg a.s./ha,	0.0024	0.0007	1.2	0.33

Note: German model = geometric mean values

^a Gloves for mixing/ loading and gloves for application

Estimation of operator exposure using the UK POEM model:

Operator exposure was estimated according to the revised Predictive Operator Exposure Model (UK POEM) 2003. The model assumes a workload of 50 ha per day for field crops, e.g. cereals. For rice culture in Europe, a considerably lower workload is appropriate. For the present modelling a conservative workload of 20 ha/day has been utilised. A summary of the estimated exposures calculated for bensulfuron methyl is presented in Table 2. 8. Details of the estimation of exposure calculations are presented in Appendix 2.

Table 2. 8: UK POEM operator exposure estimation for Bensulfuron methyl 60WG

Crop	Application method	Exposure (mg a.s./kg bw/day)		% of AOEL	
		No PPE	PPE ^a	No PPE	PPE ^a
Field crop 200 L/ha	Tractor mounted/trailed boom sprayer, hydraulic nozzles, 0.06 kg a.s./ha	0.0140	0.0057	7	2.85

^a Gloves for mixing/loading and gloves for application

Summary of operator exposure estimations

Operator exposure and risk estimations for field crop applications have been made using the German and UK models. A fully acceptable margin of safety for operators was demonstrated using both models with or without the use of PPE (gloves). Considering the conservative assumptions of the models, the overall estimated risk to operators is considered to be fully acceptable when loading, mixing, and during application by tractor mounted equipment in rice, according to good agricultural practices and label specified directions for use.

2.3.6.2 Bystander Exposure

Bensulfuron methyl 60WG has a relatively low use rate, and is applied by ground-directed tractor-mounted hydraulic nozzles that produce large non-respirable spray droplets. Bensulfuron methyl and Bensulfuron methyl 60WG have low volatility and when considered along with the low inhalation toxicity, supports negligible inhalation exposures and risks to bystanders. Potential dermal exposure is estimated using drift estimates based on data published by EPPO (Ganzelmeier, et. al., 1995). Assuming a bystander may be within 10 meters of the spray application, the data shows that for field crops (e.g., rice), the drift estimate at this distance is 0.3%.

The following bystander exposure assumptions were made: the maximum application rate for Bensulfuron methyl 60WG of 100g/ha in rice was used and the spray was evenly distributed over the treated area (10,000

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m²), equating to an application rate of 10 mg/m²; a bystander located 10 meters from the field might receive 0.3% drift, thus the deposition could reach 0.03 mg/m²; if one-half the body surface (approximately 1 m²) is uncovered, the skin deposition would be 0.018 mg bensulfuron methyl. Using the 1.7% value from the *in vivo* dermal penetration study as human skin absorption value, the absorbed dose would be 0.00032 mg bensulfuron methyl; for a 60 kg body weight, the exposure would be 0.0000051 mg/kg bw/day of bensulfuron methyl.

A comparison with the proposed AOEL of 0.2 mg/kg bw/day for bensulfuron methyl shows there is a margin of safety >40,000. This gives assurance that it is unlikely that any adverse health effect may result in bystanders exposed to bensulfuron methyl from agricultural use of Bensulfuron methyl 60WG. Accordingly, measurement of bystander exposure is not required.

2.3.6.3 Worker Exposure

Bensulfuron methyl 60WG herbicide is labelled for use on field crop, rice. Plant metabolism studies carried out in rice demonstrated that bensulfuron methyl was rapidly metabolised indicating that residues would not be found in grain at harvest. In addition rice is mechanically harvested, which further reduces the potential for exposure. Therefore, it is unlikely that any significant exposure to Bensulfuron methyl 60WG will occur. For these reasons, the establishment of a re-entry interval for workers is not necessary.

2.4 Residues

2.4.1 Residue relevant to consumer safety

2.4.1.1 Use patterns

It is intended to support the use of the herbicide bensulfuron methyl on rice, both on flooded and saturated soil conditions, both in pre-sowing and in post-emergence application.

2.4.1.2 Residue trials

Trials to meet EU requirements according to or exceeding GAP requirements were carried out in flooded and saturated land rice with formulations containing bensulfuron methyl.

From flooded rice paddies, residue levels in rice grain at commercial harvest were below the limit of quantification: <LOQ of 0.020 mg/kg for grain specimens harvested during the 1995 and 1996 growing seasons (6 trials) and <LOQ of 0.010 mg/kg for grain samples harvested during the 2000 growing season (3 trials). Residue levels in rice grain grown in saturated soil conditions at commercial harvest were below the limit of quantification (0.010 mg/kg).

Residue levels in rice straw from field trials in flooded conditions were below the limit of quantification (<LOQ of 0.05 mg/kg) for 3 trials. In saturated soil conditions residue levels were below the limit of quantification of 0.05 mg/kg for specimens harvested during the 2002 growing season (3 trials), except for one residue value of 0.1 mg/kg.

2.4.1.3 Storage stability

Bensulfuron Methyl is stable in rice grain up to 42 months at -24°C and in rice straw up to 18 months at -20°C.

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2.4.1.4 Effect of industrial or household processing

According to the European guidelines in Appendix E doc. 7035/VI/95 rev.5 (22/7/97) processing studies are not necessary “if no significant (>0.1 mg/kg) or no analytically quantifiable residues occur in the plant product being processed”. No quantifiable bensulfuron methyl residues were found in any mature rice grain specimen at the time of harvest. Therefore, no processing study is necessary.

2.4.1.5 Livestock feeding studies

No significant residues (≥ 0.1 mg/kg of the total diet received) occur in crops fed to animals; the dietary burden (mg/kg diet/day), calculated using values from submitted residue trials, is above the threshold of 0.1 mg/kg diet/day for dairy and beef cattle, poultry and pigs. According to the European guidelines in Appendix G doc. 7031/VI/95 rev.4 (22/7/96) livestock feeding studies are not necessary to assess human exposure to bensulfuron methyl from animal food sources.

2.4.1.6 Residues in succeeding or rotational crops

Bensulfuron methyl is degraded in soil relatively quickly (mean soil DT50 in field trials ranges from 4 to 14 days), therefore, it is very unlikely that significant quantities ($\geq 10\%$ of applied active substance) will remain in the soil 100 days after application. However, a confined rotational crop study was conducted.

The total radioactive residues in the [phenyl(U)- ^{14}C]bensulfuron methyl and [pyrimidine-2- ^{14}C]bensulfuron methyl treated soils at planting were <0.01 mg/kg. The radioactivity residues did not accumulate in rotational crops grown in Keyport silt-loam soil treated with ^{14}C bensulfuron methyl at the rate of 67.2 g a.s./ha and aged for 120 days prior to the planting. The majority of soil radioactivity was extracted. Unextracted radioactivity was <0.002 mg/kg. Bensulfuron methyl was the only radioactive residue in soil samples and was present at 0.005-0.006 mg/kg. Total ^{14}C residues in food items from wheat, onions, garlic, cabbage, and beets grown in the soil treated were less than 0.01 mg/kg. Since all plant samples contained less than 0.01 mg/kg (10 $\mu\text{g/kg}$) total ^{14}C residues, further work to characterise radiolabeled metabolites was not attempted.

2.4.1.7 Estimates of potential and actual dietary exposure through diet and other means

The calculation of the potential intake of bensulfuron methyl residues in rice is made based on the proposed MRLs of 0.02 mg/kg, and compared to the ADI (0.2 mg/kg bw/day) proposed in the toxicological evaluation.

Chronic dietary risk assessment

TMDIs were calculated using the WHO/GEMS Food European Regional diet for adults and the WHO/GEMS Consumption Cluster Diets, the UK approach based on the diet for adults, infants, toddlers, 4-6 years-old children, 7-10 years-old children, 11-14 years-old children, 15-18 years-old children, vegetarians and elderly people and the German approach based on the diet for children 2-5 years old.

A summary of the chronic dietary risk assessments is given in Table 2.4.1

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Table 2. 9: Summary of the chronic dietary risk assessment for bensulfuron methyl

Diet/model	Person	TMDI (µg/kg bw/day)	% of ADI
WHO/FAO European Regional	Adult	0.004	<0.1
WHO/FAO Consumption Cluster Diets			
Cluster B	Adult	0.011	<0.1
Cluster E	Adult	0.004	<0.1
Cluster F	Adult	0.004	<0.1
Cluster D	Adult	0.011	<0.1
UK Consumer Exposure Model	Adult	0.045	<1
	Infant	0.056	<1
	Toddler	0.094	<1
	4-6 Years	0.074	<1
	7-10 Years	0.10	<1
	11-14 Years	0.078	<1
	15-18 Years	0.053	<1
	Vegetarian	0.04	<1
	Elderly (Own home)	0.023	<1
	Elderly (Residential)	0.0097	<1
German model	Child 2-5 years	0.005	<0.1

The dietary intake of the residue of concern is far below the proposed ADI. No chronic risk to the consumer is to be expected by way of residue intake with food.

No Acute Reference Dose (ARfD) has been established because toxicological end points are not relevant for acute oral dietary exposure; consequently no acute dietary exposure has been estimated.

2.4.2 Definition of the residues relevant to MRLs

The fate of Bensulfuron methyl has been investigated in rice plants, in livestock (goat, hen) and in rotational crops metabolism studies. Based on the metabolism data, residues for plants, plant products and products of animal origin is proposed as bensulfuron methyl.

2.4.2.1 Metabolism in plants

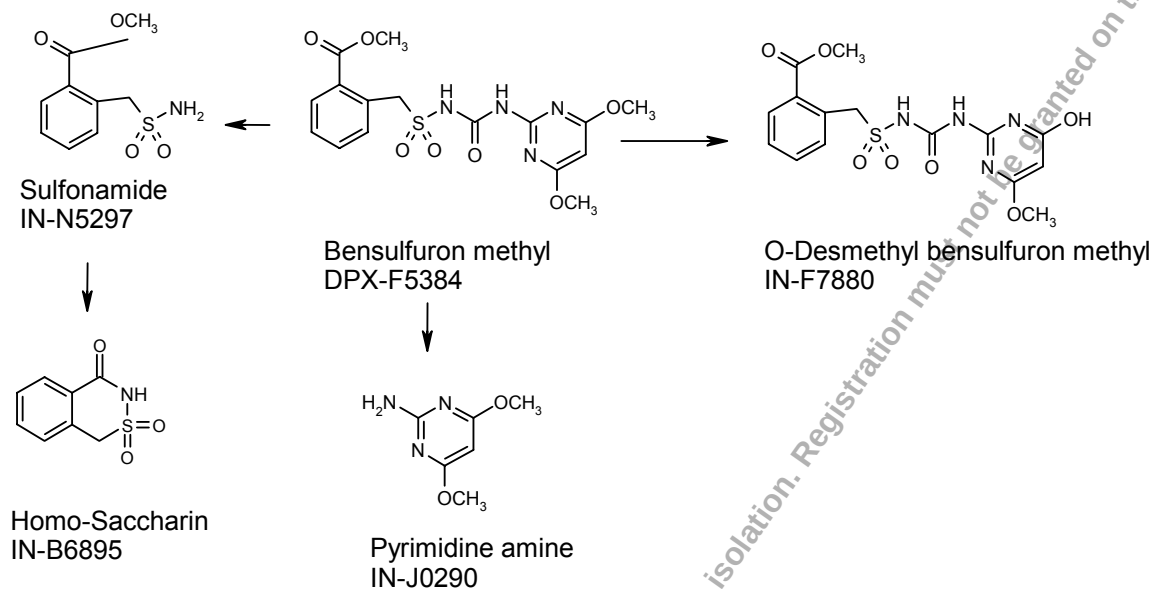
The following primary metabolic steps were noted in rice plants:

O-desmethylation of the pyrimidine ring yielding O-desmethyl-bensulfuron methyl (IN-F7880);
sulfonylurea bridge cleavage which produces sulfonamide (IN-N5297) and pyrimidine amine (IN-J0290). The sulfonamide cyclises to yield homo-saccharin (IN-B6895). The total radioactive residues in rice straw and grain from [phenyl(U)-¹⁴C]bensulfuron methyl and [pyrimidine-2-¹⁴C]bensulfuron methyl were very low (0.003 to 0.009 mg/kg and 0.003 mg/kg, respectively).

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Figure 2. 3: Proposed metabolic pathway of bensulfuron methyl in Japonica rice plants



2.4.2.2 Metabolism in animals

According to the European Guideline in Appendix F doc. 7030/VI/95 rev.3 (22/7/1997) livestock metabolism studies are only required if residues in livestock feed are likely to exceed 0.1 mg/kg total diet. Although not necessary, livestock metabolism studies were conducted and reported below as additional information. In particular, metabolism of bensulfuron methyl in livestock was conducted with lactating goats and laying hens. In the lactating goat study, only the [phenyl(U)-¹⁴C]bensulfuron methyl metabolism was examined. In the laying hens study, both [phenyl(U)-¹⁴C]bensulfuron methyl and [pyrimidine-2-¹⁴C]bensulfuron methyl metabolism was examined.

The primary pathway was O-desmethylation of the pyrimidine ring yielding O-desmethyl-bensulfuron methyl (IN-F7880). A second metabolic pathway involved hydroxylation of the phenyl ring to form IN-W8956. Another major metabolite was formed in the goat by hydroxylation of the pyrimidine ring to yield IN-N8989. A minor metabolic pathway in the goat involved cleavage of the sulfonylurea bridge to form the sulphonamide (IN-N5297). A minor pathway observed in the hen involved hydroxylation of the phenyl ring to yield IN-W8956.

The fate of bensulfuron methyl in livestock was investigated in the lactating goat using a.i. labelled with ¹⁴C in the phenyl ring. Essentially, the entire administered radioactivity was recovered in the urine (approximately 52%) and faeces (approximately 49%). The total ¹⁴C residues found in various organs and tissues in the goat, with the exception of liver tissue, were all below the level of detection (0.3 mg/kg). The residue level found in the liver tissue was 0.4 mg/kg. A very low level was found in milk (0.018 to 0.031 mg/kg).

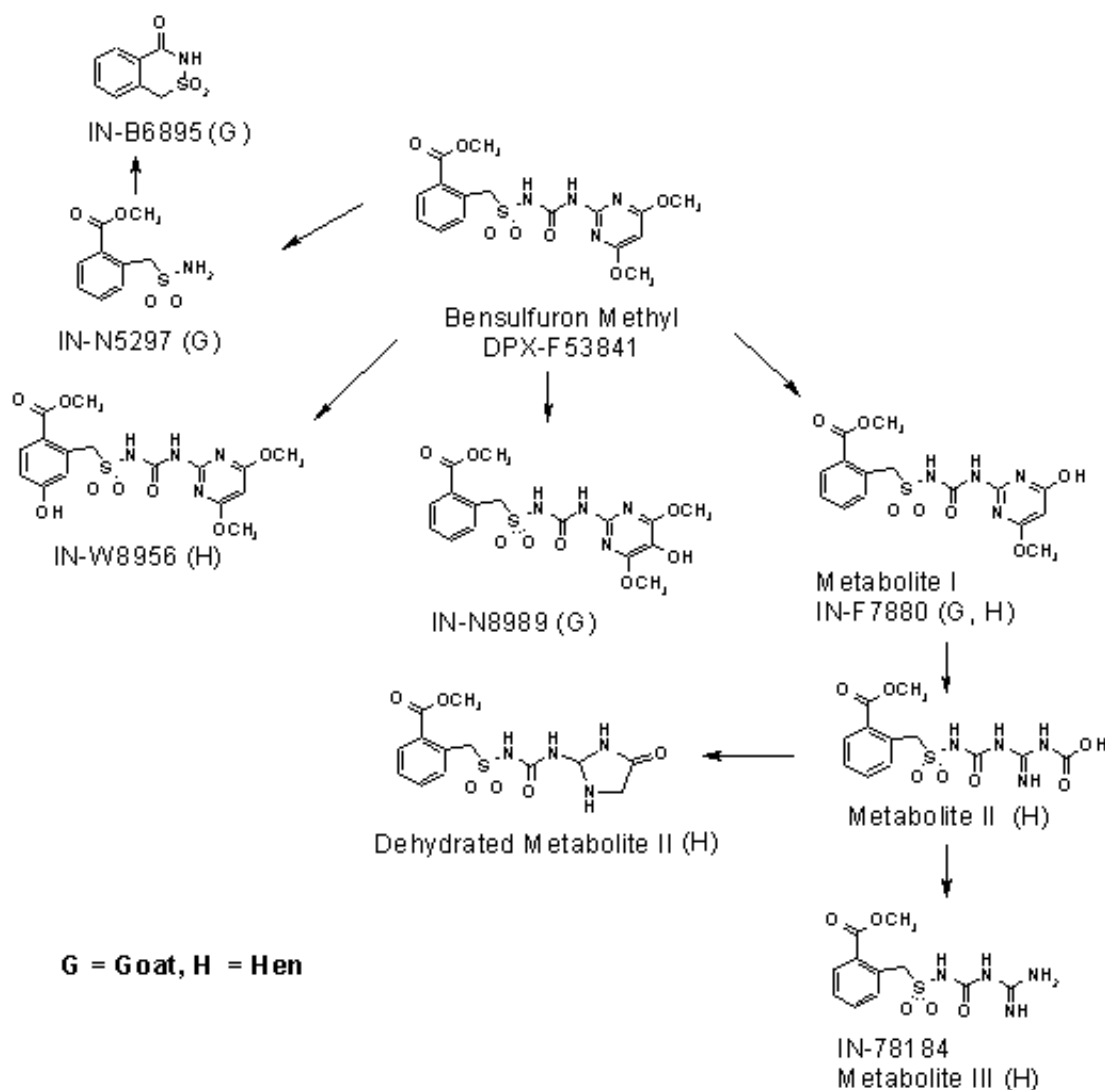
In laying hens fed with [phenyl(U)-¹⁴C]bensulfuron methyl and [pyrimidine-2-¹⁴C]bensulfuron methyl, elimination of dosed radioactivity was rapid and approximately 80% in laying hen. Bensulfuron methyl residues in the hen, eggs, blood, and tissues, except the GI tract, were below the detection limit (0.002 mg/kg). No radioactivity was detected in the eggs; only the GI tract and liver had ¹⁴C residue levels at or above 0.01%

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(0.1% in the liver and 0.6-0.8% in the GI tract). The total ¹⁴C residue levels in the GI tract were between 0.012 and 0.014 mg/kg.

Figure 2. 4: Proposed metabolic pathway of bensulfuron methyl in livestock



2.4.2.3 Proposed residue definition

Plant:

Based on the results of the metabolism study on rice plants and on the toxicological evaluation, the definition of residue for monitoring and risk assessment purposes is proposed as bensulfuron methyl.

Animal:

Since the livestock dietary burden is below the trigger value of 0.1 mg/kg total diet, no metabolism studies are required. Additional information was provided for goats and hens. Based on this and on the toxicological

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evaluation, the proposed residue definition for monitoring and risk assessment purposes can be given as bensulfuron methyl.

2.4.3 Residues relevant to worker safety

See section 2.3.6.4.

2.4.4 Proposed EU MRLs and compliance with existing MRLs

Trials to meet EU requirements according to or exceeding GAP requirements were carried out in flooded and saturated land rice with formulations containing bensulfuron methyl. For flooded rice residue levels in rice grain at commercial harvest were below the limit of quantification: <LOQ of 0.020 mg/kg (6 trials) and <LOQ of 0.010 mg/kg (3 trials). The MRL for rice grain in flooded rice paddies is calculated at 0.020 mg/kg. Since residue levels in rice grain in saturated soil conditions (4 trials) at commercial harvest were below the limit of quantification (0.010 mg/kg), the MRL for rice grain is proposed at 0.010 mg/kg.

Therefore, an EU-MRL (estimated as the worst case) of 0.02 mg/kg is proposed.

Residue levels in rice straw from field trials in flooded conditions were below the LOQ of 0.05 mg/kg for 3 trials. In saturated soil conditions residue levels were below the LOQ of 0.05 mg/kg for 3 trials, except for one residue value of 0.1 mg/kg. The EU-MRL is proposed at 0.1 mg/kg.

Currently no EU-MRLs have been set for bensulfuron methyl. National MRLs for rice have been set in the following countries: France 0.05 mg/kg; Italy 0.05 mg/kg; Portugal 0.05 mg/kg; Spain 0.05 mg/kg; Hungary 0.02 mg/kg.

In Table 2. 10: the highest residues found in supervised residue trials, the STMR, the calculated R_{max}, R_{ber} and MRL are summarised for flooded and saturated conditions separately. Moreover the EU-MRLs (estimated as the worst case equal to 0.02 mg/kg) are proposed.

Table 2. 10: Summary of found residues and proposed EU MRLs for bensulfuron in rice grain and rice straw

Crop	Field conditions	Highest residue	STMR	R _{max}	R _{ber}	MRL	Proposed EU-MRL
Rice grain	Flooded	0.02 mg/kg	0.02 mg/kg	0.0318mg/kg	0.04 mg/kg	0.02 mg/kg	0.02 mg/kg
	Saturated	0.01 mg/kg	0.01 mg/kg	0.01 mg/kg	0.02 mg/kg	0.01 mg/kg	
Rice straw	Flooded	0.05 mg/kg	0.05 mg/kg	0.05 mg/kg	0.1 mg/kg	0.05 mg/kg	0.1 mg/kg
	Saturated	0.1 mg/kg	0.05 mg/kg	0.19 mg/kg	0.17 mg/kg	0.1 mg/kg	

2.4.5 Proposed EU import tolerances and compliance with existing MRLs

No EU import tolerances as been submitted.

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2.4.6 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs

No CAC MRLs have been established or proposed.

2.5 Fate and behaviour in the environment

2.5.1 Definition of the residues relevant to the environment

Soil. The major soil degradation products of bensulfuron methyl are IN-J0290, IN-N5297, IN-D1R84, and IN-R9419. Mineralisation to carbon dioxide is contributed significantly to the degradation of bensulfuron methyl in soil (up to 40% applied radiolabel). IN-T5831 was present at levels >10% in the soil photolysis study, but was never observed in other laboratory soil degradation studies.

Water and sediment. In water/sediment studies, IN-J0290, IN-R9419, and IN-N5297 were the major degradation products in the water phase and IN-J0290 was the only major metabolite in sediment (other than non-extractable residues).

Groundwater. In case of application in saturated land (1 cm water) in sand scenarios, major metabolites IN-N5297, and the minor metabolites IN-T5831 and IN-DAT97 are the residue of concern.

Air. No residues are expected

2.5.2 Fate and behaviour in soil

The aerobic route of degradation of bensulfuron methyl has been presented for three studies using 6 different soils. The proposed degradation pathway of bensulfuron methyl in soils is shown in Figure 2. 5. The main metabolic pathway involves ester hydrolysis of bensulfuron methyl to form IN-R9419, which in turn can undergo sulfonylurea bridge hydrolysis to form IN-D1R84 and IN-J0290. These metabolites are subsequently mineralised to carbon dioxide. An alternative pathway involves sulfonylurea bridge hydrolysis of bensulfuron methyl itself to form IN-N5297 and again, IN-J0290. IN-N5297 could in turn undergo ester hydrolysis to form IN-D1R84. Another minor pathway involves O-demethylation of bensulfuron methyl to form IN-F7880, and hydrolysis of the sulfonylurea linkage of bensulfuron methyl to yield IN-J0290 and IN-N5297. IN-B6895 was a significant metabolite in older aerobic and anaerobic metabolism studies with bensulfuron methyl but a minor degradate in the most current aerobic study (DuPont-4325). IN-B6895 formation (from IN-N5297) is believed to be an artefact of the considerably more basic soil extraction conditions used in previous studies.

The effect of soil photolysis was investigated in one study using one soil. The rate of degradation of bensulfuron methyl was faster in the irradiated samples as compared to non-irradiated samples, indicating that photolysis is also a significant degradation mechanism for bensulfuron methyl. In the irradiated samples, IN-T5831 (pyrimidine urea) was observed as a major product at level of up to 11.9% of applied radioactivity at the end of the 15-day study. This product was also observed in the natural water photolysis study but not observed in any of the aerobic or anaerobic soil degradation studies. This indicates that formation of IN-T5831 is predominantly photo-catalysed product. Minor common metabolites IN-J0290, IN-N5297, and IN-B6895 were also observed (<8.3%) from the cleavage of sulfonylurea bridge of bensulfuron methyl.

Under anaerobic conditions, bensulfuron methyl degrades mainly *via* hydrolysis of the sulfonylurea bridge to

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form IN-N5297 and IN-J0290. An alternative pathway involves ester hydrolysis of bensulfuron methyl to form IN-R9419.

Based on analysis of the aerobic soil metabolism studies, four metabolites in soil are considered major metabolites (>10% applied radiolabel in one test sample or $\geq 5\%$ applied radioactivity in two or more test samples or plateau not reached at the end of the study jet): IN-J0290, IN-N5297, IN-D1R84, and IN-R9419.

To summarise, the following reactions are believed to be involved in bensulfuron methyl degradation in soils:

Hydrolysis of bensulfuron methyl to form IN-J0290 and IN-N5297

De-esterification of the methyl ester to form IN-R9419

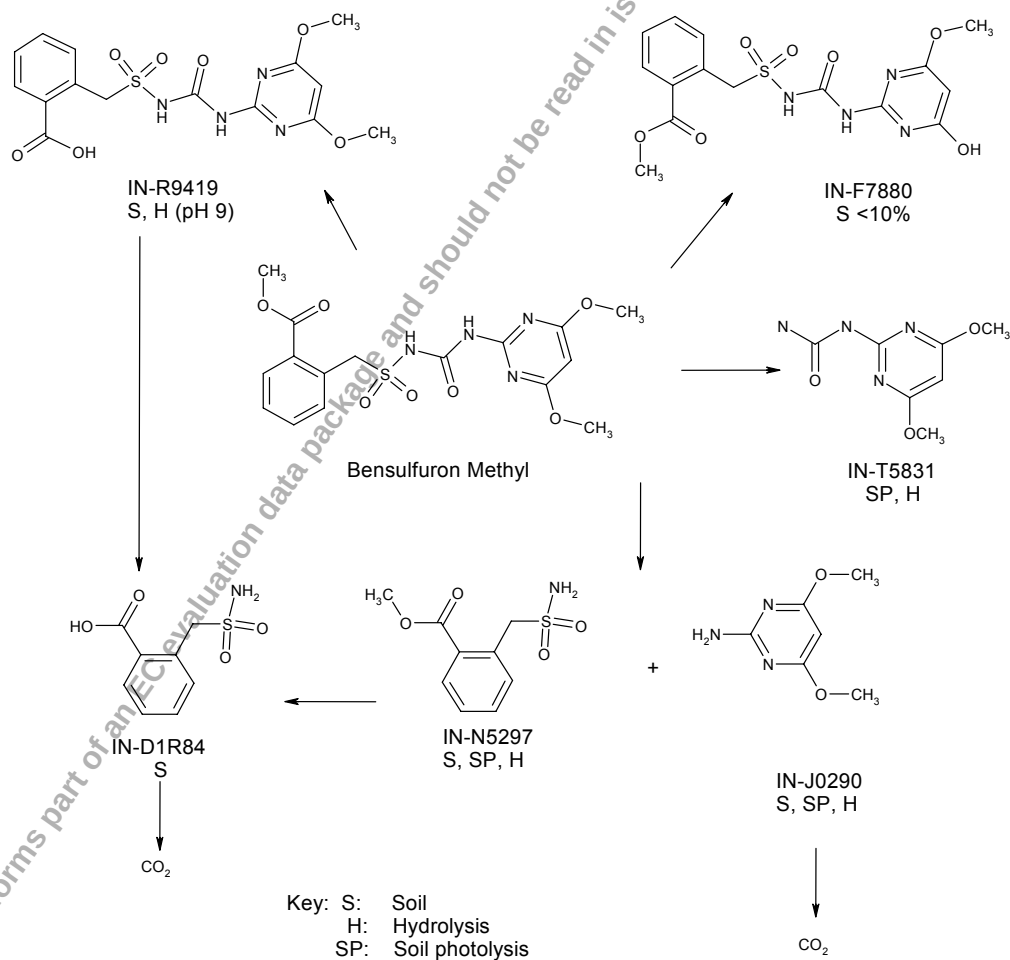
Hydrolysis of the sulfonylurea bridge of IN-R9419 to form IN-D1R84 and IN-J0290

O-demethylation of the pyrimidine amine of bensulfuron methyl to form IN-F7880

Photolysis of the bensulfuron methyl to form IN-T5831

Further mineralisation to CO₂ and formation of non-extractable residues (NER)

Figure 2. 5: Proposed degradation pathway of bensulfuron methyl in soil



The rate of degradation of bensulfuron methyl has been presented for three laboratory studies using six different soils (1 Italian soil, 3 U.S. soils, and 2 Japanese soils). The soils covered a range of soil textures and soil pH

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(5.2-6.5). Bensulfuron methyl degrades in soils with DT₅₀ values ranging from 25 to 102 days.

The DT₅₀ and DT₉₀ values resulted from the laboratory studies on bensulfuron methyl are reported in Table 2. 11.

Table 2. 11: Summary of DT₅₀ and DT₉₀ values for bensulfuron methyl in aerobic soils

Soil Name/ Origin	Texture	pH	Soil Moisture	Incubation T (°C)	DT ₅₀ days	DT ₉₀ days	r ²	Method of calculation
Pavia, Italy	Loamy sand	5.2	50% / 0 bar	20	25	84	>0.957	Non-Lin. SFO
Flanagan, US	Silt loam	5.6	70% WHC	25	89	294	0.978	Non-Lin. SFO
Keyport, US	Silt loam	6.7	70% WHC	25	89	294	0.941	Non-Lin. SFO
Nagano, Japan	Sandy loam	5.2	70% WHC	25	65	214	0.875	Non-Lin. SFO
Tochigi, Japan	Clay loam	6.1	70% WHC	25	102	339	0.809	Non-Lin. SFO
California, USA	Silt loam	6.5	70% WHC	25	90	297	0.840	Non-Lin. SFO

Radiolabel laboratory studies show that the aerobic degradation of bensulfuron methyl results in the formation of carbon dioxide (up to 42%), non-extractable residue (up to 38%), and degradation products IN-J0290, IN-F7880, IN-N5297, IN-R9419, and IN-D1R84. The rates of degradation of soil degradation products of bensulfuron methyl have been determined in aerobic laboratory soil studies using four European soils with soil pH ranging from 5.8 to 8.1. The average DT₅₀ values, from laboratory studies, were 11, 16, 30, 13, and 13 days for IN-R9419, IN-F7880, IN-N5297, IN-J0290, and IN-D1R84, respectively. Soil pH did not affect the rate of degradation of bensulfuron methyl degradation products in these studies. The laboratory DT₅₀ and DT₉₀ values for metabolites are reported in Table 2. 12.

Table 2. 12: Summary of DT₅₀ and DT₉₀ values for IN-R9419, IN-F7880, IN-N5297, IN-J0290, and IN-D1R84 in aerobic soils

Soil Name/ Origin	Texture	pH	Soil Moisture	Incubation T(°C)	DT ₅₀ (days)	DT ₉₀ (days)	r ²	Method of calculation
IN-R9419								
Pavia, Italy	Loamy sand	5.2	50% of 0 bar	20	54.4	181	>0.95 7	SFO parent/ metabolite
Namsheim, France	Sandy loam	8.1	50% WHC	20	20	65	0.960	Non-linear SFO
Pavia, Italy	Sandy loam	5.8	50% WHC	20	29	95	0.950	Non-linear SFO
Speyer 2.2, Germany	Loamy sand	5.9	50% WHC	20	8	27	0.975	Non-linear SFO
Vercelli, Italy	Silt loam	6.2	50% WHC	20	20	65	0.877	Non-linear SFO
IN-F7880								
Pavia, Italy	Loamy sand	5.2	50% of 0 bar	20	30.5	101	>0.95 7	SFO parent/ metabolite
Namsheim, France	Sandy loam	8.1	50% of WHC	20	4.1	13.5	0.994	Non-linear SFO

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Soil Name/ Origin	Texture	pH	Soil Moisture	Incubation T(°C)	DT ₅₀ (days)	DT ₉₀ (days)	r ²	Method of calculation
Pavia, Italy	Sandy loam	5.8	50% of WHC	20	18.8	62.4	0.957	Non-linear SFO
Speyer 2.2, Germany	Loamy sand	5.9	50% of WHC	20	5.6	18.4	0.890	Non-linear SFO
Vercelli, Italy	Silt loam	6.2	50% of WHC	20	20.2	67.1	0.947	Non-linear SFO
IN-N5297								
Namsheim, France	Sandy loam	8.0	50% of WHC	20	7	23	0.995	Non-linear SFO
Pavia, Italy	Sandy loam	5.5	50% of WHC	20	63	208	0.924	Non-linear SFO
Speyer 2.2, Germany	Loamy sand	6.7	50% of WHC	20	4	13	0.997	Non-linear SFO
Vercelli, Italy	Silt loam	6.1	50% of WHC	20	45	148	0.951	Non-linear SFO
IN-J0290								
Namsheim, France	Sandy loam	8.0	50% of WHC	20	19	63	0.936	Non-linear SFO
Pavia, Italy	Sandy loam	5.5	50% of WHC	20	18	60	0.880	Non-linear SFO
Speyer 2.2, Germany	Loamy sand	6.7	50% of WHC	20	3	10	0.995	Non-linear SFO
Vercelli, Italy	Silt loam	6.1	50% of WHC	20	13	42	0.864	Non-linear SFO
IN-D1R84								
Namsheim, France	Sandy loam	8.0	50% of WHC	20	11	35	0.981	Non-linear SFO
Pavia, Italy	Sandy loam	5.5	50% of WHC	20	17	55	0.934	Non-linear SFO
Speyer 2.2, Germany	Loamy sand	6.7	50% of WHC	20	3	11	0.958	Non-linear SFO
Vercelli, Italy	Silt loam	6.1	50% of WHC	20	19	62	0.970	Non-linear SFO

Bensulfuron methyl degrades under anaerobic condition with an average DT₅₀ value of 118 days. Photolysis of bensulfuron methyl resulted in an estimated half-life of 22-32 days with continuous irradiation equivalent to 44-64 days for a 12-hour photo period.

The field dissipation study of bensulfuron methyl was also determined at three locations in Northern Italy, which are typical for the rice producing areas. Bensulfuron methyl was applied to rice paddies in a single application over each of three years (1994, 1995, and 1996). The active substance degrades rapidly in the field with DT₅₀ values ranging from 4 days to 14 days. Bensulfuron methyl shows little potential for accumulation as evidenced by a DT₉₀ ranging from 14 days to 48 days.

Bensulfuron methyl was moderately adsorbed to soils from the US and Italy with an organic carbon content ranging from 0.6% to 4.4% and pH values ranging from 5.2 to 6.6. The Freundlich constants (K_f) values ranged from 1.4 to 14 and K_{foc} values ranged from 205 to 684.

The adsorption/desorption behaviour of the degradation products IN-J0290, IN-D1R84, IN-F7880, IN-N5297, and IN-R9419 were studied. The adsorption/desorption behaviour of IN-J0290 was studied in five soils with

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organic carbon content ranging from 0.5% to 3.1% and pH values from 5.2 to 7.8. IN-J0290 was moderately sorbed in these soils with the K_f values ranged from 0.9 to 45.3 mL/g and the K_{Foc} ranged from 58-1460 for an average of 458 mL/g. Mean K_d , K_{oc} , and K_{om} values calculated from the concentrations in aqueous solution and adsorbed to soil at adsorption equilibrium reflects the variable adsorption on IN-J0290. IN-J0290 that was absorbed was moderately desorbed. The average Freundlich 1/n value of IN-J0290 was 0.80. IN-R9419 sorption was studied in five soils and found to be also moderately sorbed in these soils with organic carbon content ranging from 0.6 to 3.0% and pH values from 5.8 to 8.1. The K_f values ranged from 0.3 to 17.4 and K_{foc} values ranged from 28 to 580. The average K_{foc} was 225 mL/g. K_{Foc} values calculated from the Freundlich adsorption constants for the five soil types ranged widely, suggesting that factors other than organic carbon content of the soil may have influenced the adsorption of IN-R9419. Mean K_d , K_{oc} , and K_{om} values calculated from the concentrations in aqueous solution and adsorbed to soil at adsorption equilibrium reflect the variable adsorption of IN-R9419. IN-R9419 that was absorbed was moderately desorbed. The average Freundlich 1/n value of IN-R9419 was 0.90. IN-D1R84 sorption was studied in 5 soils with organic carbon content ranging from 0.6% to 3.0% and pH values from 5.8 to 8.1. IN-D1R84 was weakly adsorbed with K_{foc} values ranging from 2 to 21 for an average value of 9 mL/g. K_f values ranged from 0.02 to 0.2 mL/g. The average Freundlich 1/n value of IN-D1R84 was 0.71. IN-N5297 was weakly to moderately sorbed to the five soil with organic carbon content ranging from 0.5-3.1% and pH values from 5.2-7.8. K_{foc} values ranged from 15 to 92 and the average K_{foc} was 36 mL/g with adsorption tended to correlate with the organic carbon content of the soil. K_f values ranged from 0.07 to 2.8 mL/g. The average Freundlich 1/n value of IN-N5297 was 0.92. The adsorption of IN-F7880 was studied in five soils and found to be moderately adsorbed to soils. The soils have organic carbon content ranging from 0.6% to 3.0% and pH values from 5.6 to 8.1. The K_f values ranging from 0.5-14.2 mL/g and K_{foc} values ranged from 75 to 472 mL/g. The average K_{foc} was 206 mL/g. The average Freundlich 1/n value of IN-F7880 was 1.0.

Predicted environmental concentrations in soil (PEC_{soil}) values for bensulfuron methyl and metabolites were calculated using the procedures described in Med-Rice (2003). PEC_{soil} was defined as the PEC in paddy soil. The amount of compound applied to the flooded paddy (less that intercepted by the rice crop) was assumed to instantaneously and irreversibly sorb to the paddy soil. This sorption is determined by the compound distribution coefficient ($K_{oc} \times$ fraction organic carbon of soil), the depth of the paddy water, depth of paddy soil active in the sorption process, and the paddy soil bulk density. For the Tier 1 calculations, the paddy water depth was defined both as 10 cm and 1 cm, the two supported types of application, depth of paddy soil, having either 1.8% organic carbon (clay scenario) or 0.9% organic carbon (sand scenario), with an active depth of 5 cm and bulk density of 1.5 g/cm³. Foliar interception was conservatively assumed not to occur, so 100% of the applied compound reached the paddy water and was available for sorption to soil.

PEC_{soil} values for metabolites were calculated in the same manner as for bensulfuron methyl, but with the dose rate determined using the maximum percentage formed in any environmental fate study and the molecular weight conversion. The maximum initial PEC_{soil} values observed, from Med-Rice Tier I calculation method, are listed in Table 2. 13. The clay scenario resulted in the highest initial paddy soil concentrations (PEC_{soil}) in each case due to the higher soil organic carbon level.

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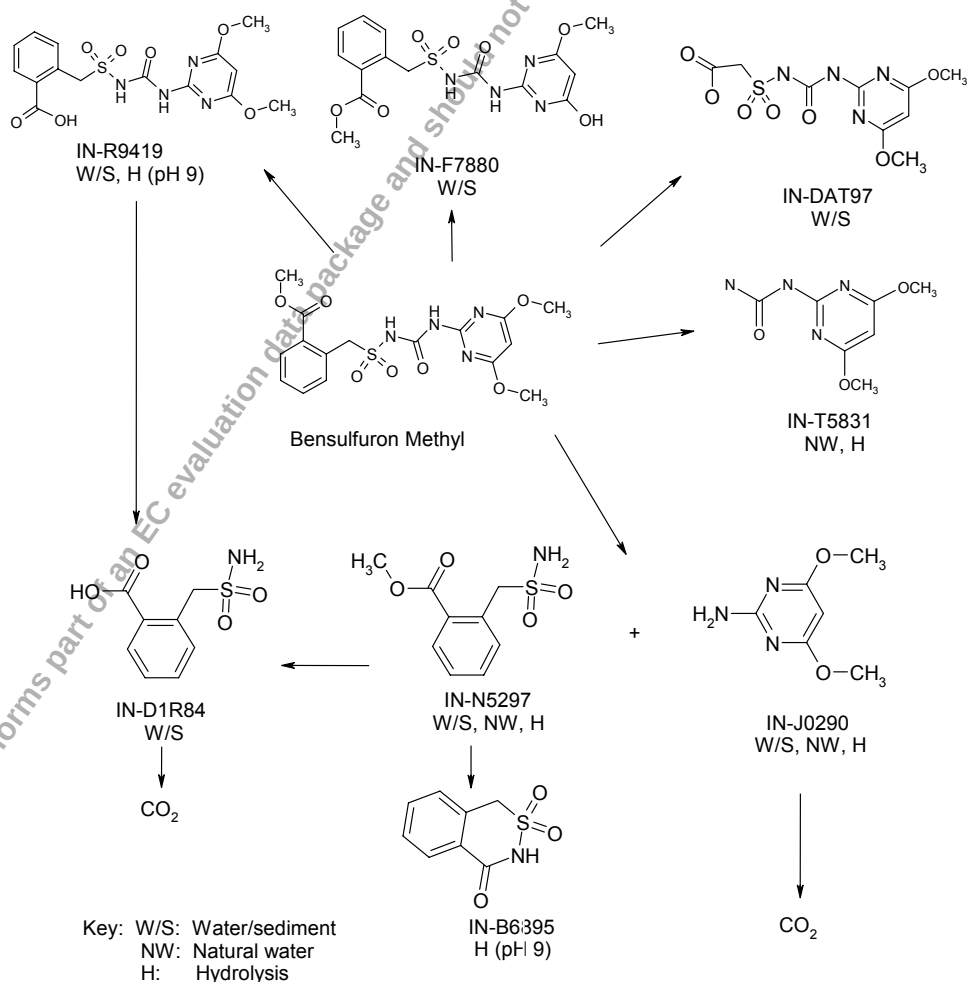
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Table 2. 13 Med-Rice Tier I Calculations: Maximum initial PEC_{soil}

Calculation method	Compound	Maximum initial PEC _{soil} values (µg/kg)			
		Clay scenario	Sand scenario	Clay scenrio	Sand scenrio
		10 cm water	10 cm water	1 cm water	1 cm water
Med-Rice Tier 1	Bensulfuron methyl	64.7	54.4	78.2	76.0
	IN-F7880	5.51	4.36	7.23	6.99
	IN-R9419	16.1	12.9	20.8	20.1
	IN-D1R84	0.826	0.437	4.18	2.88
	IN-J0290	11.9	10.5	13.6	13.4
	IN-N5297	4.62	2.76	11.7	10.0
	IN-T5831	0.572	0.302	2.90	2.00
	IN-DAT97	0.670	0.354	3.39	2.34

2.5.3 Fate and behaviour in water

The proposed degradation pathway of bensulfuron methyl in aquatic systems is presented in Figure 2. 6.

Figure 2. 6: Proposed degradation pathways of bensulfuron methyl in the aquatic systems

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Hydrolytic degradation of bensulfuron methyl in aqueous buffer solutions was determined at pH 4, 7, and 9. Bensulfuron methyl hydrolysed rapidly at pH 4. Hydrolysis is a significant degradation process for bensulfuron methyl under acidic conditions, but hydrolysis is much less significant under neutral or basic conditions. The hydrolysis of the sulfonylurea bridge of bensulfuron methyl produces IN-J0290 and IN-N5297. IN-N5297 cyclises to form homosaccharin (IN-B6895). At pH 9, de-esterification of bensulfuron methyl occurs to form IN-R9419. The DT_{50} for bensulfuron methyl for hydrolysis at pH 4 and 9 was 6 and 141 days, respectively. Bensulfuron methyl was stable at pH 7.0.

The aqueous photodegradation of bensulfuron methyl was investigated at pH 5, 7, and 9. The degradation of bensulfuron methyl in aqueous solution exposed to natural sunlight is dependent on the pH of the solution with half-lives ranging from 13 days at pH 5 to greater than 200 days at pH 9. However, when observed degradation rates are corrected for the hydrolysis component, the photolysis component is insignificant (half-life greater than 400 days) and independent of pH in the range of 5-9. These results are consistent with the UV absorption spectrum of bensulfuron methyl that showed little or no absorption in the region above 290 nm. The quantum efficiency of bensulfuron methyl was calculated to be 0.00003. Since sunlight reaching the earth's surface only contains significant radiation above 290 nm, little or no direct photolysis of bensulfuron methyl is expected.

The photolytic stability of bensulfuron methyl was studied in two natural waters and sterile pH 7 aqueous buffer solutions. The test systems were continuously irradiated for 15 days using a xenon arc simulated sunlight source (intensity equal to midday summer sunlight at a latitude of 52°N; equivalent to 28 days of sunlight) at 25°C under sterile conditions. The photolysis half-life of bensulfuron methyl in Cavrini Farm was 10 days as compared to 29 days in sterile pH 7 buffer, which suggests that the increase in the rate of degradation of bensulfuron methyl in Cavrini Farm is primarily due to indirect photolysis of bensulfuron methyl. In the Ten-Mile Creek natural water system, the photolysis half-life was 89 days. The longer half-life of bensulfuron methyl in the Ten-Mile Creek natural water test system compared to the pH 7 buffer test system is most likely a result of the high dissolved organic carbon (DOC) of the Ten-Mile Creek water. The high DOC concentration of the water not only reduced the light intensity (25% reduction), but may also be responsible for scavenging of free radicals from the test system. The major degradation product that formed in the irradiated natural water system >10% was IN-T5831. Based on the results of this study, indirect photolysis may contribute significantly to elimination of bensulfuron methyl from the environment and direct photolysis will be a minor route of elimination.

Photodegradation of bensulfuron methyl in a simulated paddy system was also studied in two water/sediment systems collected from Cavrini, Italy and Lonoke, Kansas, U.S.A. In this high tier study, which represented the real field situation of the rice paddy system, bensulfuron methyl dissipated rapidly in the water phase of Cavrini system with the metabolite IN-R9419 detected at greater than 10% AR. Several other minor degradation products were also observed, but at levels <10% AR. For the dark control samples, bensulfuron methyl degraded at a slower rate with several other degradation products observed, but none exceeding 10% AR. The amount of bensulfuron methyl in the water decreased from 87.1% AR at Day 0 to 31.5% at Day 26. In the Lonoke water/sediment system, bensulfuron methyl degraded rapidly in the water phase with the metabolite, IN-R9419, detected at greater than 10% AR and declined at 26 days. Several other degradation products were also

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observed, but none exceeding 5% AR. In the dark control samples, the amount of bensulfuron methyl in the water decreased from 88.6% AR at Day 0 to 29.0% at Day 26. In contrast to the irradiated samples, bensulfuron methyl degraded at a slower rate with the metabolite, IN-F7880 detected and increased to 11.4% in water phase at 26 days. Several other degradation products were also observed but at levels <3% AR. The calculated DT₅₀ values of bensulfuron methyl in the water phase ranged from 7.7 days in the Cavrini system, 6.7 days in the Lonoke system, and 50.3 days in the pH 7 system. The calculated DT₉₀ values in the water system ranged from 25.6 days in the Cavrini system, 22.4 days in the Lonoke system, and 167 days in the pH 7 system.

The rate and route of degradation of bensulfuron methyl was studied in two Italy water/sediment systems. Bensulfuron methyl degrades rapidly in both the Pavia and Vercelli water sediment systems with DT₅₀ values in the water phase of 21 and 16 days, respectively. In the sediment phase, bensulfuron methyl, had DT₅₀ values of 47 and 82 in the Pavia and Vercelli test systems, respectively. The DT₅₀ values for bensulfuron methyl in Pavia and Vercelli total test systems were 37 and 122 days, respectively. The major degradation products in water phase were IN-J0290 and IN-N5297, which exceeded 10%. IN-J0290 exceeded 10% in the sediment of the Pavia test system and non-extractable residues exceeded in both test systems. Mineralisation to ¹⁴CO₂ accounted for 16.7 to 26.1% AR for pyrimidine and phenyl labels, respectively. Other minor degradation products that formed below 10% in the total phase were IN-R9419, IN-F7880, IN-DAT97, and IN-D1R84. The DT₅₀ values of IN-DAT97, IN-F7880, and IN-R9419 in the total phase of Pavia test system were 35, 39, and 7 days, respectively. The DT₅₀ values of IN-J0290, IN-DAT97, IN-F7880, IN-N5297, and IN-R9419 in the total phase of Vercelli test system were 21, 31, 38, 79, and 4 days, respectively.

The rate of degradation of bensulfuron methyl was also studied in two Japan and one US water/sediment system. Bensulfuron methyl degraded under aerobic aquatic conditions. IN-N5297 (sulfonamide), IN-J0290 (pyrimidine amine), and IN-F7880 were identified as the major degradation products (<10%). The averaged DT₅₀ values of bensulfuron methyl were 66, 50, and 87 days for California, Nagano, and Tochigi soil systems, respectively. The respective averaged DT₉₀ values were 220, 167, and 289 days. An uncommon aquatic degradation product IN-N8989 was also detected and peaked to 11.5% at 7 days in the [¹⁴C-phenyl] label but quickly declined to 0.5% after 14 days in California soil system. The formation of IN-N8989 was not significant (<1.7% AR) in the [¹⁴C-pyrimidine] label, suggesting that this was a transient product. The formation of ¹⁴CO₂ was negligible in either label.

2.5.3.1 Groundwater

Annual average PEC_{gw} values were calculated for bensulfuron methyl and metabolites IN-J0290, IN-DAT97, IN-F7880, IN-R9419, IN-N5297, IN-D1R84, and IN-T5831 based on the procedures described in Med-Rice (2003), with some modification. The calculation procedure was modified after a mass balance accounting error was noted in the equations used to calculate PEC_{gw}. When following the Med-Rice equations the mass of compound leached could be higher than the amount applied. This is due to the fact that when calculating PEC_{pw} there is no accounting for the dilution effect from inflowing water to replace water lost by infiltration leading to over estimation of the amount bensulfuron methyl remaining in the infiltrating paddy water on which PEC_{gw} is based. To account for the inflowing water dilution effect (mass loss to infiltration), the infiltration rates for the

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clay (1 mm/d) and sand scenarios (10 mm/d) were converted to rate constants (0.01 and 0.1 d⁻¹, respectively). These rate constants were added to equations 4, 5, 8, and 10 given in section 5.3 of Med-Rice (2003). In this way the “dissipation” of compound in paddy water due to dilution is accounted for in the same manner as already done for paddy outflow when the paddy is open.

Estimation of concentrations in groundwater was simulated per proposed (GAP); in addition foliar interception was conservatively assumed not to occur (100% reaching the flooded paddy surface). Where available, the longest total system first-order DT₅₀ values from the water/sediment study were used to represent degradation in paddy water and paddy soil. Alternatively, the geometric mean DT₅₀ from the aerobic soil degradation study was selected. The average K_{foc} was used to represent sorption. Two level of water were considered: 1 cm and 10 cm. PEC_{gw} values for metabolites were calculated in the same manner as for bensulfuron methyl, but with the dose rate determined using the maximum percentage formed in any environmental fate study and the molecular weight conversion. The annual average PEC_{gw} values for bensulfuron methyl and its degradation products is showed in Table 2. 14 below.

Table 2. 14: PEC_{gw} values determined using a modification of the procedures given in Med-Rice (2003)

Compound	Annual average PEC _{gw} (µg/L) ^{a,b}		
	Clay scenario (10 and 1 cm water)	Sand scenario (10 cm water)	Sand scenario (1 cm water)
bensulfuron methyl	0.0000	0.0391	0.0356
IN-F7880	0.0000	0.0149	0.0154
IN-R9419	0.0000	0.0000	0.0000
IN-D1R84	0.0000	0.0126	0.0629
IN-J0290	0.0000	0.0000	0.0000
IN-N5297	0.0000	0.0633	0.1545
IN-T5831	0.0000	0.0275	0.126
IN-DAT97	0.0003 (0.0007 with 1 cm water)	0.0524	0.229

No problem for leaching are identified for bensulfuron methyl and major metabolites in the clay scenario with both types of application. For the sand scenario, the typical application on flooded soil (10 cm) does not show a significant risk for groundwater. On the other hand, application on saturated land might present some leaching concerns for the major metabolites IN-N5297, and for the minor metabolites IN-T5831 and IN-DAT97. This concern should be addressed by those MS, where the application on saturated land is a common practice in areas characterised by sand scenarios for rice.

2.5.3.2 Surface water and sediment

Tier 1 PEC_{sw} and PEC_{sed} values were calculated for bensulfuron methyl and metabolites IN-J0290, IN-DAT97, IN-F7880, IN-R9419, IN-N5297, IN-D1R84, and IN-T5831 using the procedures described in Med-Rice (2003).

The initial paddy water PEC (PEC_{pw}) was based on the maximum application rate, paddy water depth of 10 cm and instantaneous and irreversible sorption to paddy soil. The Tier 1 approach for PEC_{sw} and PEC_{sed} assumes

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loading of a static ditch adjacent to a treated paddy from both spray drift at the time of application and from drainage water from the paddy after a five-day holding time. Partitioning between ditch water and ditch sediment is handled in the same manner as for the paddy. The contribution from both drift and drainage are summed to obtain initial PEC_{sw} and PEC_{sed} values.

The maximum Tier 1 bensulfuron methyl concentrations in paddy water (PEC_{pw}) ranged from 11.4 to 19.2 $\mu\text{g/L}$ on application day following instantaneous partitioning with the paddy soil. Metabolite PEC_{pw} ranged from 1.45 $\mu\text{g/L}$ for IN-J0290 to 8.53 $\mu\text{g/L}$ for IN-N5297. In all cases the highest initial paddy water concentrations were observed in the sand scenario, which is defined to have half the soil organic carbon of the clay scenario (0.9% versus 1.8%), resulting in less partitioning to paddy soil and more remaining in the water column.

In the receiving ditch, Tier 1 PEC_{sw} values for bensulfuron methyl and metabolites were highest in the sand scenario. Bensulfuron methyl PEC_{sw} ranged from 1.08 to 1.75 $\mu\text{g/L}$. Metabolite PEC_{sw} ranged from 0.126 $\mu\text{g/L}$ for IN-J0290 to 0.716 $\mu\text{g/L}$ for IN-N5297. Loading of compounds into the ditch from spray drift was much lower than from drainage water coming from the paddy.

The larger amount reaching the receiving ditch from the sand scenario paddy further resulted in higher Tier 1 PEC_{sed} values compared to the clay scenario. PEC_{sed} values ranged from 4.51 $\mu\text{g/kg}$ to 7.19 $\mu\text{g/kg}$ for bensulfuron methyl. Metabolite PEC_{sed} ranged from 0.0440 $\mu\text{g/kg}$ for IN-T5831 to 1.17 $\mu\text{g/kg}$ for IN-R9419.

Higher tier PEC values were determined for bensulfuron methyl using RICEWQ version 1.64 for the paddy (PEC_{pw}) and RIVWQ version 2.02 for ditches, canals, and the river (PEC_{sw} and PEC_{sed}). A single post emergence application of bensulfuron methyl was simulated to occur 30 days post sowing (representative of BBCH 20, tillering) in each year with 50% foliar interception (this value was assumed according to literature and estimates from field studies with bensulfuron methyl in Italy. Simulations of the watershed were conducted with 20-year daily meteorological data representative of rice production areas in southern France, Greece, Italy, Portugal, and Spain.

Bensulfuron methyl PEC_{sw} values from RICEWQ/RIVWQ were consistent with available monitoring data. The average paddy water concentration at the time of application was approximately 30 to 33 $\mu\text{g/L}$ dropping to approximately 8 $\mu\text{g/L}$ by the time of drainage. Based on data combined across all meteorological scenarios and for a 20 years period of time, the average maximum bensulfuron methyl PEC_{sw} was 34.0 $\mu\text{g/L}$ in paddies, 4.22 $\mu\text{g/L}$ in ditches, 1.42 $\mu\text{g/L}$ in canals, and 0.365 $\mu\text{g/L}$ in the river. The average maximum bensulfuron methyl PEC_{sed} was 14.5 $\mu\text{g/kg}$ in paddies, 2.60 $\mu\text{g/kg}$ in ditches, 1.21 $\mu\text{g/kg}$ in canals, and 0.768 $\mu\text{g/kg}$ in the river.

In order to support refinement of the higher tier aquatic risk assessment, 14-day time weighted average (TWA) PEC_{sw} and PEC_{sed} values for bensulfuron methyl were calculated. All 14-d TWA values in each simulation year were calculated for each “sampling” point in the RICEWQ/RIVWQ watershed. There were 10 sampling points for treated paddies, ditches, and canals and one sampling point for the river at the exit of the watershed. The 90th percentile of these 14-d TWA values was calculated for each of the 20 simulation years. The 50th percentile of the 90th percentile values was then calculated to obtain a conservative 14-d TWA value for use in aquatic risk assessment. The method of taking the 50th percentile of the 90th percentile values in higher tier assessments has been supported in recent discussions within the EUFRAM Maths group. The overall 50th percentile 14-d TWA

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value, calculated from the 90th percentile values from all five meteorological scenarios, was 0.088 µg/L in treated paddies, 0.032 µg/L in ditches, 0.006 µg/L in canals, 0.004 µg/L in the river.

The 50th percentile of the 90th percentile 14-d TWA PEC_{sed} values, from all meteorological scenarios together, was 3.76 µg/kg for treated paddies, 1.59 µg/kg for ditches, 0.695 µg/kg for canals, and 0.463 µg/kg for the river.

2.5.4 Fate and behaviour in air

Currently, no models have been recommended for the estimation of the predicted environmental concentrations of chemicals in air. In the absence of a recommended model, volatilisation losses and predicted concentrations in air adjacent to treated fields were calculated by means of a volatilisation estimation method developed by Dow Chemical.

Based on this methods, together with the lowest water solubility value (2.1 mg/L at pH), the average soil sorption coefficient of 315 mL/g and the vapour pressure of 2.8×10^{-12} Pa at 25°C it can be predicted that $1.4 \times 10^7\%$ of applied bensulfuron methyl would be lost from a treated field into the air within 24 hours. Assuming a uniformly mixed stagnate layer of air to a height of 1 m over a treated field, the PEC_{AIR} in this layer would be negligible following application (8.4×10^{-6} µg/m³). In addition no redeposition can occur since bensulfuron methyl is not a volatile compound.

2.6 Effects on non-target species

Bensulfuron methyl is a herbicide belonging to the sulfonylurea class. The mode of action of sulfonylurea herbicides is inhibition of the plant enzyme acetolactate synthase (ALS), which is needed to make the essential amino acids isoleucine, leucine and valine.

Bensulfuron methyl is used in rice culture for the control of a range of broadleaved weeds (Dicotyledonous), aquatic broadleaved weeds (Monocotyledonous not Graminae) like Alismataceae, Butomaceae, Pontederiaceae, Typhaceae, and Cyperaceae weeds. It acts mainly through foliar uptake and to a lesser extent by root uptake.

Bensulfuron methyl is applied once per cropping season at a maximum seasonal rate of 60 g a.i./ha.

The product can be applied in pre-sowing to the crop (typically from 2 to 5 days before sowing) in flooded rice or in post-emergence to the crop both in flooded or dry land conditions (typically from 20 to 45 days and from 20 to 50 days after sowing, respectively). The application is made to the ground using equipment as tractor-mounted, ground-directed broadcast sprayers with water volumes ranging between 200 and 400 L/ha. Depending on the local cultivation practice, application may be performed between two leaves (growth stage BBCH 12) and maximum tillering of the crop (growth stage BBCH 29). Typical seasonal application timing is between mid April and the end of June.

2.6.1 Effects on birds (Annex IIA 8.1, Annex IIIA 10.1)

Bensulfuron methyl is of low acute toxicity to birds, producing no mortality at the maximum dose levels used in the single oral and short-term dietary tests. No significant treatment-related effects were observed on reproductive parameters in the test with mallards at the highest dose tested.

The key toxicological endpoints used for the Risk Assessment Calculation are the following:

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Study (species)	LD ₅₀ , LC ₅₀ , NOEL	LD ₅₀ , LC ₅₀ , NOEL (converted to daily dose)
Acute Oral Toxicity (mallard duck)	>2510 mg/kg bw	-
Short-term Dietary Toxicity (5 day) (bobwhite quail)	>5,620 ppm	>1678 mg a.i./kg bw/d
Subchronic and Reproductive Toxicity (147 day) (mallard duck)	560 ppm	83 mg a.i./kg bw/d

The scenarios considered for the risk assessment included the consumption of contaminated food (of vegetal origin and insects), the secondary poisoning and the uptake of contaminated water. The risk assessments were conducted in a stepwise approach according to the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO/4145/2000, draft September 2002).

1. Consumption of contaminated food

The TER_{as}, TER_{st} and TER_{lt} exceed the Annex VI trigger values in all the representative scenarios, indicating that no risk is foreseen for birds on an Acute, Short and Long Time Scale from the application of Bensulfuron methyl.

2. Bioaccumulation and food chain behaviour

According to the SANCO/4145/2002 (Chapter 4) for organic chemicals with a log P_{ow} >3 a potential for bioaccumulation should be assessed. The log K_{ow} at pH 5 was 2.18 (highest measured log K_{ow}) for Bensulfuron methyl and therefore an assessment of potential risk to earthworm- and fish-eating birds is not necessary. However, in order to fully assess the potential risk to birds from exposure to residues contained in food items not covered in the standard exposure scenarios, the potential risk to birds consuming earthworms or fish was assessed. On the basis of the TER_{lt} values, the risk can be considered acceptable.

3. Exposure via drinking water

Taking into consideration the predicted uses of Bensulfuron methyl, the exposure to the active substance residues via drinking water is possible mainly for the birds species that frequent open water bodies, species that are liable to ingest water contaminated.

The TER_{lt} calculated on the basis of the worst case PEC_{sw}, is above the relevant trigger values (5), indicating that the consumption of water after the application of Bensulfuron methyl does not pose a risk for the birds population.

2.6.2 Effects on aquatic organisms (Annex IIA 8.2, Annex IIIA 10.2)

Bensulfuron methyl has low acute and chronic toxicity to all freshwater and marine fish and aquatic invertebrates, however, it is toxic to algae and aquatic plants under the laboratory test conditions. Bensulfuron methyl has a very low potential for bioconcentration. The metabolites of Bensulfuron methyl demonstrated low toxicity to all aquatic species tested.

Active substance and formulation

A summary of the aquatic toxicity endpoints selected for the risk assessment are presented in the Table below.

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Test organism	Test Substance	Duration, conditions	Toxicological Endpoint (mg a.i./L)	Concentration n/m*
Fish				
<i>Oncorhynchus mykiss</i>	a.i.	96 hr, static	LC ₅₀ > 66	m
<i>Oncorhynchus mykiss</i> ELS	a.i.	90 d, flow through	NOEC = 1.5	n
<i>Procambarus clarki</i>	a.i.	flow through	BCF (whole) = 1.6	
Invertebrates				
<i>Procambarus clarki</i>	a.i.	96 hr, static	LC ₅₀ > 71	m
<i>Daphnia magna</i>	a.i.	21 d, static renewal	NOEC = 12	m
Sediment dwellings				
<i>Chironomus tentans</i>	DPX-JM206 60WG	96 hr, static	LC ₅₀ > 125	m
Algae				
<i>Selenastrum capricornutum</i>	DPX-F5384 60WG	120 hr, static	E _r C ₅₀ = 0.0173	n
Aquatic plants				
<i>Lemna gibba</i>	a.i.	14 d, static	E _r C ₅₀ = 0.0008	n

*n = nominal; m = measured

The approaches used to examine the potential risk of Bensulfuron methyl 60WG to aquatic organisms follow the recommendations given in the SANCO/1090/2000 (Med-Rice, 2003).

A Tier 1 acute and chronic risk assessment was conducted assuming aquatic organisms inhabit the rice paddy fields during flood. Assuming as exposure the maximum initial Tier 1 PEC_{pw}, the acute TERs exceed the Annex VI triggers, except for algae and aquatic plants. The chronic TERs, exceed the Annex VI triggers, indicating that Bensulfuron methyl poses a low chronic risk to fish and invertebrates, even when the highest potential exposure is considered.

Further assessment was performed to determine the risk to algae and aquatic plants potentially inhabiting ditches receiving outflow from rice paddies treated with Bensulfuron methyl. The resulting Tier 1 TER for algae is only just below the Annex VI trigger of 10 and therefore it may be concluded that Bensulfuron methyl poses a minimal risk to algae inhabiting receiving ditches. It is to be considered that inhibition of both algal species by Bensulfuron methyl was found to be reversible when cells previously exposed to Bensulfuron methyl were transferred to fresh, untreated medium. Moreover, Bensulfuron methyl dissipates rapidly in natural aquatic systems. Therefore, under actual field conditions, risk to algae in ditches adjacent to rice paddies is expected lower than the estimated.

The Tier 1 TER for *Lemna* shows an unacceptable risk of Bensulfuron methyl for aquatic plants. A refined risk assessment was conducted to investigate potential risk to aquatic plants under more realistic conditions than described in the Tier 1 Med-Rice exposure scenarios. In particular, risk to aquatic plants inhabiting ditches, canals and rivers receiving outflow from treated rice paddies was considered; TERs were calculated using average maximum daily PECs from RICEWQ/RIVWQ simulations and the NOAEC of 4 µg/L (based on recovery test).

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The resulting TERs for the river, but not the canal or ditch scenarios exceeded the trigger of 10. Risk assessment still need to be refined. Moreover, RMS has considered the NOAEC of 4 µg/L not acceptable: the recovery test gives information on the potential for recovery of *Lemna*, but does not allow to extrapolate a NOAEC value useful for the risk assessment.

Notifier has further refined the risk to aquatic plants.

Higher-tiered modelling was used to obtain the 90th percentile 14-d TWA PEC_{sw} values for each of 20 simulation years and 5 meteorological scenarios. The TER, calculated on the basis of the average 90th percentile 14-d TWA PEC_{sw} (worst case) and the lowest EC₅₀ for *Lemna*, resulted equal to 25 (above the EU Annex VI trigger of 10). Therefore, it can be concluded that the risk to aquatic plants is acceptable under more realistic exposure conditions.

To strongly support this conclusion, results of biological greenhouse screening on 18 aquatic plant species were used to evaluate the potential range of sensitivities of aquatic plants. A comparison of EC₅₀s for all 21 aquatic plant species for which data are available (18 aquatic macrophytes, two algae and *Lemna*), demonstrates that *Lemna* is the most sensitive species. This suggests that a risk assessment based on laboratory studies with *Lemna*, in which test concentrations are maintained over the entire test period over-predicts risk to aquatic plants likely to be posed by Bensulfuron methyl under field conditions. The inclusion of additional aquatic plant species in the risk assessment may well address uncertainty associated with inter-species sensitivity. Moreover, the availability of several tested species could allow a Species Sensitivity Distribution analysis and a trigger reduction, for national level authorizations.

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Metabolites

A summary of the aquatic toxicity endpoints selected for the risk assessment are presented in the Table below.

Table 2. 15: Summary of toxicity studies of metabolites of Bensulfuron methyl for aquatic organisms

Test organism	Test Substance	Duration, conditions	Toxicological Endpoint (mg/L)	Concentration n/m [#]
<i>Oncorhynchus mykiss</i>	IN-J0290	96 hr, static	LC ₅₀ > 97	m
<i>Daphnia magna</i>		48 hr, static	EC ₅₀ > 100	n
<i>Daphnia magna</i>		21 days, static renewal	NOEC = 24.9	m
<i>Selenastrum capricornutum</i>		72 hr, static	E _r C ₅₀ > 120	n
<i>Lemna gibba</i>		14 d, static	E _{f/b} C ₅₀ > 100	n
<i>Oncorhynchus mykiss</i>	IN-N5297	96 hr, static	LC ₅₀ > 118	m
<i>Daphnia magna</i>		48 hr, static	EC ₅₀ > 117	m
<i>Daphnia magna</i>		21 days, static renewal	NOEC = 12.7	m
<i>Selenastrum capricornutum</i>		72 hr, static	E _{b/r} C ₅₀ > 120	n
<i>Lemna gibba</i>		14 d, static	E _{f/b} C ₅₀ > 120	n
<i>Selenastrum capricornutum</i>	IN-D1R84	72 hr, static	E _r C ₅₀ = 36.2	n
<i>Lemna gibba</i>		14 d, static	E _{f/b} C ₅₀ > 130	n
<i>Selenastrum capricornutum</i>	IN-R9419	72 hr, static	E _r C ₅₀ = 37.3	n
<i>Lemna gibba</i>		14 d, static	E _f C ₅₀ = 6.2	n
<i>Selenastrum capricornutum</i>	IN-T5831	72 hr, static	E _r C ₅₀ = 99.1	n
<i>Lemna gibba</i>		14 d, static	E _f C ₅₀ = 120.9	n
<i>Selenastrum capricornutum</i>	IN-F7880	72 hr, static	E _r C ₅₀ = 32.3	n
<i>Lemna gibba</i>		14 d, static	E _f C ₅₀ = 1.18	n
<i>Selenastrum capricornutum</i>	IN-DAT97	72 hr, static	E _r C ₅₀ = 33.7	n
<i>Lemna gibba</i>		14 d, static	E _f C ₅₀ = 79.1	n

[#] n = nominal; m = measured

A Tier 1 acute risk assessment was conducted for all Bensulfuron metabolites potentially produced in soil or aquatic water/sediment systems. The assessment is based on the worst-case assumptions of assuming aquatic organisms inhabit the rice paddy fields during flood and are exposed to maximum concentrations (calculated according to the Med-Rice (2003) model) of the metabolites.

On the basis of TER values, it may be concluded that Bensulfuron methyl metabolites pose a low acute risk to aquatic organisms including the most sensitive organisms to Bensulfuron methyl.

Two Bensulfuron methyl metabolites occurred in the sediment phase of the laboratory water/sediment degradation studies at levels exceeding 10% of applied radioactivity after 14 days. This finding triggers the need for an assessment of potential risk to sediment organisms.

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The TERs far exceed Annex VI decision making criterion of 10 and suggest that neither metabolites poses a long-term risk to aquatic invertebrates in the water column or the sediment.

Risk to sediment dwelling invertebrate species

Bensulfuron methyl was found to partition to sediment in a water/sediment fate study and therefore it is appropriate to assess its potential risk to sediment-dwelling organisms. A long-term study with *Chironomus* was not conducted because Bensulfuron methyl demonstrates very low acute and long-term/reproductive toxicity to aquatic invertebrates. Tests with *Daphnia magna* resulted in an 48-h EC₅₀ of >130 mg a.i./L and a 21-d NOEC of 12 mg a.i./L. In an acute, water-only test with the sediment organism *Chironomus tentans*, Bensulfuron methyl had a 96-h EC₅₀ >125 mg a.i./L.

The low toxicity to aquatic invertebrates, including sediment-dwelling invertebrates and moderately rapid dissipation of Bensulfuron methyl in sediment systems (mean, whole-system DT₅₀ = 48d) supports the conclusion that Bensulfuron methyl poses a minimal risk to sediment-dwelling invertebrate species.

2.6.3 Effects on terrestrial vertebrates other than birds (Annex IIIA 10.3)

Toxicity testing with the formulated product, Bensulfuron methyl 60WG on terrestrial vertebrates was conducted and the endpoints used in the risk assessment are summarised below.

Test substance	Test organism	Exposure type	LD ₅₀ (mg/kg bw)	NOEL (mg s./kg bw/d)
Bensulfuron methyl	Rat	Acute oral	>5000	-
Bensulfuron methyl	Rat	Two-generation reproduction	-	20.9 ^a (250) ^b

^a NOEL in terms of daily dose is an average for F1 males based on slightly lower body weight in F1 adult males at 7500 ppm and females based on lower body weight in F1 litters at 7500 ppm.

^b NOEL in terms of dietary concentration of Bensulfuron methyl (mg a.i./kg feed).

The scenarios considered for the risk assessment included the consumption of contaminated food (of vegetal origin and insects), the secondary poisoning and the uptake of contaminated water. The risk assessments were conducted in a stepwise approach according to the SANCO/4145/2000.

1. Consumption of contaminated food

Acute and long-term TERs exceed relevant Annex VI criteria of 10 and 5, respectively.

2. Bioaccumulation and food chain behaviour

According to the SANCO/4145/2002 (Chapter 4) for organic chemicals when a log P_{ow} is >3 a potential for bioaccumulation should be assessed. The log K_{ow} at pH 5 (highest measured log K_{ow}) was 2.18 for Bensulfuron methyl and therefore an assessment of potential risk to earthworm- and fish-eating mammals is not requested. However the potential for bioaccumulation will be considered and assessed according to the SANCO/4145/2000.

The TERIt resulting from this first-Step assessment were above the trigger value 5.

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3. Exposure via drinking water

Taking into consideration the predicted uses of Bensulfuron methyl, the exposure to the active substance residues via drinking water is possible mainly for the mammals species that frequent open water bodies, species that are liable to ingest water contaminated.

On the basis of the worst case PEC_{sw}, Tier 1 TER_{It} for mammals potentially exposed to Bensulfuron methyl through drinking water are acceptable (>5).

2.6.4 Effects on Bees (Annex IIA 8.3.1, Annex IIIA 10.4)

Based on the maximum application rate specified on the GAP (60 g a.i./ha) and the endpoints from acute oral and contact toxicity tests, the hazard quotients were calculated.

Test substance	Exposure route	Max. application rate of Bensulfuron methyl 60WG (g a.i./ha)	LD ₅₀ (µg a.i./bee)	HQ
Bensulfuron methyl	oral	60	>51.41	<1.2
Bensulfuron methyl	contact	60	>100	<0.6

The Q_{HO} and Q_{HC} for Bensulfuron methyl are below the Annex VI decision making criterion of 50. In addition, the very low toxicity of Bensulfuron methyl formulated product, Bensulfuron methyl 60WG, to non-target arthropods suggests that the formulation would be no more toxic to bees than the active substance. Therefore, it may be concluded that Bensulfuron methyl 60WG poses a low risk to honey bees.

2.6.5 Effects on Other arthropods species (Annex IIA 8.3.2, Annex IIIA 10.5)

Worst-case (Tier 1) laboratory studies bioassays with Bensulfuron methyl 60WG were conducted on the predatory mite, *Typhlodromus pyri*, and the aphid parasitoid, *Aphidius rhopalosiphi*. The endpoints used in the risk assessment are presented below.

Species	Test	Measurement endpoint	Endpoint value
<i>Aphidius rhopalosiphi</i>	Tier 1	LR ₅₀	> 600 g a.i./ha
<i>Typhlodromus pyri</i>	Tier 1	LR ₅₀	> 600 g a.i./ha

Risk assessment methods for non-target arthropods are based on recommendations from the Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-target Arthropods, ESCORT 2 (Candolfi *et al.* 2001).

Based on the HQ values (<2) for the two sensitive indicator species, *Aphidius rhopalosiphi* and *Typhlodromus pyri*, Bensulfuron methyl 60WG poses a very low risk to in-field and off-field non-target arthropod populations, when used according to Good Agricultural Practice.

2.6.6 Effects on earthworms (Annex IIA 8.4, Annex IIIA 10.6)

Bensulfuron methyl and its soil metabolites have low toxicity to earthworms.

The TER_a values far exceed the relevant Annex VI decision-making criterion of 10 for earthworms. Therefore, it can be concluded that acute risk to earthworms from the use of Bensulfuron methyl 60WG in rice will be low.

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Chronic earthworm testing with Bensulfuron methyl or its soil degradates was not considered necessary due to low persistence in field, extremely low acute earthworm toxicity and low PEC_{soil} for both the parent and its soil degradates.

2.6.7 Effects on other soil non-target macro-organisms (Annex IIIA 10.6.2)

Based on the longest DT_{50} value from the field dissipation study, the field DT_{90} is estimated to be approximately 40 days. Evidence from earthworms, honeybees, and beneficial arthropods toxicity tests suggest low toxicity of Bensulfuron methyl 60WG residues to non-target invertebrate fauna. Therefore, Bensulfuron methyl 60WG, when applied according to Good Agricultural Practice, is expected to pose little acute or long-term risk to soil non-target macro-organisms and no further testing is warranted.

Bensulfuron methyl 60WG is not expected to affect organic matter breakdown in the soil ($DT_{90} < 365$ days) and no further testing is warranted.

2.6.8 Effects on soil non-target micro-organisms (Annex IIA 8.5, Annex IIIA 10.7)

Laboratory testing of Bensulfuron methyl 60WG, Bensulfuron methyl and the major soil degradates suggests an acceptable risk to soil microorganisms. Deviations between treatments and controls were $< 25\%$ for both nitrogen transformation and carbon mineralisation by the end of the studies, even at concentrations far exceeding the PEC_{soil} .

2.6.9 Effects on other non-target organisms (flora and fauna) believed to be at risk (Annex IIA 8.6, Annex IIIA 10.8)

A quantitative risk assessment approach following recommendations outlined in SANCO/10329/2002 was taken to estimate potential risk to non-target terrestrial plants. TERs, reported in the Tables below, were determined based on drift deposition at 1m, and 5m from the edge of the paddy and the ER_{50} values from the seedling emergence and vegetative vigour tests. A regulatory trigger of 5 was considered for initial risk estimation because 10 species of plants were tested.

For soil application, 9 of the 10 species tested exceeded the regulatory trigger at 1m, the trigger was not exceeded for the most sensitive species, oilseed rape; all species passed the trigger at 5m.

For foliar exposure, 6 of the 10 species tested exceeded the regulatory trigger at 1m, and all species passed the trigger at 5m.

In conclusion, the risk of Bensulfuron methyl to sensitive off-crop non-target terrestrial plants when exposed to spray drift via soil or foliar exposure is considered acceptable with a buffer strip of 5m.

2.6.10 Effects on biological methods for sewage treatment (Annex IIA 8.7)

Basing on the results that the maximum effect of Bensulfuron methyl on activated sludge corresponds to 6.4 % inhibition of the respiration at the tested concentrations of 100 mg/L, the risk for the biological methods of sewage treatment is considered to be low.

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Appendix 1: Standard terms and abbreviation

Technical Terms

A	ampere
ACH	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD ₅₀	approximate median lethal dose, 50%
AOEL	acceptable operator exposure level
AMD	automatic multiple development
approx.	approximate
as	active substance
at. wt.	atomic weight
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
b.p.	boiling point
BSP	bromosulfophthalein
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10 ⁻²)
°C	degree celsius (centigrade)
CAD	computer aided design
cd	candela
CDA	controlled drop(let) application
CEC	cation exchange capacity
cf	confer, compare to
ChE	cholinesterase
cm	centimetre
CNS	central nervous system
CoC	code of conduct
COD	chemical oxygen demand
cu	cubic
cv	coefficient of variation
Cv	ceiling value
cyt	cytogenetic analysis
d	day
DAT	day after treatment
DL	racemic (optical configuration, a mixture of dextro- and laevo-; preceding a chemical name)
dlt	dominant lethal test
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dnd	DNA-damage
dni	DNA-inhibition
dnr	DNA-repair
dns	unscheduled DNA-synthesis

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DO	dissolved oxygen
DOC	dissolved organic carbon
DT	disappearance time
DTH	delayed-type hypersensitivity
EC ₅₀	effective concentration
ECD	electron capture detector
ELISA	enzyme linked immunosorbent assay
EMDI	estimated maximum daily intake
EP	end-use product
ERL	extraneous residue limit
F ₀	parental generation
F ₁	filial generation, first
F ₂	filial generation, second
FID	flame ionisation detector
f.p.	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
GAP	good agricultural practice
GC-EC	gas chromatography with electron capture detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
G.I.	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GPC	gel-permeation chromatography
GPPP	good plant protection practice
h	hour(s)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
hl	hectolitre
hma	host-mediated assay
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
Ht	haematocrit
I ₅₀	inhibitory dose, 50%
IC ₅₀	median immobilisation concentration
i.d.	internal diameter
ID	ionisation detector
i.m.	intramuscular
inh	inhalation
i.p.	intraperitoneal
IPM	integrated pest management
IR	infrared

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i.v.	intravenous
k	kilo
K	Kelvin
K _d	Ratio of sorbed to solution pesticide in a water-soil slurry
K _{oc}	Parameter which adjust K _d or Freundlich K for the proportion of organic carbon in the soil.
kg	kilogram
l	litre
LBC	loosely bound capacity
LC	lethal concentration
LC	liquid chromatography
LC ₅₀	lethal concentration, median
LCA	life cycle analysis
LD ₅₀	lethal dose, median; dosis letalis media
LD _{Lo}	lethal dose low
LOAEL	lowest observable adverse effect level
LOD	limit of determination
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LT	lethal threshold
m	metre
M	molar
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
µg	microgram
mg	milligram
min	minute(s)
ml	millilitre
MLD	minimum lethal dose
mm	millimetre
mma	microsomal mutagenicity test
mmo	mutation in microorganisms
mnt	micronucleus test
mo	month(s)
mol	Mol
m.p.	melting point
MP	manufacturing-use product
mrc	gene conversion and mitotic recombination
MRE	maximum residue expected
MRL	maximum residue level
msc	mutation in mammalian somatic cells
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration)
NAEL	no adverse effect level
n.d.r.	not dose-related
NEDI	no effect daily intake (mg/kg body wt/day)
NEL	no effect level
NERL	no effect residue level
NMR	nuclear magnetic resonance

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no.	number
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
nse	non standard exposure
o	ortho (indicating position in a chemical name)
ODP	ozone-depleting potential
OP	organophosphorous pesticide
otr	oncogenic transformation
p	para (indicating position in a chemical name)
Pa	pascal
2-PAM	2-pralidoxime
PC	paper chromatography
PCV	haematocrit (packed corpuscular volume)
PD	position document
PEC	predicted environmental concentration
PED	plasma-emissions-detector
PELMO	Pesticide Leaching MOdel
pH	pH-value
PHI	pre-harvest interval
pic	phage inhibition capacity
PNEC	predicted no effect concentration
p.o.	by mouth
P _{ow}	partition coefficient between n-octanol and water
ppb	parts per billion
ppm	parts per million
ppq	parts per quadrillion
ppt	parts per trillion
PSP	phenolsulphophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTT	partial thromboplastin time
RAC	raw agriculture commodity
RBC	red blood cell
R _f	ratio of fronts
RL50	residual lifetime
RNA	ribonucleic acid
rns	rinsed
RPM	reversed phase material
RRT	relative retention time
s.c.	subcutaneous
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SBLC	shallow bed liquid chromatography
see	sister chromatid exchange
SD	standard deviation
SE	standard error
SEP	standard evaluation procedure
SF	safety factor

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SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
sin	sex chromosome loss and nondisjunction
sit	specific locus test
sp/spp.	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
sp gr	specific gravity
spm	sperm morphology
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TCLo	toxic concentration, low
TD	thermionic detector, alkali flame detector
TDL _o	toxic dose low
tert	tertiary (in a chemical name)
TEP	typical end-use product
TER	Toxicity Exposure Ratio
TGAI	technical grade of the active ingredient
TLC	thin layer chromatography
T _{lm}	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
trn	heritable translocation test
TWA	time weighted average
UDS	unscheduled DNA synthesis
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
wt/vol	weight per volume
w/w	weight per weight
yr	year

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Organisations and Publications

ANSI	American National Standards Institution
BA	Biological Abstracts (Philadelphia)
BSI	British Standard Institution
CA	Chemical Abstracts
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECCA	European Crop Care Association
ECPA	European Crop Protection Association
EHCD	Environmental Health Criteria Document
EINECS	European Inventory of Existing Commercial Chemical Substances
EPPO	European and Mediterranean Plant Protection Organisation
ESA	Entomological Society of America
EU	European Union
FAO	Food and Agriculture Organisation of the UN
FJCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
GATT	General Agreement on Tariffs and Trade
GIFAP	Groupeement International des Associations Nationales de Fabricants de Produits Agrochimiques
IARC	International Agency for Research on Cancer
IBT	Industrial Bio-Test Laboratories
IMO	International Maritime Organisation
IOBC	International Organisation for Biological Control of Noxious Animals and Plants
JMAF	Japanese Ministry for Agriculture, Forestry and Fishery
IPCS	International Programme on Chemical Safety
IR-4	Interregional Research Project No 4
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
OECD	Organisation for Economic Cooperation and Development
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
SCPH	Standing Committee on Plant Health
SI	Système International d'Unites
SITC	Standard International Trade Classification
UN	United Nations
UNEP	United Nations Environment Programme
WHO	World Health Organisation
WTO	World Trade Organisation
WWF	World Wildlife Fund

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Appendix 2 Specific terms and abbreviations

Preparation (Formulation) Types and Codes*

Code	Description	Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block baits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active ingredient into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic) spraying.
EO	Emulsion, water in oil	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
EW	Emulsion, oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.
FG	Fine granule	A granule in the particle size range from 300 to 2500 µ.
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.
FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.
FW	Smoke pellet	Special form of smoke generator.
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 µ.
GP	Flo-dust	Very fine dustable powder for pneumatic application in glass-houses.
GR	Granule	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Grease	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treatment	A solution for application to the seed either directly or after dilution.

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Code	Description	Definition
MG	Microgranule	A granule in the particle size range from 100 to 600 µ.
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a pesticide	Self defining.
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.
SB	Scrap bait	Special forms of bait.
SC	Suspension concentrate	A stable suspension of active substance(s) in a fluid (= flowable concentrate) intended for dilution with water before use.
SE	Suspo-emulsion	A fluid, heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles and of fine globules in a continuous water phase.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but may contain insoluble inert ingredients.
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of the active substance after dilution with water.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance after solution in water but which may contain insoluble inert ingredients.
SS	Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small, flat plates for dissolution in water.
TP	Tracking powder	A rodenticidal contact preparation in powder form.
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

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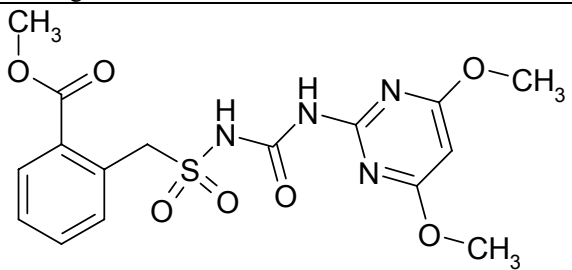
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Appendix 3 List of endpoints**Chapter 2.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling**

Active substance (ISO Common Name)	Bensulfuron methyl
Function (e.g. fungicide)	Herbicide

Rapporteur Member State	Italy
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Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Methyl α-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-o-toluate
Chemical name (CA) ‡	Methyl 2-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]=sulfonyl]methyl]benzoate
CIPAC No ‡	502
CAS No ‡	83055-99-6
EC No (EINECS or ELINCS) ‡	401-340-6
FAO Specification (including year of publication) ‡	Presented to FAO committee June 2002 and is currently under review
Minimum purity of the active substance as manufactured ‡	975 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	C ₁₆ H ₁₈ N ₄ O ₇ S
Molecular mass ‡	410.4 g/mole
Structural formula ‡	

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Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	179.4 °C (98.3%)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition (state purity)	Approximately 245°C (98.3%)
Appearance (state purity) ‡	White solid (98.3%)
Vapour pressure (state temperature, state purity) ‡	2.8×10^{-12} Pa at 25°C (extrapolated) (99.3%)
Henry's law constant ‡	6×10^{-7} Pa m ³ mol ⁻¹ at pH 5 2×10^{-11} Pa m ³ mol ⁻¹ at pH 7 4×10^{-13} Pa m ³ mol ⁻¹ at pH 9
Solubility in water (state temperature, state purity and pH) ‡	Solubilities at 25°C (99.5%) pH 5: 2.1 mg/l pH 7: 67 mg/l pH 9: 3100 mg/l
	Solubility at 20°C (99.5%) Unbuffered distilled water: 6.65 mg/ml at 20°C
Solubility in organic solvents ‡ (state temperature, state purity)	Solubilities at 20°C (99.3%) Acetone: 5.10 g/L Acetonitrile: 3.75 g/L Dichloromethane: 18.4 g/L Dimethylformamide: 70.8 g/L Ethyl acetate: 1.75 g/L n-Heptane: 3.62×10^{-4} g/L Methanol: 0.765 g/L 1-Octanol: 7.47×10^{-2} g/L o-Xylene: 0.229 g/L
Surface tension ‡ (state concentration and temperature, state purity)	74.9×10^{-3} N/m (90 % saturated solution and at 20.3°C) (97.9%)
Partition co-efficient ‡ (state temperature, pH and purity)	Parent (experimental) (99.5%): pH 5: $\log P_{ow} = 2.18$ at 25°C pH 7: $\log P_{ow} = 0.79$ at 25°C pH 9: $\log P_{ow} = -0.99$ at 25°C
	Impurities/Metabolites (calculated): IN-J0290 (pyrimidine amine): $\log P_{ow} = 0.95$ IN-N5297 (sulfonamide): $\log P_{ow} = 0.47$
Dissociation constant (state purity) ‡	pKa = 5.2 at 20°C (99.0%)
UV/VIS absorption (max.) incl ϵ ‡ (state purity, pH)	Absorption (max): 239 nm at pH 7: $\epsilon = 784 \text{ l} \times \text{mol}^{-1} \times \text{cm}^{-1}$ at 290 nm at pH 7 (98.3%)
Flammability ‡ (state purity)	Negative; Not classified (98.66%)
Explosive properties ‡ (state purity)	Negative; Not explosive (98.66%)
Oxidising properties ‡ (state purity)	Not oxidising (structural argument)

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Summary of representative uses evaluated (*Bensulfuron methyl*)*

Crop and/or situation (a)	Member State, Country or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	g as/ha (l) min – max	water L/ha min – max	g as/ha (l) min – max		
Rice	Italy Spain France (South) Greece Portugal Hungary	Londax® Sectar® Testar®	F	Broadleaved weeds and Cyperaceae	WG	600 a.s.g/kg	Flooded Rice Broadcast terrestrial	Pre-sowing application 5-2 days before sowing. Post-emergence Application to be made between 20 to 45 days after sowing. (Depending on locale, this may be between BBCH12 two leaves and BBCH 29 maximum tillers)	1	N/A	N/A	200-400	0.048-0.060	Normal Maturity (BBC H 89)	Flooded: (5-10 cm) water Do not apply within 60 days of harvest.

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(a)	Member State, Country or Region	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL (l) min – max	water L/ha min – max	g as/ha (l) min – max		
Rice	Italy Spain France (South) Greece Portugal Hungary	Londax® Sectar® Testar®	F	Broadleaved weeds and Cyperaceae	WG	600 a.s.g/kg	Saturated soil with 0-1 cm of water Broadcast terrestrial	Post-emergence Application to be made between 20 to 50 days after sowing. (Depending on locale, this may be between BBCH 12 two leaves and BBCH 29 maximum tillers)	1	NA	N/A	200-400	0.048-0.060	Normal Maturity (BBCH H 89)	Soil will be flooded with 5-10 cm of water from 2 to 5 days after the treatment and water will be kept in rice paddy for at least 15 days. Do not apply within 60 days of harvest.

[1] The risk assessment has revealed a risk in section 4.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s). (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl). (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha) (m) PHI - minimum pre-harvest interval
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Chapter 2.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Bensulfuron methyl is determined by reversed-phase HPLC, using UV detection at 236 nm. Confidential Attachment in Volume 4 Annex C
Impurities in technical as (analytical technique)	High boiling impurities are determined by reversed-phase HPLC using UV detection at 230 nm, whereas solvents are determined by GC/FID. Confidential Attachment in Volume 4 Annex C
Plant protection product (analytical technique)	Same method used in Technical as. The inert ingredients included in bensulfuron methyl 60WG are not expected to interfere with the extraction and analysis of bensulfuron methyl residues in any matrix. Therefore, no residue analytical methods have been developed specifically for bensulfuron methyl 60WG.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Bensulfuron methyl
Food of animal origin	Bensulfuron methyl
Soil	Bensulfuron methyl, IN-J0290, IN-N5297, IN-D1R84, IN-R9419
Water surface	Bensulfuron methyl, IN-J0290, IN-N5297, IN-R9419
drinking/ground	Bensulfuron methyl, IN-N5297, IN-T5831, IN-DAT97
Air	Bensulfuron methyl

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Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)

Bensulfuron methyl is extracted by homogenisation in an aqueous ammonium carbonate solution. Extracts are purified and concentrated by solid-phase extraction (SPE). Analysis options are reversed-phase HPLC utilising: column switching with UV detection or electrospray with selected ion monitoring mass spectrometry (LC/ESI/MS), or electrospray tandem mass spectrometry (LC/ESI/MS/MS).
The Limit of Quantitation (LOQ) is 0.010 ppm in rice grain and 0.050 ppm in rice straw.

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

Not needed. A foodstuff of animal origin method was not required because bensulfuron methyl residues ≥ 0.1 mg/kg do not occur in any feed items or products of animal origin after the application of bensulfuron methyl under normal agricultural practice based on metabolism studies.

Soil (analytical technique and LOQ)

Bensulfuron methyl in soil is extracted in 90% ammonium carbonate/10% methanol solution using a wrist-action shaker. Extracts are purified and concentrated by SPE. The analyte is eluted from the SPE cartridge, partitioned into ethyl acetate, evaporated to dryness, and reconstituted for reversed-phase LC/ESI/MS/MS analysis.
The Limit of Quantitation (LOQ) is 0.050 $\mu\text{g/kg}$.

Water (analytical technique and LOQ)

Bensulfuron methyl in water is extracted, purified, and concentrated by SPE. The analyte is eluted from the SPE cartridge, evaporated to dryness, and reconstituted for reversed-phase LC/ESI/MS/MS analysis.
The limit of Quantitation (LOQ) is 0.050 $\mu\text{g/L}$.

Air (analytical technique and LOQ)

Bensulfuron methyl is adsorbed on XAD-2 adsorbent from ambient and warm/humidified air and desorbed in acetonitrile. Analysis is by reversed-phase LC/ESI/MS/MS.
The Limit of Quantitation (LOQ) is 3.0 $\mu\text{g/m}^3$.

Body fluids and tissues (analytical technique and LOQ)

Not needed. A body fluids and tissues method was not required because bensulfuron methyl and its metabolites are not classified as highly toxic or toxic to humans and would not bio-accumulate in human tissues.

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

Active substance

RMS/peer review proposal

Not classified

Chapter 2.3: Impact on Human and Animal Health**Metabolism (Annex IIA, point 5.1)**

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Rate and extent of absorption:

Absorption substantially complete by 24 h after dose administration based on rise and decline of radioactivity in plasma. Peak plasma concentrations occurred at 1-4 h after oral gavage with a single low dose (20 mg/kg bw); 4 to 12 h after high dose (1000 mg/kg bw). Estimated percent dose absorbed by 24 h after 20 mg/kg dose of biliary cannulated animals was 49-68% as sum of dose recovered in bile, urine plus cage wash, and tissues minus gastrointestinal tract content. AMR 964-87

Distribution:

The elimination half-lives describing the decline of plasma radioactivity ranged from 5.3 to 9.1 h. Less than 0.3% of the dose remained in all tissues and carcass by 96 h after dose administration. The majority of the absorbed dose was excreted in bile and urine. AMR 964-87

Potential for accumulation:

Tissue-to-plasma ratios for total radioactivity were <1 for low dose and 2-5 for high dose. Residual radioactivity in plasma was undetectable by 72 h after dose administration indicating minimal potential for bio-accumulation. AMR-964-87

Rate and extent of excretion:

Excretion in urine and feces essentially complete by 48 to 72 h after administration, independent of sex, dose level, radiolabel, or single or multiple dosing. After single or multiple low dose the percent of dose excreted was 44-58% of dose in urine and 27-42% in faeces. After the high dose with pyrimidine or phenyl labels, excretion in urine was 22-30% and feces 57-66% of the dose. Biliary excretion through 24 h after dose administration was 29% and 16% in male and female rats, respectively. AMR-964-87

Metabolism in animals

Bensulfuron methyl undergoes extensive metabolism in rats primarily by *O*-demethylation and hydroxylation of the pyrimidine ring as well as sulfonamide cleavage. No major changes observed between pyrimidine or phenyl labels, sexes, low and high dose groups, or single vs. multiple dosing. AMR-964-87

Toxicologically significant compounds (animals, plants and environment)

Parent compound

Acute toxicity (Annex II A, point 5.2)

Rat LD₅₀ oral

>5000 mg/kg bw (male and female rat) HLR 239-84

Rat LD₅₀ dermal

>2000 mg/kg bw (male and female rabbit) HLO 225-83

Rat LC₅₀ inhalation

>5 mg/L (male and female rat) HLR 332-83

Skin irritation

Non-irritant (male rabbit) HLO 187-84

Eye irritation

Non-irritant (female rabbit) HLO 174-84

Skin sensitization (test method used and result)

Weight of evidence suggests bensulfuron methyl is a non-sensitizer. Negative in the Buehler and weak response in Magnusson & Kligman test methods. HLO 628-91

WARNING: This document is part of an EC evaluation data package and should not be used for registration purposes. It is not to be used as the basis of this document.

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Acute toxicity (Annex IIIA, Point 7.1)

Rat LD₅₀ oral
 Rat LD₅₀ dermal
 Rat LC₅₀ inhalation
 Skin irritation
 Eye irritation
 Skin sensitization (test method used and result)

>5000 mg/kg bw (male and female rat) HLR 680-86
>2000 mg/kg bw (male and female rabbit) HLR 708-86
Not required
Non-irritant HLR 712-86
Non-irritant HLR 618-86
Non-sensitiser by the Buehler protocol. Non-sensitiser by Maximisation test

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect

Lowest relevant oral NOAEL / NOEL

Lowest relevant dermal NOAEL / NOEL

Lowest relevant inhalation NOAEL / NOEL

Hepatotoxicity and hepatic hypertrophy. Slight effects and/or pharmacological adaptive responses were also observed in the livers of rats and mice.
NOEL = (21.4 mg/kg bw/d and 19.9 mg/kg bw/d) for male and female dogs, respectively in 1 year study. HLR 3-85
No data; not required
No data; not required

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential: Negative in 5 studies <i>in-vitro</i> and 1 study <i>in-vivo</i>
<i>In-vitro</i> gene mutation – bacteria HLR 609-81, Revision No. 1
<i>In-vitro</i> gene mutation – mammalian cells HLR 212-84
<i>In-vitro</i> chromosomal aberration test HLR 26-88
<i>In-vitro</i> unscheduled DNA synthesis HLR 278-84
<i>In-vitro</i> sister chromatid exchange HLR 683-86
<i>In-vivo</i> bone marrow chromosome aberration HLO 210-84

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Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target / critical effect

Liver hypertrophy and histological changes in the 1 year dog study HLO 35-86

Lowest relevant NOAEL / NOEL

NOEL = 750 ppm (21. and 19.9 mg/kg bw/d for male and female dogs, respectively) in a 1 year study

Carcinogenicity

No carcinogenic potential
HLO 662-85 & TX 5384-1-86

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target/critical effect

Not a reproductive toxin. Reduced parental and offspring body weights at ≥ 7500 ppm (462 mg/kg).

Lowest relevant reproductive NOAEL/NOEL

Systemic toxicity NOEL = 250 ppm for both parental animals and offspring (or 20 and 22 mg/kg bw/day, the highest values for male and female rats, respectively) in a two generation study. HLO 430-89 Volume No. 1

Developmental target/critical effect

Reduction of foetal body weight
Abnormal ossification
HLR 704-85 and HLR 1-84

Lowest relevant developmental NOAEL/NOEL

Rabbit: Systemic toxicity NOAEL = 300 mg/kg bw/day. Maternal toxicity and reduced offspring body weight at 1500 mg/kg bw HLR 704-85

Neurotoxicity/Delayed neurotoxicity (Annex IIA, point 5.7)

No data. No neurotoxic concern based on the weight of evidence from results of other studies.

Other toxicological studies (Annex IIA, point 5.8)

Supplementary studies were conducted on four bensulfuron methyl metabolites. The studies primarily consisted of acute oral toxicity range-finding studies and evaluations in a bacterial mutagenicity assay (Ames test). The metabolites represented those resulting from the following: o-demethylation of the phenyl ring (IN-R9419); hydrolysis of the sulfonylurea bridge to release the pyrimidine component (IN-J290) and the phenyl sulfonamide (IN-N5297); and rearrangement of the phenyl sulfonamide to the homosaccharin (IN-B6895). Based on this limited testing, none of the metabolites were mutagenic and none produced significant toxicity when administered by oral gavage. Only IN-J290 would be classified under Directive 67/548/EEC as harmful for acute oral toxicity (LD₅₀ 1200 mg/kg bw). However, its presence as a trace component resulting from metabolism of very low levels of bensulfuron methyl likely associated with human exposure does not represent a risk to human health.

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Medical data (Annex IIA, point 5.9)

.....

No detrimental effects on health of manufacturing personnel

Summary (Annex IIA, point 5.10)

ADI

AOEL

Drinking water limit

ArfD (acute reference dose)

Value	Study	Safety factor
0.20 mg/kg bw/day	Dog 1 year study	100x
0.2 mg/kg bw/day	Dog 1 year study	100x
0.60 mg/L (based on 1/10 fraction of ADI allocated to drinking water)	Dog 1 year study	100x
Not allocated; not necessary		

Summary of acute toxicity studies with Bensulfuron methyl 60WG (Annex IIIA, point 7.1.8)

Parameter	Species	Result	Reference
Acute oral LD ₅₀	Rat	5000 mg/kg	Sarver 1986a
Acute dermal LD ₅₀	Rabbit	>2000 mg/kg	Sarver, 1986b
Acute skin irritation	Rabbit	Non irritant	Sarver, 1986c
Acute eye irritation	Rabbit	Non irritant	Henry, 1986
Skin Sensitisation: Buehler method	Guinea Pig	Non sensitising	Moore, 2002
Maximisation test	Guinea Pig	Non sensitising	Moore, 2003

Dermal absorption (Annex IIIA, point 7.3)

.....

4,7% in vivo rat with concentrated product 1,7% in vivo rat with spray diluted product

Acceptable exposure scenarios (including method of calculation)

Operator

Workers

Bystanders

Acceptable for proposed uses (UK POEM and German exposure models)
No risk identified for proposed uses
Acceptable for proposed uses

Classification and proposed labeling

Whit regard to toxicological data

R63 Possible risk of harm to the unborn child.
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Chapter 2.4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Cereals (rice), soil treatment
Rotational crops	Not required since residues >10 % are not expected in soil 100 days after application Additional information: wheat, cabbage, onions, garlic and beets
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required since no significant, no analytically determinable residues occur in the plant or plant product to be processed.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable since no processing studies have to be performed

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not required. Since dietary burden well below 0.1 mg/kg total diet. Additional information: Lactating ruminants (goat) Laying poultry (hens)
Time needed to reach a plateau concentration in milk and eggs	Additional information: Milk: the plateau was reached at day four of a seven-days study (0.027-0.031 mg/kg) Eggs: residues <LOD (0.002 mg/kg)
Animal residue definition for monitoring	Bensulfuron methyl
Animal residue definition for risk assessment	Bensulfuron methyl
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Not applicable since no livestock metabolism study is required
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	Additional information: Negligible residues found in rotational crops; Residue definition in succeeding crops is bensulfuron methyl.
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Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	Rice grain: up to 42 months at -24 °C, rice straw up to 18 months at -20 °C.
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Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)

Muscle

Liver

Kidney

Fat

Milk

Eggs

Conditions of requirement of feeding studies		
No	No	No
No	No	No
No	No	No
Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices: Mean (max) mg/kg		
No data, not required	No data, not required	No data, not required
No data, not required	No data, not required	No data, not required
No data, not required	No data, not required	No data, not required
No data, not required	No data, not required	No data, not required
No data, not required		
	No data, not required	

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Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/ comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Rice grain	S flooded land	3 x < 0.01 mg/kg; 6 x < 0.02 mg/kg	MRL can be set	0.02 mg/kg	0.02 mg/kg	0.01 mg/kg
Rice grain	S saturated land	4 x < 0.01 mg/kg	MRL can be set	0.01 mg/kg	0.01 mg/kg	0.01 mg/kg
Rice straw	S flooded land	3 x < 0.05 mg/kg	MRL can be set	0.05 mg/kg	0.05 mg/kg	0.05 mg/kg
Rice straw	S saturated land	3 x < 0.05 mg/kg; 1 x 0.1 mg/kg	MRL can be set	0.1 mg/kg	0.1 mg/kg	0.05 mg/kg

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

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Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.2 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	WHO/GEMS European diet, 2003: 0.000004 mg/kg/day (<0.1%) WHO/GEMS Cluster Consumption Diets, 2005 Cluster B: 0.000011 mg/kg/day (<0.1%) Cluster E: 0.000004 mg/kg/day (<0.1%) Cluster F: 0.000004 mg/kg/day (<0.1%) Cluster: D 0.000011 mg/kg/day (<0.1%)
TMDI (% ADI) according to national (to be specified) diets	UK Consumer Exposure Model 2006 Adult: 0.000045 mg/kg/day (<1%) Infant: 0.000056 mg/kg/day (<1%) Toddler: 0.000094 mg/kg/day (<1%) 4-6 years old child: 0.000074 mg/kg/day (<1%) 7-10 years old child: 0.0001 mg/kg/day (<1%) 11-14 years old child: 0.000078 mg/kg/day (<1%) 15-18 years old child: 0.000053 mg/kg/day (<1%) Vegetarian: 0.00004 mg/kg/day (<1%) Elderly/own home: 0.000023 mg/kg/day (<1%) Elderly/residential: 0.0000097 mg/kg/day (<1%) German model: 2-5 years old child: 0.000005 mg/kg/day (<0.1%)
IEDI (WHO European Diet) (% ADI)	Not required since TMDI is below 100%
NEDI (specify diet) (% ADI)	Not required since TMDI is below 100%
Factors included in IEDI and NEDI	Not required since IEDI, NEDI not necessary
ARfD	Not applicable
IESTI (% ARfD)	Not applicable
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not applicable
Factors included in IESTI and NESTI	Not applicable

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Rice grain	0.02 mg/kg
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When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure

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Chapter 2.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days	Phenyl: 13.0% (after 95 days), 14.2% (after 122 days) Pyrimidine: 4.51% (after 95 days), 5.32% (after 122 days)
Non-extractable residues after 100 days	Phenyl: 24.9% (after 95 days), 22.8% (after 122 days) Pyrimidine: 25.7% (after 95 days), 29.1% (after 122 days)
Relevant metabolites - name and/or code, % of applied (range and maximum)	IN-R9419 (27.7%); IN-D1R84 (18.2%); IN-J0290 (pyrimidine amine 21.0%); IN-F7880 (4.30%), IN-N5297 (sulphonamide, 6.83%)

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	DT ₅₀ of bensulfuron (phenyl label): 118 days (average, n=1) IN-N5297, IN-J0290, and IN-R9419 major degradation products
Soil photolysis	Average DT ₅₀ = 27 days with continuous irradiation; Adjusted DT ₅₀ = 44-64 days with a 12-hour photo-period Major degradation products: IN-N5297 (sulfonamide) IN-T5831 (pyrimidinyl urea)

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Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation

Laboratory studies (range or median, with n value, with r^2 value)

Software program ModelManager® (ver. 1.1, Cherwell Scientific Limited). Non linear SFO						
DT _{50lab} (25°C, aerobic): bensulfuron methyl						
<u>Soil</u>	<u>MWHC^b</u>	<u>%OC</u>	<u>pH_w</u>	<u>DT₅₀ (d)</u>	<u>r²</u>	
Silt loam	70%	2.4	5.6	89	0.978	
Silt loam	70%	1.0	6.7	89	0.941	
Sandy loam	70%	1.2	5.2	65	0.875	
Clay loam	70%	6.1	6.1	102	0.809	
Silt loam	70%	1.1	6.5	90	0.84	
DT _{50lab} (20°C, aerobic)						
Loamy sand	50%	0.5	5.2	25	0.957	
DT _{50lab} (20°C, aerobic) IN-J0290						
<u>Soil</u>	<u>MWHC^b</u>	<u>%OC</u>	<u>pH_w</u>	<u>DT₅₀ (d)</u>	<u>r²</u>	
Sandy loam F	50%	0.8	8.0	19	0.936	
Sandy loam	50%	0.3	5.5	18	0.880	
Loamy sand	50%	2.5	6.7	3	0.995	
Silt loam	50%	1.0	6.1	13	0.864	
DT _{50lab} (20°C, aerobic) IN-N5297						
<u>Soil</u>	<u>MWHC^b</u>	<u>%OC</u>	<u>pH_w</u>	<u>DT₅₀ (d)</u>	<u>r₂</u>	
Sandy loam	50%	0.8	8.0	7	0.995	
Sandy loam	50%	0.3	5.5	63	0.924	
Loamy sand	50%	2.5	6.7	4	0.997	
Silt loam	50%	1.0	6.1	45	0.951	
DT _{50lab} (20°C, aerobic) IN-R9419						
<u>Soil</u>	<u>MWHC^b</u>	<u>%OC</u>	<u>pH_w</u>	<u>DT₅₀ (d)</u>	<u>r²</u>	
Sandy loam	50%	1.0	8.1	20	0.960	
Sandy loam	50%	0.6	5.8	29	0.950	
Loamy sand	50%	2.1	5.9	8	0.975	
Silt loam	50%	1.2	6.2	20	0.877	
Loamy sand	50%	0.5	5.2	54	>0.957	
DT _{50lab} (20°C, aerobic) IN-D1R84						
<u>Soil</u>	<u>MWHC^b</u>	<u>%OC</u>	<u>pH_w</u>	<u>DT₅₀ (d)</u>	<u>r²</u>	
Sandy loam	50%	1.0	8.1	11	0.981	
Sandy loam	50%	0.6	5.8	17	0.934	
Loamy sand	50%	2.1	5.9	3	0.958	
Silt loam	50%	1.2	6.2	19	0.970	
DT _{50lab} (20°C, aerobic) IN-F7880						
<u>Soil</u>	<u>MWHC^b</u>	<u>%OC</u>	<u>pH_w</u>	<u>DT₅₀ (d)</u>	<u>r₂</u>	
Sandy loam	50%	1.0	8.1	4.1	0.994	
Sandy loam	50%	0.6	5.8	18.8	0.957	
Loamy sand	50%	2.1	5.9	5.6	0.958	
Silt loam	50%	1.2	6.2	20.2	0.947	
Loamy sand	50%	0.5	5.2	30.5	>0.957	

^b MWHC = Maximum Water Holding Capacity (0 bar)

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DT _{90lab} (25°C, aerobic): bensulfuron methyl						
Soil	MWHC ^b	%OC	pH _w	DT ₉₀ (d)	r ²	
Silt loam	70%	2.4	5.6	294	0.978	
Silt loam	70%	1.0	6.7	294	0.941	
Sandy loam	70%	1.2	5.2	214	0.875	
Clay loam	70%	6.1	6.1	339	0.809	
Silt loam	70%	1.1	6.5	297	0.84	
DT _{90lab} (20°C, aerobic)						
Loamy sand	50%	0.5	5.2	84	0.957	
DT _{90lab} (20°C, aerobic) IN-J0290						
Soil	MWHC ^b	%OC	pH _w	DT ₉₀ (d)	r ²	
Sandy loam F	50%	0.8	8.0	63	0.936	
Sandy loam	50%	0.3	5.5	60	0.880	
Loamy sand	50%	2.5	6.7	10	0.995	
Silt loam	50%	1.0	6.1	42	0.864	
DT _{90lab} (20°C, aerobic) IN-N5297						
Soil	MWHC ^b	%OC	pH _w	DT ₉₀ (d)	r ₂	
Sandy loam	50%	0.8	8.0	23	0.995	
Sandy loam	50%	0.3	5.5	208	0.924	
Loamy sand	50%	2.5	6.7	13	0.997	
Silt loam	50%	1.0	6.1	148	0.951	
DT _{90lab} (20°C, aerobic) IN-R9419						
Soil	MWHC ^b	%OC	pH _w	DT ₉₀ (d)	r ²	
Sandy loam	50%	1.0	8.1	65	0.960	
Sandy loam	50%	0.6	5.8	95	0.950	
Loamy sand	50%	2.1	5.9	27	0.975	
Silt loam	50%	1.2	6.2	65	0.877	
Loamy sand	50%	0.5	5.2	181	>0.957	
DT _{90lab} (20°C, aerobic) IN-D1R84						
Soil	MWHC ^b	%OC	pH _w	DT ₉₀ (d)	r ²	
Sandy loam	50%	1.0	8.1	35	0.981	
Sandy loam	50%	0.6	5.8	55	0.934	
Loamy sand	50%	2.1	5.9	11	0.958	
Silt loam	50%	1.2	6.2	62	0.970	
DT _{90lab} (20°C, aerobic) IN-F7880						
Soil	MWHC ^b	%OC	pH _w	DT ₉₀ (d)	r ₂	
Sandy loam	50%	1.0	8.1	13.5	0.994	
Sandy loam	50%	0.6	5.8	62.4	0.957	
Loamy sand	50%	2.1	5.9	18.4	0.958	
Silt loam	50%	1.2	6.2	67.1	0.947	
Loamy sand	50%	0.5	5.2	101	>0.957	
^b MWHC = Maximum Water Holding Capacity (0 bar)						
DT _{50lab} (10°C, aerobic): Not relevant						
DT _{50lab} (25°C, anaerobic): bensulfuron methyl						
Soil	MWHC ^b	%OC	pH _w	DT ₅₀	(d)	r ²
Silt loam	N/A	1.1	7.0	118	0.880	
Degradation in the saturated zone: Not required						
DT _{50f} :						
Water	pH _w	DT ₅₀ (d)	r ²			
Ceretto Lomellina (94)	7.5-8.3	2	0.834			
Ceretto Lomellina (95)	8.2-8.9	1.5	0.947			
Ceretto Lomellina (96)	7.5-8.2	3	0.708			
Villarboit (94)	7.6-8.6	4	0.985			
Villarboit (95)	7.3-7.9	3	0.927			

Field studies (state location, range or median with n value)

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Villarboit (96)	7.3-8.5	3	0.892		
Rosate (94)	8.5-8.6	5	0.721		
Rosate (95)	7.3-8.7	5	0.973		
Rosate (96)	6.9-7.8	6	0.908		
Soil	%OC	pH_s	DT₅₀ (d)	r²	
Ceretto Lomellina (94)		0.8	6.2	12	0.937
Ceretto Lomellina (95)		0.8	6.2	4	0.843
Ceretto Lomellina (96)		0.8	6.2	7	0.963
Villarboit (94)	1.2	5.7	14	0.983	
DT _{90f} :					
Water	pH_w	DT₉₀ (d)	r²		
Ceretto Lomellina (94)	7.5-8.3	7	0.834		
Ceretto Lomellina (95)	8.2-8.9	5	0.947		
Ceretto Lomellina (96)	7.5-8.2	10	0.709		
Villarboit (94)	7.6-8.6	12	0.985		
Villarboit (95)	7.3-7.9	10	0.927		
Villarboit (96)	7.3-8.5	11	0.892		
Rosate (94)	8.5-8.6	18	0.721		
Rosate (95)	7.3-8.7	18	0.973		
Rosate (96)	6.9-7.8	19	0.908		
Soil	%OC	pH_s	DT₉₀ (d)	r²	
Ceretto Lomellina (94)		0.8	6.2	39	0.937
Ceretto Lomellina (95)		0.8	6.2	14	0.843
Ceretto Lomellina (96)		0.8	6.2	23	0.963
Villarboit (94)	1.2	5.7	48	0.983	
Soil accumulation and plateau concentration:					
Not relevant					

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Soil adsorption/desorption (Annex IIA, point 7.1.2) K_f/K_{oc}

Bensulfuron methyl						
Soil	OC%	pH	K_f	K_{foc}	l/n	
Sandy loam	1.2	6.5	2.5	205	0.89	
Sandy loam	0.6	6.6	1.4	219	0.88	
Silt loam	4.4	5.2	12	276	0.97	
Silt loam	2.5	5.4	14	561	0.93	
Published article from Cavanna et al., (1998)						
Silt loam)	1.2	5.7	8.4	684	1.07	
Sandy loam	0.8	6.2	2.8	364	1.08	
Loamy-sand	0.9	6.2	4.8	552	1.06	
IN-F7880 (K_f and K_{foc} in mL/g)						
Soil	OC%	pH	K_f	K_{foc}	l/n	
Sandy loam	1.0	8.1	1.6	161	0.92	
Sandy loam	0.6	5.8	0.5	75	0.90	
Loamy sand	2.2	5.9	3.1	140	1.14	
Silt loam	1.0	6.1	2.2	181	1.01	
Clay loam	3.0	5.6	14.2	472	1.05	
IN-J0290						
Soil	OC%	pH	K_f mL/g	K_{foc}	l/n	
Sandy loam	0.7	7.8	0.90	123	0.79	
Loamy sand	0.5	5.2	2.3	452	0.81	
Loamy sand	2.1	6.7	1.2	58	0.85	
Silt loam	1.2	6.1	2.35	196	0.82	
Silt loam	3.1	5.5	45.3	1460	0.71	
IN-N5297						
Soil	OC%	pH	K_f	K_{foc}	l/n	
Sandy loam	0.7	7.8	0.14	20	0.92	
Loamy sand	0.5	5.2	0.074	15	0.92	
Loamy sand	2.1	6.4	0.40	19	0.94	
Silt loam	1.2	5.8	0.43	36	0.93	
Silt loam	3.1	5.5	2.8	92	0.91	
IN-R9419						
Soil	OC%	pH	K_f	K_{foc}	l/n	
Sandy loam	1.0	8.1	0.3	28	0.93	
Sandy loam	0.6	5.8	1.49	248	0.89	
Loamy sand	2.2	5.9	1.86	84.5	0.91	
Silt loam	1.0	6.1	1.87	187	0.89	
Clay loam	3.0	5.6	17.4	580	0.89	
IN-D1R84						
Soil	OC%	pH	K_f	K_{foc}	l/n	
Sandy loam	1.0	8.1	0.0173	2	0.45	
Sandy loam	0.6	5.8	0.123	21	0.84	
Loamy sand	2.2	5.9	0.133	6	0.71	
Silt loam	1.0	6.1	0.103	10	0.77	
Clay loam	3.0	5.6	0.231	8	0.78	

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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K_d

Bensulfuron methyl:					
AMR 254-84: (K _d and K _{oc} values were recalculated by notifier from raw data)					
Soil	OC%	pH	K _d	K _{oc}	
Sandy loam		1.2	6.5	2.9	241
Sandy loam		0.6	6.6	1.6	250
Silt loam		4.4	5.2	13.3	303
Silt loam		2.5	5.4	7.2	689
K _{ds} are not available from Publication of Cavanna <i>et al.</i> , (1998)					
IN-J0290					
Soil	OC%	pH	K _d	K _{oc}	
Sandy loam		0.7	7.8	1.71	245
Loamy sand		0.5	5.2	4.76	952
Loamy sand		2.1	6.7	2.01	96
Silt loam		1.2	6.1	4.69	391
Silt loam		3.1	5.5	212	6849
IN-N5297					
Soil	OC%	pH	K _d	K _{oc}	
Sandy loam		0.7	7.8	0.17	25
Loamy sand		0.5	5.2	0.09	18
Loamy sand		2.1	6.4	0.48	23
Silt loam		1.2	5.8	0.54	45
Silt loam		3.1	5.5	3.86	125
IN-R9419					
Soil	OC%	pH	K _d	K _{oc}	
Sandy loam		1.0	8.1	0.33	33
Sandy loam		0.6	5.8	2.04	341
Loamy sand		2.2	5.9	2.49	113
Silt loam		1.0	6.1	2.65	265
Clay loam		3.0	5.6	25.9	862
IN-D1R84					
Soil	OC%	pH	K _d	K _{oc}	
Sandy loam		1.0	8.1	0.09	9
Sandy loam		0.6	5.8	0.19	32
Loamy sand		2.2	5.9	0.30	14
Silt loam		1.0	6.1	0.19	19
Clay loam		3.0	5.6	0.47	16
IN-F7880					
Soil	OC%	pH	K _d	K _{oc}	
Sandy loam		1.0	8.1	2.2	222
Sandy loam		0.6	5.8	0.7	65
Loamy sand		2.2	5.9	2.1	95
Silt loam		1.0	6.1	2.2	187
Clay loam		3.0	5.6	13.5	449
No					

pH dependence (yes/no) (if yes, type of dependence)

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Mobility in soil (Annex II A, point 7.1.3, Annex III A, point 9.1.2)

Column leaching

Not included

Aged residues leaching

Not included

Lysimeter/field leaching studies

Field monitoring studies of bensulfuron methyl from surface and groundwater samples were conducted in rice growing regions in East and East Sesia, Italy in 1997 and 1998.

pH of water: 6.8-8.0
pH of groundwater: 6.8-8.3

Groundwater samples were removed at different levels (2 m to 19 m)

The two –year study suggested that the impact of bensulfuron methyl in the entire water system of the region was negligible. No phenomena of accumulation, mobility into groundwater, and persistence were noted. The presence of bensulfuron methyl in surface water is limited to the period of application (about 30 days between mid-May and mid-June), and is influenced by precipitation and/or regulation of the water in the chambers. The maximum concentration found in water was 0.32 ppb in the Marcova and 0.16 ppb in the Sesia in the proximity of the mouth of the Roggione di Sartirana on June 2, 1998.

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation

Tier 1: Med-Rice (2003)
Higher tier: RICEWQ 1.64 and RIVWQ 2.02

Application rate

60 g a.s./ha to flooded paddies

PEC_{SOIL} (paddy soil) in the Med-Rice clay scenario (µg/kg dry weight) – 10 cm water

Chemical	Actual or TWA (µg/kg)	Days after application										
		0	1	2	4	7	14	21	28	42	50	100
bensulfuron methyl	Actual	64.7	64.0	63.3	61.8	59.6	54.9	50.6	46.6	39.5	36.0	20.0
	TWA	--	64.4	64.0	63.2	62.2	59.7	57.4	55.2	51.1	49.0	38.1
IN-F7880	Actual	5.51	5.46	5.42	5.32	5.18	4.88	4.58	4.31	3.81	3.56	2.29
	TWA	-	5.49	5.46	5.42	5.35	5.19	5.03	4.89	4.61	4.46	3.67
IN-R9419	Actual	16.1	14.6	13.2	10.8	7.99	3.96	1.96	0.970	0.238	0.106	0.0007
	TWA	--	15.4	14.6	13.3	11.6	8.67	6.73	5.40	3.77	3.19	1.61
IN-D1R84	Actual	0.826	0.772	0.721	0.630	0.514	0.319	0.198	0.123	0.0476	0.0276	0.0009
	TWA	--	0.799	0.773	0.724	0.658	0.533	0.440	0.370	0.273	0.235	0.122
IN-J0290	Actual	11.9	11.6	11.2	10.5	9.48	7.54	5.99	4.76	3.00	2.31	0.447
	TWA	--	11.7	11.6	11.2	10.7	9.57	8.62	7.80	6.47	5.86	3.50
IN-N5297	Actual	4.62	4.52	4.42	4.22	3.95	3.37	2.88	2.46	1.80	1.50	0.487
	TWA	--	4.57	4.52	4.42	4.28	3.96	3.68	3.43	2.99	2.77	1.84
IN-T5831	Actual	0.572	0.554	0.536	0.502	0.454	0.361	0.287	0.228	0.144	0.111	0.0214
	TWA	--	0.563	0.554	0.536	0.511	0.458	0.413	0.374	0.310	0.281	0.168
IN-DAT97	Actual	0.670	0.658	0.646	0.623	0.590	0.518	0.456	0.401	0.310	0.268	0.107
	TWA	--	0.664	0.658	0.646	0.629	0.591	0.556	0.524	0.467	0.439	0.307

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

Volume 1 – Appendix 3

PEC_{soil} (paddy soil) in the Med-Rice sand scenario (µg/kg dry weight) -) – 10 cm water

Chemical	Actual or TWA (µg/kg)	Days after application										
		0	1	2	4	7	14	21	28	42	50	100
bensulfuron methyl	Actual	54.4	53.7	53.1	51.9	50.1	46.2	42.5	39.2	33.2	30.2	16.8
	TWA	--	54.1	53.8	53.2	52.2	50.2	48.2	46.4	42.9	41.1	32.0
IN-F7880	Actual	4.36	4.32	4.28	4.21	4.10	3.86	3.63	3.41	3.02	2.81	1.81
	TWA	--	4.34	4.32	4.28	4.23	4.10	3.98	3.86	3.65	3.53	2.90
IN-R9419	Actual	12.9	11.7	10.6	8.66	6.41	3.17	1.57	0.777	0.190	0.0852	0.0006
	TWA	--	12.3	11.7	10.6	9.30	6.95	5.39	4.32	3.02	2.56	1.29
IN-D1R84	Actual	0.437	0.408	0.381	0.333	0.271	0.169	0.105	0.0651	0.0252	0.0146	0.0005
	TWA	--	0.422	0.408	0.382	0.348	0.282	0.233	0.195	0.144	0.124	0.0642
IN-J0290	Actual	10.5	10.1	9.81	9.19	8.32	6.61	5.26	4.18	2.64	2.03	0.392
	TWA	--	10.3	10.1	9.82	9.36	8.40	7.57	6.85	5.68	5.14	3.07
IN-N5297	Actual	2.76	2.70	2.64	2.52	2.36	2.02	1.72	1.47	1.07	0.897	0.291
	TWA	--	2.73	2.70	2.64	2.56	2.37	2.20	2.05	1.79	1.66	1.10
IN-T5831	Actual	0.302	0.293	0.283	0.265	0.240	0.191	0.152	0.121	0.0761	0.0585	0.0113
	TWA	--	0.298	0.293	0.283	0.270	0.242	0.218	0.198	0.164	0.148	0.0886
IN-DAT97	Actual	0.354	0.348	0.342	0.329	0.312	0.274	0.241	0.212	0.164	0.142	0.0566
	TWA	--	0.351	0.348	0.342	0.335	0.312	0.294	0.277	0.247	0.232	0.162

Maximum value of PEC_{soil} (paddy soil) in the Med-Rice sand and clay scenario (µg/kg dry weight) – 1 cm water

Compound	Clay scenario	Sand scenario
	PEC _{soil} µg/kg	PEC _{soil} µg/kg
Bensulfuron methyl	78.2	76.0
IN-F7880	7.23	6.99
IN-R9419	20.8	20.1
IN-D1R84	4.18	2.88
IN-J0290	13.6	13.4
IN-N5297	11.7	10.0
IN-T5831	2.90	2.00
IN-DAT97	3.39	2.34

PEC_{soil} (paddy soil) from RICEWQ/RIVWQ

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Summary for individual meteorological scenarios							
Meteorological scenario	Number of simulation years	maximum daily PEC _{SW} (µg/kg dry weight) ^a					
		Minimum	25 th %	Average	Median	75 th %	Maximum
France	200	10.1	13.0	15.0	14.2	16.8	22.6
Greece	200	10.7	12.8	13.8	13.0	14.0	20.9
Italy	200	7.89	13.2	15.3	15.1	16.8	25.7
Portugal	200	6.84	12.8	15.0	14.9	17.1	22.5
Spain	200	10.1	11.9	13.7	12.6	15.0	25.7
Overall summary – data from all meteorological scenarios combined							
Meteorological scenario	Number of simulation years	maximum daily PEC _{SW} (µg/L)					
		Minimum	25 th %	Average	Median	75 th %	Maximum
France, Greece, Italy, Portugal, and Spain data combined	1000	6.84	12.6	14.5	13.8	16.3	25.7

^a The maximum daily PEC_{SW} value in each simulation year was selected. All simulations were 20 years. Since one treated paddy node was evaluated from each of 10 management blocks, the total number of simulation years of PEC data was 20 × 10 = 200 for each meteorological scenario and 1000 years in aggregate.

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Hydrolysis of active substance and relevant metabolites (DT₅₀) (state pH and temperature)

pH4: DT ₅₀ =6.1 days at 25°C Major metabolites that were formed: IN-J0290 (98.3%) for pyrimidine label and IN-N5297 (98.6%) for phenyl label
pH7: Stable at 25°C
pH9: 141 days at 25°C Major metabolite that was formed: IN-R9419, at 15.5% for pyrimidine label and 14.6% for phenyl label

Photolytic degradation of active substance and relevant metabolites

Photolytic degradation of [phenyl(U)-¹⁴C]label was used at pH 5, 7, and 9; [pyrimidine-2-¹⁴C] label was used at pH 9. Continuous direct sunlight (global radiation 285-2800 nm) for up to 30 days.

pH	DT ₅₀	Corrected DT ₅₀
5 (phenyl)	13	>1000
7 (phenyl)	251	505
9 (phenyl)	223	405
9 (pyrimidine)	286	>1000

No major metabolites were observed

Photolytic degradation of bensulfuron methyl was determined in natural water and pH 7 buffer solution Continuous irradiation xenon arc lamp for 15 days.

Water source	DT ₅₀	R ²
Cavrini Farm Pond water	10	0.824
Ten-Mile Creek water	89	0.876
Irradiated sterile buffer	29	0.848
Non-irradiated sterile buffer	stable	nd

Photolytic degradation of bensulfuron methyl was determined in a simulated paddy system and pH 7 buffer solution

Water/sediment source	DT ₅₀	R ²
Total systems:		
Irradiated Cavrini Farm Pond system	12.7	
	0.993	
Non-irradiated Cavrini Farm Pond system	33.1	
	0.936	
Irradiated Lonoke system	14.2	0.944
Non-irradiated Lonoke system	35.9	0.963
Water:		
Irradiated Cavrini Farm Pond water	7.7	
	0.987	
Non-irradiated Cavrini Farm Pond water	14.3	
	0.937	
Irradiated Lonoke water	6.7	0.930
Non-irradiated Lonoke water	15.8	0.991
Irradiated sterile buffer	50.3	0.937

Readily biodegradable (yes/no)

No

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Degradation in water/sediment

- DT₅₀ water

Bensulfuron methyl	
Pavia (loamy sand)	Vercelli (silt loam)
21 d	16 d
IN-J0290	
55.3 d	74.6 d
IN-N5297	
Not major met.	106 d
IN-F7880	
60.6 d	Not major met.
IN-DAT97	
54.3 d	394 d
IN-R9419	
9.1 d	7.0 d

- DT₉₀ water

Bensulfuron methyl	
Pavia (loamy sand)	Vercelli (silt loam)
69 d	52 d
IN-J0290	
184 d	254 d
IN-N5297	
Not major met.	353 d
IN-F7880	
201 d	Not major met.
IN-DAT97	
180 d	n.a.
IN-R9419	
30.1 d	23.2 d

- DT₅₀ whole system

Bensulfuron methyl	
Pavia (loamy sand)	Vercelli (silt loam)
37 d	59 d
IN-N5297	
Not major met.	30.8 d
IN-F7880	
39.2 d	79.1 d
IN-DAT97	
34.6 d	37.8
IN-R9419	
6.9 d	3.5 d

- DT₉₀ whole system

Bensulfuron methyl	
Pavia (loamy sand)	Vercelli (silt loam)
122 d	195 d
IN-N5297	
Not major met.	102 d
IN-F7880	
115 d	263 d
IN-DAT97	
115 d	126 d
IN-R9419	
22.9 d	11.6 d

Mineralisation

Pyrimidine label:	
Pavia (loamy sand)	Vercelli (silt loam)
16.7% (130d)	16.6% (130d)
Phenyl label:	
Pavia (loamy sand)	Vercelli (silt loam)
26.1% (130d)	14.9% (130d)

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Non-extractable residues

Pyrimidine label:
Pavia (loamy sand) Vercelli (silt loam)
25% (100d) 43% (130d)
Phenyl
Pavia Vercelli
14% (100d) 32%(130d)
Phenyl & Pyrimidine labels
Pavia Vercelli
Total 7.6-7.9% (130d) 23.3-24.9% (130d)
Water 0.3-0.4% (130d) 5.1 - 6.9% (130d)
Sediment 7.3-7.5% (130d) 18.0-18.2% (130d)

Distribution in water / sediment systems (active substance)

Distribution in water / sediment systems (metabolites)

Relevant metabolites that were formed >10% in Pavia and Vercelli systems (in total system):

IN-J0290

Pyrimidine Pavia Vercelli
Total 19.7% (130d) 8.2% (40d)
Water 10.1% (70d) 5.1% (0d)
Sediment 18.4% (130d) 4.7% (40d)

IN-DAT97

Pyrimidine label: Pavia Vercelli
Total 9.9% (50d) 3.6% (40d)
Water 8.4% (50d) 3.0% (40d)
Sediment 1.9% (100d) 0.9% (100d)

Phenyl label:

Total 1.4 (50d) 0.5% (70d)
Water 1.4% (50d) 0.5% (70d)
Sediment 1.9% (100d) 0.9% (100d)

IN-F7880

Pyrimidine label: Pavia Vercelli
Total 9.71% (40d) 4.5% (70d)
Water 9.04% (40d) 2.9% (70d)
Sediment 4.11% (21d)% 1.62% (70d)

Phenyl

Total 9.51%(70d) 5.34% (70d)
Water 5.42%(70d) 2.5% (130d)
Sediment 4.09% (70d) 3.0% (70d)

IN-N5297

Pyrimidine label: Pavia Vercelli
Total N/A N/A
Water N/A N/A
Sediment N/A N/A

Phenyl label:

Total 31.73% (130d) 16.13%(50d)
Water 27.30% (130d) 10.28% (50d)
Sediment 4.43% (130d) 5.85% (50d)

IN-D1R84

Pyrimidine label: Pavia Vercelli
Total N/A N/A
Water N/A N/A
Sediment N/A N/A

Phenyl label:

Total 4.17% (130d) 9.95%(130d)
Water <1.62% (130d) 7.31% (130d)
Sediment 2.55% (130d) 2.64% (130d)

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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PEC (surface water) (Annex IIIA, point 9.2.3)

Method of calculation

Tier 1: Med-Rice (2003)

Higher tier: RICEWQ 1.64 and RIVWQ 2.02.

Application rate

60 g a.s./ha to flooded paddies

Main routes of entry

drainage water from treated paddy and spray drift

PEC_{PW} (paddy water) in the Med-Rice clay scenario (µg/L)

Chemical	Actual or TWA (µg/L)	Days after application										
		0	1	2	4	7	14	21	28	42	50	100
bensulfuron methyl	Actual	11.4	11.3	11.2	10.9	10.5	9.69	8.92	8.22	6.97	6.35	3.53
	TWA	--	11.4	11.3	11.2	11.0	10.5	10.1	9.73	9.02	8.64	6.72
IN-F7880	Actual	1.49	1.47	1.46	1.44	1.40	1.31	1.24	1.16	1.03	0.959	0.619
	TWA	--	1.48	1.47	1.46	1.44	1.40	1.36	1.32	1.24	1.20	0.990
IN-R9419	Actual	3.99	3.61	3.26	2.67	1.97	0.977	0.484	0.239	0.0587	0.0263	0.0002
	TWA	--	3.79	3.61	3.28	2.86	2.14	1.66	1.33	0.931	0.789	0.397
IN-D1R84	Actual	5.10	4.77	4.45	3.87	3.17	1.97	1.22	0.761	0.294	0.171	0.0057
	TWA	--	4.93	4.77	4.46	4.06	3.29	2.72	2.28	1.68	1.45	0.750
IN-J0290	Actual	1.45	1.40	1.36	1.27	1.15	0.914	0.726	0.577	0.364	0.280	0.0542
	TWA	--	1.42	1.40	1.36	1.29	1.16	1.05	0.947	0.785	0.711	0.424
IN-N5297	Actual	7.13	6.97	6.82	6.52	6.09	5.21	4.45	3.80	2.77	2.32	0.752
	TWA	--	7.05	6.98	6.82	6.60	6.12	5.68	5.29	4.61	4.28	2.84
IN-T5831	Actual	3.53	3.42	3.31	3.10	2.81	2.30	1.77	1.41	0.889	0.683	0.132
	TWA	--	3.47	3.42	3.31	3.15	2.83	2.55	2.31	1.92	1.73	1.03
IN-DAT97	Actual	4.13	4.06	3.99	3.84	3.64	3.20	2.82	2.48	1.92	1.65	0.661
	TWA	--	4.10	4.06	3.99	3.88	3.65	3.43	3.24	2.88	2.71	1.90

PEC_{PW} (paddy water) in the Med-Rice sand scenario (µg/L)

Chemical	Actual or TWA (µg/L)	Days after application										
		0	1	2	4	7	14	21	28	42	50	100

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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bensulfuron methyl	Actual	19.2	19.0	18.7	18.3	17.7	16.3	15.0	13.8	11.7	10.7	5.9
	TWA	--	19.1	19.0	18.7	18.4	17.7	17.0	16.4	15.1	14.5	11.3
IN-F7880	Actual	2.35	2.33	2.31	2.27	2.21	2.08	1.96	1.84	1.63	1.52	0.979
	TWA	--	2.34	2.33	2.31	2.28	2.21	2.15	2.08	1.97	1.90	1.56
IN-R9419	Actual	6.39	5.78	5.23	4.28	3.16	1.57	0.775	0.383	0.0940	0.0421	0.0003
	TWA	--	6.08	5.79	5.26	4.59	3.43	2.66	2.14	1.49	1.26	0.636
IN-D1R84	Actual	5.39	5.04	4.71	4.11	3.35	2.08	1.29	0.804	0.311	0.180	0.0060
	TWA	--	5.21	5.04	4.72	4.29	3.48	2.87	2.41	1.78	1.53	0.793
IN-J0290	Actual	2.54	2.46	2.38	2.23	2.02	1.60	1.28	1.01	0.640	0.492	0.0952
	TWA	--	2.50	2.46	2.38	2.27	2.04	1.84	1.66	1.38	1.25	0.745
IN-N5297	Actual	8.53	8.34	8.15	7.79	7.28	6.22	5.32	4.54	3.31	2.77	0.898
	TWA	--	8.43	8.34	8.16	7.89	7.31	6.80	6.33	5.52	5.12	3.39
IN-T5831	Actual	3.73	3.61	3.50	3.27	2.97	2.36	1.87	1.49	0.940	0.722	0.140
	TWA	--	3.67	3.61	3.50	3.34	2.99	2.70	2.44	2.02	1.83	1.09
IN-DAT97	Actual	4.37	4.29	4.22	4.06	3.85	3.38	2.98	2.62	2.02	1.75	0.699
	TWA	--	4.33	4.30	4.22	4.11	3.86	3.63	3.42	3.05	2.86	2.00

PEC_{SW} (receiving ditch water) in the Med-Rice clay scenario (µg/L)

Chemical	Actual or TWA (µg/L)	Days after application										
		0	1	2	4	7	14	21	28	42	50	100
bensulfuron methyl	Actual	1.08	1.07	1.06	1.03	0.997	0.918	0.846	0.779	0.661	0.602	0.334
	TWA	--	1.08	1.07	1.06	1.04	0.998	0.959	0.923	0.854	0.819	0.637
IN-F7880	Actual	0.140	0.139	0.138	0.135	0.132	0.124	0.117	0.110	0.0970	0.0905	0.0584
	TWA	--	0.140	0.139	0.138	0.136	0.132	0.128	0.124	0.117	0.114	0.0934
IN-R9419	Actual	0.239	0.216	0.195	0.160	0.118	0.0585	0.0290	0.0143	0.0035	0.0016	0.0000
	TWA	--	0.227	0.216	0.197	0.171	0.128	0.0994	0.0798	0.0557	0.0472	0.0238
IN-D1R84	Actual	0.340	0.318	0.297	0.259	0.211	0.131	0.0817	0.0507	0.0196	0.0114	0.0004
	TWA	--	0.329	0.318	0.298	0.271	0.220	0.181	0.152	0.112	0.0968	0.0500
IN-J0290	Actual	0.126	0.122	0.118	0.111	0.100	0.0796	0.0632	0.0502	0.0317	0.0244	0.0047
	TWA	--	0.124	0.122	0.118	0.113	0.101	0.0910	0.0824	0.0684	0.0619	0.0369
IN-N5297	Actual	0.602	0.589	0.576	0.551	0.514	0.440	0.376	0.321	0.234	0.196	0.0635
	TWA	--	0.596	0.589	0.576	0.557	0.517	0.480	0.447	0.390	0.362	0.239
IN-T5831	Actual	0.281	0.272	0.263	0.246	0.223	0.177	0.141	0.112	0.0706	0.0543	0.0105
	TWA	--	0.276	0.272	0.263	0.251	0.225	0.203	0.184	0.152	0.138	0.0823
IN-DAT97	Actual	0.354	0.347	0.341	0.329	0.311	0.274	0.241	0.212	0.164	0.141	0.0565
	TWA	--	0.351	0.347	0.341	0.332	0.312	0.294	0.277	0.247	0.232	0.162

PEC_{SW} (receiving ditch water) in the Med-Rice sand scenario (µg/L)

Chemical	Actual or TWA (µg/L)	Days after application										
		0	1	2	4	7	14	21	28	42	50	100

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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bensulfuron methyl	Actual	1.75	1.73	1.71	1.67	1.61	1.48	1.37	1.26	1.07	0.972	0.540
	TWA	--	1.74	1.73	1.71	1.68	1.61	1.55	1.49	1.38	1.32	1.03
IN-F7880	Actual	0.215	0.214	0.212	0.208	0.203	0.191	0.179	0.169	0.149	0.139	0.897
	TWA	--	0.214	0.214	0.212	0.209	0.203	0.197	0.191	0.180	0.174	0.144
IN-R9419	Actual	0.371	0.336	0.303	0.248	0.184	0.0909	0.0450	0.0223	0.0055	0.0024	0.0000
	TWA	--	0.353	0.336	0.306	0.266	0.199	0.154	0.124	0.0866	0.0734	0.0369
IN-D1R84	Actual	0.359	0.336	0.314	0.274	0.223	0.139	0.0862	0.0536	0.0207	0.0120	0.0004
	TWA	--	0.347	0.336	0.314	0.286	0.232	0.191	0.161	0.119	0.102	0.0528
IN-J0290	Actual	0.210	0.204	0.197	0.185	0.167	0.133	0.106	0.0839	0.0530	0.0407	0.0079
	TWA	--	0.207	0.204	0.197	0.188	0.169	0.152	0.138	0.114	0.103	0.0617
IN-N5297	Actual	0.716	0.700	0.684	0.654	0.611	0.522	0.446	0.381	0.278	0.232	0.0754
	TWA	--	0.708	0.700	0.684	0.662	0.614	0.570	0.531	0.463	0.430	0.284
IN-T5831	Actual	0.296	0.287	0.278	0.260	0.236	0.187	0.149	0.118	0.0746	0.0573	0.0111
	TWA	--	0.292	0.287	0.278	0.265	0.238	0.214	0.194	0.161	0.146	0.0868
IN-DAT97	Actual	0.373	0.367	0.360	0.347	0.328	0.289	0.254	0.223	0.173	0.149	0.0597
	TWA	--	0.370	0.367	0.360	0.350	0.329	0.310	0.292	0.260	0.244	0.171

PEC_{sw} (paddy water, ditch water, canal water and river water) from RICEWQ/RIVWQ (µg/L)

Summary for individual meteorological scenarios								
Meteorological scenario	Water body	Number of simulation years	maximum daily PEC _{sw} (µg/L) ^a					
			Minimum	25 th %	Average	Median	75 th %	Maximum
France	paddy	200	15.2	27.5	33.8	32.5	37.8	148
	ditch	200	2.00	2.98	4.44	4.16	5.55	16.3
	canal	200	0.664	1.00	1.48	1.40	1.88	3.30
	river	20	0.170	0.242	0.350	0.358	0.424	0.625
Greece	paddy	200	23.3	29.1	33.4	32.3	36.4	78.6
	ditch	200	1.97	2.25	3.22	2.88	3.70	8.40
	canal	200	0.635	0.755	1.06	0.924	1.23	2.41
	river	20	0.152	0.185	0.231	0.217	0.237	0.434
Italy	paddy	200	13.7	25.7	34.9	30.4	36.0	223
	ditch	200	1.98	3.63	5.29	4.99	6.19	26.3
	canal	200	0.636	1.21	1.76	1.78	2.14	3.61
	river	20	0.224	0.400	0.540	0.456	0.639	1.13
Portugal	paddy	200	12.2	25.1	33.1	30.3	36.2	256
	ditch	200	2.02	3.51	4.60	4.34	5.66	9.24
	canal	200	0.656	1.16	1.58	1.53	1.96	3.05
	river	20	0.160	0.336	0.393	0.383	0.451	0.655
Spain	paddy	200	21.1	29.5	34.7	34.3	38.7	59.6
	ditch	200	1.97	2.58	3.55	3.25	3.99	8.23
	canal	200	0.657	0.868	1.20	1.06	1.31	3.18
	river	20	0.177	0.194	0.313	0.225	0.411	0.812

Distribution of 90th percentile 14-day TWA PEC_{sed} values for bensulfuron methyl for all meteorological scenarios combined (µg/L)

Treated paddies N = 100	Ditches N = 100	Canals N = 100	River N = 100
50 th % = 0.088	50 th % = 0.032	50 th % = 0.006	50 th % = 0.004
80 th % = 0.201	80 th % = 0.040	80 th % = 0.009	80 th % = 0.010
90 th % = 0.295	90 th % = 0.046	90 th % = 0.011	90 th % = 0.015
95 th % = 0.385	95 th % = 0.049	95 th % = 0.013	95 th % = 0.018
99 th % = 0.433	99 th % = 0.072	99 th % = 0.016	99 th % = 0.038
99.9 th % = 0.494	99.9 th % = 0.079	99.9 th % = 0.017	99.9 th % = 0.042

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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PEC (sediment)

Method of calculation

Tier 1: Med-Rice (2003)

Higher tier: RICEWQ 1.64 and RIVWQ 2.02

Application rate

60 g a.s./ha to flooded paddies

PEC_{SED} (receiving ditch sediment) in the Med-Rice clay scenario (µg/kg dry weight)

Chemical	Actual or TWA (µg/kg)	Days after application										
		0	1	2	4	7	14	21	28	42	50	100
bensulfuron methyl	Actual	4.51	4.46	4.41	4.31	4.16	3.83	3.53	3.25	2.76	2.51	1.39
	TWA	--	4.49	4.46	4.41	4.33	4.16	4.00	3.85	3.56	3.41	2.65
IN-F7880	Actual	0.415	0.412	0.408	0.401	0.391	0.367	0.346	0.325	0.288	0.268	0.173
	TWA	--	0.414	0.412	0.408	0.403	0.391	0.379	0.368	0.348	0.336	0.277
IN-R9419	Actual	0.761	0.688	0.622	0.509	0.376	0.186	0.0922	0.0457	0.0112	0.0050	0.0000
	TWA	--	0.724	0.689	0.626	0.546	0.408	0.317	0.254	0.178	0.150	0.0757
IN-D1R84	Actual	0.0533	0.0498	0.0466	0.0406	0.0331	0.0206	0.0128	0.0080	0.0031	0.0018	0.0001
	TWA	--	0.0516	0.0499	0.0467	0.0424	0.0344	0.0284	0.0238	0.0176	0.0152	0.0078
IN-J0290	Actual	0.697	0.674	0.652	0.611	0.554	0.440	0.349	0.278	0.175	0.135	0.0261
	TWA	--	0.685	0.674	0.653	0.622	0.558	0.503	0.455	0.378	0.342	0.204
IN-N5297	Actual	0.366	0.358	0.350	0.335	0.313	0.267	0.228	0.195	0.142	0.119	0.0386
	TWA	--	0.362	0.358	0.350	0.339	0.314	0.292	0.272	0.237	0.220	0.146
IN-T5831	Actual	0.0440	0.0426	0.0412	0.0386	0.0350	0.0278	0.0221	0.0175	0.0111	0.0085	0.0016
	TWA	--	0.0433	0.0426	0.0412	0.0393	0.0353	0.0318	0.0288	0.0239	0.0216	0.0129
IN-DAT97	Actual	0.0554	0.0544	0.0535	0.0515	0.0488	0.0429	0.0377	0.0332	0.0257	0.0222	0.0089
	TWA	--	0.0549	0.0544	0.0535	0.0520	0.0489	0.0460	0.0434	0.0387	0.0363	0.0254

PEC_{SED} (receiving ditch sediment) in the Med-Rice sand scenario (µg/kg dry weight)

Chemical	Actual or TWA (µg/kg)	Days after application										
		0	1	2	4	7	14	21	28	42	50	100
bensulfuron methyl	Actual	7.19	7.11	7.02	6.86	6.62	6.10	5.62	5.18	4.39	4.00	2.22
	TWA	--	7.15	7.11	7.02	6.90	6.63	6.37	6.13	5.68	5.44	4.23
IN-F7880	Actual	0.634	0.628	0.623	0.612	0.596	0.561	0.528	0.496	0.439	0.409	0.264
	TWA	--	0.631	0.628	0.623	0.615	0.597	0.579	0.562	0.531	0.513	0.422
IN-R9419	Actual	1.17	1.06	0.960	0.785	0.581	0.287	0.142	0.0704	0.0173	0.0077	0.0001
	TWA	--	1.12	1.06	0.966	0.842	0.630	0.489	0.392	0.274	0.232	0.117
IN-D1R84	Actual	0.0563	0.0526	0.0491	0.0429	0.0350	0.0217	0.0135	0.0084	0.0032	0.0019	0.0001
	TWA	--	0.0544	0.0526	0.0493	0.0448	0.0363	0.0300	0.0252	0.0186	0.0160	0.0083
IN-J0290	Actual	1.14	1.10	1.06	0.996	0.902	0.717	0.570	0.453	0.286	0.220	0.0425
	TWA	--	1.12	1.10	1.06	1.01	0.910	0.820	0.742	0.616	0.558	0.333
IN-N5297	Actual	0.435	0.426	0.416	0.398	0.372	0.318	0.271	0.232	0.169	0.141	0.0459
	TWA	--	0.430	0.426	0.416	0.403	0.373	0.347	0.323	0.282	0.261	0.173
IN-T5831	Actual	0.0465	0.0450	0.0435	0.0407	0.0369	0.0293	0.0233	0.0185	0.0117	0.0090	0.0017
	TWA	--	0.0457	0.0450	0.0435	0.0415	0.0372	0.0336	0.0304	0.0252	0.0228	0.0136
IN-DAT97	Actual	0.0585	0.0575	0.0564	0.0544	0.0515	0.0453	0.0398	0.0350	0.0271	0.0234	0.0094
	TWA	--	0.0580	0.0575	0.0564	0.0549	0.0516	0.0486	0.0458	0.0408	0.0383	0.0268

For presentation purposes, PEC values were rounded to three significant figures or to a maximum of four decimal places.

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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PEC_{SED} (ditch sediment, canal sediment, and river sediment) from RICEWQ/RIVWQ

<i>Summary for individual meteorological scenarios</i>								
Meteorological scenario	Water body	Number of simulation years	maximum daily PEC _{sw} (µg/kg dry weight) ^a					
			Minimum	25 th %	Average	Median	75 th %	Maximum
	ditch	200	1.23	1.74	2.83	2.36	3.24	21.9
	canal	200	0.483	0.843	1.25	1.16	1.59	2.92
	river	20	0.484	0.589	0.789	0.751	0.982	1.16
	ditch	200	1.15	1.36	1.84	1.54	1.92	9.37
	canal	200	0.445	0.675	0.831	0.775	0.943	2.44
	river	20	0.401	0.441	0.520	0.491	0.558	0.789
	ditch	200	1.21	2.11	3.30	3.03	3.59	33.3
	canal	200	0.518	1.17	1.57	1.58	1.99	3.32
	river	20	0.571	0.823	1.00	1.05	1.19	1.42
	ditch	200	1.19	2.02	2.96	2.88	3.53	12.8
	canal	200	0.512	1.08	1.43	1.41	1.72	2.62
	river	20	0.457	0.793	0.916	0.912	1.05	1.32
	ditch	200	1.20	1.47	2.06	1.76	2.19	12.0
	canal	200	0.474	0.738	0.968	0.848	1.04	2.42
	river	20	0.449	0.487	0.618	0.520	0.715	1.06
<i>Overall summary – data from all meteorological scenarios combined</i>								
Meteorological scenario	Water body	Number of simulation years	maximum daily PEC _{sw} (µg/L)					
			Minimum	25 th %	Average	Median	75 th %	Maximum
	ditch	1000	1.15	1.58	2.60	2.12	3.18	33.3
	canal	1000	0.445	0.784	1.21	1.06	1.58	3.32
	river	100	0.401	0.520	0.768	0.718	0.974	1.42

Distribution of 90th percentile 14-day TWA PEC_{sw} values for bensulfuron methyl for all meteorological scenarios combined (µg/L)

Treated paddy N = 100	Ditches N = 100	Canals N = 100	River N = 100
50th% = 3.756	50th% = 1.594	50th% = 0.695	50th% = 0.463
80th% = 4.355	80th% = 2.110	80th% = 1.012	80th% = 0.676
90th% = 4.511	90th% = 2.452	90th% = 1.140	90th% = 0.741
95th% = 4.645	95th% = 2.607	95th% = 1.197	95th% = 0.790
99th% = 4.742	99th% = 3.275	99th% = 1.278	99th% = 0.839
99.9th% = 4.929	99.9th% = 3.397	99.9th% = 1.366	99.9th% = 0.920

PEC (sediment)

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g. modelling, monitoring, lysimeter)
Application rate

Annual average calculation based on Med-Rice (2003).
Two water depths considered: 1 cm and 10 cm.
60 g a.s./ha

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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PEC_(gw)

Compound	Annual average PEC _{Gw} (µg/L) ^{a,b}		
	Clay scenario	Sand scenario	Sand scenario
	10 and 1 cm water	10 cm water	1 cm water
bensulfuron methyl	0.0000	0.0391	0.0356
IN-F7880	0.0000	0.0149	0.0154
IN-R9419	0.0000	0.0000	0.0000
IN-D1R84	0.0000	0.0126	0.0629
IN-J0290	0.0000	0.0000	0.0000
IN-N5297	0.0000	0.0633	0.1545
IN-T5831	0.0000	0.0275	0.126
IN-DAT97	0.0003 (0.0007 with 1 cm water)	0.0524	0.229

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air

Quantum yield of direct phototransformation

Photochemical oxidative degradation in air (DT₅₀)

Volatilization

No data, not required
0.00003 in sterile pH 7 buffer
DT ₅₀ : 0.611 hours based on 12-hr day; 1.5×10^6 OH radicals per cm ³
From plant surfaces: Bensulfuron methyl is a non-volatile crystalline solid. The vapour pressure is less than 3×10^{-12} Pa at 20°C, and volatilization is not expected.
From soil: volatilization is not expected.

PEC (air)

Method of calculation

Empirical "Dow method" for amount volatilised from a soil surface in 24 hours. Assumption of a uniformly mixed stagnate layer of air over a treated field to a height of 1 m

Step 1
Soil surface volatilization estimation using the "Dow method" (Thomas, 1995):

$$k_v = 4.4 \times 10^7 \left(\frac{v_p}{K_{oc} \times S} \right)$$

where:
 k_v = rate constant for volatilization, day⁻¹
 v_p = vapor pressure of chemical in air, mm Hg
 K_{oc} = organic carbon partition coefficient, mL/g
 S = water solubility, mg/L

Step 2
Estimate of initial daily loss from a treated field:

$$loss = (1 - \exp(-k_v)) \times 100$$

where:
 $loss$ = percent of applied compound volatilised from soil surface within 24 hours after application
 k_v = rate constant for volatilisation, day⁻¹

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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PEC_(a)

Maximum concentration

$8.4 \times 10^{-6} \mu\text{g}/\text{m}^3$

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment

Bensulfuron methyl

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)

Italy, with SIGMA 60DF
 Type of study: Monitoring of surface and groundwaters in Italy in the district of East and West Sesia (Italy) to evaluate contamination by bensulfuron methyl.
 Soil samples were collected at the rice field in East and West of Sesia at the piezometer site. Samples were taken every 0.5 meters for the first 5 meters and every meter for the next 15 meters.
 The two-year study of bensulfuron methyl indicated that bensulfuron methyl had no impact in the entire water systems of the region. No phenomena of accumulation, mobility into groundwater, and persistence were observed.

Surface water (indicate location and type of study)

Italy, with DPX-JM206 60WG (SIGMA 60DF)
 Type of study: Monitoring of surface and ground waters in Italy in the district of East and West Sesia to evaluate contamination by bensulfuron methyl.
 Location: Four surface water samples from East Sesia and two from West Sesia, Italy.
 The two-year study of bensulfuron methyl indicated that bensulfuron methyl had no impact in the entire water systems of the region. No phenomena of accumulation, mobility into groundwater, and persistence were observed. The presence of bensulfuron methyl in surface water is limited to the period of application (about 30 days between mid-May and mid-June), and is influenced by precipitation and /or regulation of the water in the chambers. The maximum concentration found in water was 0.32 ppb in the Marcova and 0.16 ppb in the Sesia in the proximity of the mouth of the Roggione di Sartirana on June 2, 1998.

Italy, with SIGMA 60DF
 Two surface water monitoring studies were made to evaluate the environmental fate of bensulfuron methyl following use of DPX-JM206 60WG herbicide used during rice production in Italy. The selected surface water sampling locations represent main irrigation channels and permanent waterways that receive drainage from rice paddies surrounding Vercelli, Italy. The data show that bensulfuron methyl is only detectable in the waterways during the two months following application of DPX-JM206 60WG, and that the concentrations are very low (<0.7 µg/L) even during that two-month period. Monitoring results from these two studies support the conclusion that bensulfuron methyl does not pose a significant threat of persistent contamination in the waterways of the monitored area.
 DuPont-15347

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Ground water (indicate location and type of study)

Italy with DPX-JM206 60WG
 Type of study: Monitoring of surface and groundwater in Italy in the district of East and West Sesia to evaluate contamination by bensulfuron methyl.
 Location: Groundwater from East and West Sesia, Italy was sampled using 6 piezometers adjacent to a 1.5-ha rice paddy treated with SIGMA.
 The two –year study of bensulfuron methyl indicated that bensulfuron methyl had no impact in the entire water systems of the region. No phenomena of accumulation, mobility into groundwater, and persistence were observed. The presence of bensulfuron methyl in surface water is limited to the period of application (about 30 days between mid-May and mid-June), and is influenced by precipitation and /or regulation of the water in the chambers. The maximum concentration found in water was 0.32 ppb in the Marcova and 0.16 ppb in the Sesia in the proximity of the mouth of the Roggione di Sartirana on June 2, 1998.

Air (indicate location and type of study)

Not relevant

Chapter 2.6: Effect on non target species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to birds

LD50= >2510 mg/kg bw (male and female mallard duck)

Acute toxicity to mammals

LD50 = >5000 mg/kg bw (rat)

Dietary toxicity to birds

LC50 of > 5620 ppm(mallard duck, bobwhite quail)
 >1678 mg a.i./kg bw/day, bobwhite quail
 >1690 mg a.i./kg bw/day, mallard duck

Reproductive toxicity to birds

NOEC = 560 ppm (83 mg a.i./kg bw/day, mallard duck)

Reproductive toxicity to mammals

NOEL = 250 ppm (20.9 mg a.i./kg bw/day, rat)

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg a.i./ha)	Crop	Category (e.g., insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.06	Rice	Large herbivorous bird	Acute	>669	10
0.06	Rice	Insectivorous bird	Acute	>772	10
0.06	Rice	Small herbivorous mammal	Acute	>422	10
0.06	Rice	Insectivorous mammal	Acute	>9434	10
0.06	Rice	Large herbivorous bird	Short-term	>835	10
0.06	Rice	Insectivorous bird	Short-term	>927	10
0.06	Rice	Large herbivorous bird	Long-term	78.3	5
0.06	Rice	Insectivorous bird	Long-term	45.9	5
0.06	Rice	Small herbivorous mammal	Long-term	6.22	5
0.06	Rice	Insectivorous mammal	Long-term	108	5

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Effects on aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg a.i./L)
Laboratory tests				
<i>Oncorhynchus mykiss</i>	Active substance	96 hours	Mortality LC ₅₀	>66
<i>Procambarus clarki</i>	Active substance	96 hours	Mortality LC ₅₀	>71
<i>Oncorhynchus mykiss</i>	Active substance	90 days	ELS NOEC	1.5
<i>Daphnia magna</i>	Active substance	21 days	Immobilisation NOEC	12
<i>Lemna gibba</i>	Active substance	14 days	Growth EC ₅₀	0.0008
<i>Selenastrum capricornutum</i>	DPX-F5384 60WG	72 hours	Growth rate EC ₅₀	0.0173
<i>Chironomus tentans</i>	DPX-JM206 60WG	96 hours	Mortality EC ₅₀	>125
<i>Oncorhynchus mykiss</i>	IN-J0290	96 hours	Mortality LC ₅₀	>97
<i>Oncorhynchus mykiss</i>	IN-N5297	96 hours	Mortality LC ₅₀	>118
<i>Daphnia magna</i>	IN-J0290	48 hours	Immobilisation EC ₅₀	>100
<i>Daphnia magna</i>	IN-N5297	48 hours	Immobilisation EC ₅₀	>117
<i>Daphnia magna</i>	IN-J0290	21 days	Immobilisation NOEC	24.9
<i>Daphnia magna</i>	IN-N5297	21 days	Reproduction NOEC	12.7
<i>Selenastrum capricornutum</i>	IN-J0290	72 hours	Growth rate EC ₅₀	> 120
<i>Selenastrum capricornutum</i>	IN-D1R84	72 hours	Growth rate EC ₅₀	36.2
<i>Selenastrum capricornutum</i>	IN-N5297	72 hours	Growth rate EC ₅₀	>120
<i>Selenastrum capricornutum</i>	IN-F7880	72 hours	Growth rate EC ₅₀	32.3
<i>Selenastrum capricornutum</i>	IN-DAT97	72 hours	Growth rate EC ₅₀	33.7
<i>Selenastrum capricornutum</i>	IN-T5831	72 hours	Growth rate EC ₅₀	99.1
<i>Selenastrum capricornutum</i>	IN-R9419	72 hours	Growth rate EC ₅₀	37.3
<i>Lemna gibba</i>	IN-J0290	14 days	Growth EC ₅₀	>100
<i>Lemna gibba</i>	IN-N5297	14 days	Growth EC ₅₀	>120
<i>Lemna gibba</i>	IN-F7880	14 days	Growth EC ₅₀	1.18
<i>Lemna gibba</i>	IN-T5831	14 days	Growth EC ₅₀	97.9
<i>Lemna gibba</i>	IN-R9419	14 days	Growth EC ₅₀	6.2
<i>Lemna gibba</i>	IN-D1R84	14 days	Growth EC ₅₀	>130
<i>Lemna gibba</i>	IN-DAT97	14 days	Growth EC ₅₀	79.1

Microcosm or mesocosm tests	Not required
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Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Acute Tier 1 TERs for aquatic organisms exposed to the maximum Med-Rice PEC in paddy water (PEC_{pw})

Test Substance	Test organism	EC ₅₀ or LC ₅₀ (mg a.i./L)	Max. PEC _{pw} (mg a.i./L) ^a	TER	Annex VI Trigger
Active substance	<i>Oncorhynchus mykiss</i>	>66	0.0192	>3438	100
Active substance	<i>Procambarus clarki</i>	>71	0.0192	>3698	100
DPX-JM206 60WG	<i>Chironomus tentans</i>	>125	0.0192	>6510	100
DPX-F5384 60WG	<i>Selenastrum capricornutum</i>	0.0173	0.0192	0.90	10
Active substance	<i>Lemna gibba</i>	0.0008	0.0192	0.04	10

^a Determined using the Tier 1 Med-Rice (2003) calculation method.

Acute Tier 1 TERs for aquatic organisms exposed to maximum PEC in paddy water (PEC_{pw}) of metabolites of Bensulfuron methyl

Test Substance	Test organism	Toxicological endpoint (mg/L)	Max. PEC _{pw} (mg/L) ^a	TER	Annex VI Trigger
IN-J0290	<i>Oncorhynchus mykiss</i>	>97	0.00254	>38189	100
	<i>Daphnia magna</i>	>100	0.00254	>39370	100
	<i>Selenastrum capricornutum</i>	>120	0.00254	>47244	10
	<i>Lemna gibba</i>	>100	0.00254	>39370	10
IN-N5297	<i>Oncorhynchus mykiss</i>	>118	0.00853	>13833	100
	<i>Daphnia magna</i>	>117	0.00853	>13716	100
	<i>Selenastrum capricornutum</i>	>120	0.00853	>14068	10
	<i>Lemna gibba</i>	>120	0.00853	>14068	10
IN-D1R84	<i>Selenastrum capricornutum</i>	36.2	0.00539	6716	10
	<i>Lemna gibba</i>	>130	0.00539	>24119	10
IN-R9419	<i>Selenastrum capricornutum</i>	37.3	0.00639	5837	10
	<i>Lemna gibba</i>	6.2	0.00639	970	10
IN-T5831	<i>Selenastrum capricornutum</i>	99.1	0.00373	26568	10
	<i>Lemna gibba</i>	97.9	0.00373	26247	10
IN-F7880	<i>Selenastrum capricornutum</i>	32.3	0.00235	13745	10
	<i>Lemna gibba</i>	1.18	0.00235	502	10
IN-DAT97	<i>Selenastrum capricornutum</i>	33.7	0.00437	7712	10
	<i>Lemna gibba</i>	79.1	0.00437	18101	10

^a Determined using the Tier 1 Med-Rice (2003) model

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Summary of long-term Tier 1 TERs for aquatic organisms exposed to maximum PEC in paddy water (PEC_{pw}) of Bensulfuron methyl

Test Substance	Test organism	NOEC (mg a.i./L)	Max. PEC _{pw} (mg a.i./L) ^a	TER	Annex VI Trigger
Active substance	<i>Oncorhynchus mykiss</i>	1.5	0.0192	78	10
Active substance	<i>Daphnia magna</i>	12	0.0192	625	10

^a Determined using the Tier 1 Med-Rice (2003) model

Summary of long-term Tier 1 TERs for aquatic organisms exposed to maximum PEC in the paddy water (PEC_{pw}) of Bensulfuron methyl metabolites

Test Substance	Test organism	NOEC (mg a.i./L)	Max. PEC _{pw} (mg a.i./L) ^a	TER	Annex VI Trigger
IN-J0290	<i>Daphnia magna</i>	24.9	0.00254	9803	10
IN-N5297	<i>Daphnia magna</i>	12.7	0.00853	1489	10

^a Determined using the Tier 1 Med-Rice (2003) model

Summary of Tier 1 TERs for algae and *Lemna* exposed to Bensulfuron methyl in ditches receiving outflow from treated rice paddies

Test substance	Test organism	EC ₅₀ (mg a.i./L)	Max. PEC _{sw} (mg a.i./L) ^a	TER	Annex VI trigger
Active substance	<i>Selenastrum capricornutum</i>	0.0173	0.00175	9.90	10
Active substance	<i>Lemna gibba</i>	0.0008	0.00175	0.46	10

^a Determined using the Tier 1 Med-Rice (2003) calculation method.

Higher-Tiered risk assessment for aquatic plants based on RICEWQ/RIVWQ modeling: TERs for *Lemna* based on 14-d TWA PEC_{sw} in Ditches Outside Rice Paddies

Species	Endpoint	Endpoint value (µg a.i./L)	14-d TWA PEC _{sw} (µg/L) ^a	TER	Trigger value
<i>Lemna</i>	14-d EC ₅₀	0.8	0.032	25	10

^a 50th percentile of the 90th percentile values from each of 100 simulation years (20 simulation years × 5 meteorological scenarios × 1, 90th percentile 14-d TWA PEC_{sw} value per year = 100 values).

Bioconcentration

Bioconcentration factor (BCF)

Annex VI Trigger for the bioconcentration factor

Clearance time (CT₅₀)

(CT₉₀)

Level of residues (%) in organisms after the 14-day depuration phase

1.6 (<i>Procambarus clarkii</i>)
1000
327
Not applicable (???)
Not applicable; will not accumulate (<0.4mg/g ¹⁴ C)

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	LD ₅₀ of >51.41 µg a.i./bee
Acute contact toxicity	LD ₅₀ of >100 µg a.i. /bee

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg a.i./ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
0.06	Rice	oral	<1.2	50
		contact	<0.6	50

Field or semi-field tests	Not triggered
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Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance	Dose (g a.i./ha)	Endpoint	Effects
Laboratory tests					
<i>Aphidius rhopalosiphi</i>	Nymph	DPX-F5384 60WG	60, 300, 600	LR ₅₀	>600
<i>Typhlodromus pyri</i>	Adult	DPX-F5384 60WG	60, 300, 600	LR ₅₀	>600

Hazard quotients Tier 1 for the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* (Annex IIIA, point 10.5)

Test organism	Application rate	LR ₅₀	In-field HQ	Off-field HQ*	Trigger
<i>Aphidius rhopalosiphi</i>	0.060 kg a.i./ha	>600 g a.i./ha	<0.1	<0.0028	2
<i>Typhlodromus pyri</i>	0.060 kg a.i./ha	>600 g a.i./ha	<0.1	<0.0028	2

* calculated with 2.77% drift at 1 m

Field or semi-field tests	Not requested
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Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

Volume 1 – Appendix 3

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

	Bensulfuron methyl
Acute toxicity	LC ₅₀ >1000 mg a.i./kg soil dry wt
Reproductive toxicity	Not required
	IN-D1R84
Acute toxicity	LC ₅₀ >1000 mg a.i./kg soil dry wt
Reproductive toxicity	Not required
	IN-F7880
Acute toxicity	LC ₅₀ >1000 mg a.i./kg soil dry wt
Reproductive toxicity	Not required
	IN-N5297
Acute toxicity	LC ₅₀ >1000 mg a.i./kg soil dry wt
Reproductive toxicity	Not required
	IN-R9419
Acute toxicity	LC ₅₀ >1000 mg a.i./kg soil dry wt
Reproductive toxicity	Not required
	IN-J0290
Acute toxicity	LC ₅₀ >1000 mg a.i./kg soil dry wt
Reproductive toxicity	Not required

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Test substance	Crop	Time-scale	LC ₅₀ (mg a.i./kg soil dry wt)	TER	Annex VI Trigger
Active substance	Rice	acute	>1000	>15 456	10
IN-D8526	Rice	acute	>1000	>181 488	10
IN-F7880	Rice	acute	>1000	>62 112	10
IN-N5297	Rice	acute	>1000	>1.21 x 10 ⁶	10
IN-R9419	Rice	acute	>1000	>84 034	10
IN-J0290	Rice	acute	>1000	>216 450	10

Effects on other soil non-target macro-organisms (Annex IIA, point 8.6, Annex IIIA, point 10.6.2)

Other non-target macro-organisms are not expected to be at risk from exposure to residues Bensulfuron methyl 60WG. Evidence from earthworms, honeybees, and beneficial arthropods toxicity tests suggest low toxicity of Bensulfuron methyl 60WG residues to non-target invertebrate fauna. Therefore, Bensulfuron methyl 60WG, when applied according to Good Agricultural Practice, is expected to pose little acute or long-term risk to soil non-target macro-organisms and no further testing is warranted.

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization	No significant effects at 5x field application rate (500g Bensulfuron methyl 60WG/ha)
Carbon mineralization	No significant effects at 5x field application rate (500g Bensulfuron methyl 60WG/ha)

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

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Effects on non-target plants (Annex IIA, point 8.6)

Species	Test Substance	Time-scale	End point	Toxicity
Ten plants	DPX-F5384 60WG	Seedling emergence and growth 21 days	ER ₅₀	2.41 g a.i./ha (Oilseed rape)
Ten plants	DPX-F5384 60WG	Vegetative vigour 21 days	ER ₅₀	2.08 g a.i./ha (Soybean)

Toxicity/exposure ratios for non-target plants (Tier 2 deterministic approach and refinement)

	21 days ER ₅₀ (g a.i./ha)	Exposure (g a.i./ha)	TER	Trigger value
Seedling emergence	2.41	1.66 ^a	1.45	5
Seedling emergence	2.41	0.342 ^b	7.05	
Vegetative vigour	2.08	1.66 ^a	1.3	5
Vegetative vigour	2.08	0.342 ^b	6.1	

^a60 g a.i./ha (application rate) x 2.77% (spray drift rate for a distance of 1 m of the field edge)^b60 g a.i./ha (application rate) x 0.57% (spray drift rate for a distance of 5 m of the field edge)**Classification and proposed labelling** (Annex IIA, point 10)

with regard to ecotoxicological data

Symbol:	N
Risk phrase	R50/53
Safety phrase	S60, S61

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LEVEL 3

**Proposed decision with respect to the application for
inclusion of the active substance in Annex I**

Bensulfuron Methyl

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Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

Level 3

3. Proposed decision with respect to the application for inclusion of the active substance in Annex I

3.1 Background to the proposed decision

Bensulfuron methyl is a sulfonylurea herbicide which can be formulated as water dispersible granules (WG). Data submitted for bensulfuron methyl active substance show no evidence of adverse physical and chemical properties. Data submitted for Bensulfuron methyl 60WG formulated product indicate that the product is stable under accelerated storage conditions, shows no adverse physical-chemical properties which could impact user's safety, and possesses favourable characteristics with regard to spray tank behaviour and application.

All recently developed and validated analytical methods are considered suitable for the determination of bensulfuron methyl in the technical material, plant protection product, rice grain and rice straw, soil, water and air. However, due to the revised definition of residue in soil, in surface water and in drinking/groundwater a request will follow for the submission of suitable analytical methods for the determination of specific metabolites in these matrices.

Bensulfuron methyl is a herbicide of low acute toxicity by the oral, dermal and inhalation routes of exposure. According to Directive 67/548/EEC, classification for acute oral, dermal, and inhalation toxicity should not apply. Chronic studies with bensulfuron methyl conducted in rats and mice showed no carcinogenic effects. Moreover, the weight of evidence indicates that bensulfuron methyl is not genotoxic.

In the developmental toxicity study in rats a NOAEL of 500 mg/kg bw/day was set, based on abnormal ossification and reduced pups weight found at 2000 mg/kg bw/day (maternal NOAEL). In light of these findings the RMS proposes that bensulfuron methyl should be classified under R 63 (possible risk of harm to the unborn child).

The proposed ADI is 0.2 mg/kg/day. Compared with the AOEL of 0.2 mg/kg/day, a fully acceptable margin of safety for operators was demonstrated using both models (German and UK POEM) without the use of PPE (gloves). Similarly, for both workers and bystander the risk is acceptable for proposed uses.

No Acute Reference Dose (ARfD) has been established because toxicological end points are not relevant for acute oral dietary exposure.

Bensulfuron Methyl poses no concern for consumer exposure

Bensulfuron methyl and its major metabolites have been fully characterised for fate and behaviour in the environment. The active substance and the metabolites show little potential for accumulation. No problem for leaching are identified for bensulfuron methyl and major metabolites in the clay scenario with both types of application. For the sand scenario, the typical application on flooded soil (10 cm water) does not show a significant risk for groundwater. On the other hand, application on saturated land (1 cm water) might present some leaching concerns for the major metabolites IN-N5297, and for the minor metabolites IN-T5831 and IN-

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

Level 3

DAT97. These concern should be addressed by those MSs, where the application on saturated land is a common practice in areas characterised by sand scenarios for rice crop.

The effect of Bensulfuron methyl on birds and mammals was not considered to pose an unacceptable risk.

The Med-Rice guidance (2003) was used to establish the level of exposure of Bensulfuron methyl to aquatic species. No unacceptable risks were identified for aquatic organisms living in drainage ditches at the edge of field, after risk refinement. Bioaccumulation was not considered to pose a direct risk to fish.

The assessment of the effect of Bensulfuron methyl on bees, other arthropod species, earthworms, soil macro and micro organisms have shown no unacceptable risk, at the proposed GAP.

Assessment of the risk posed to non target plants was considered to be acceptable providing a no spray buffer zone of 5 m.

3.2 Proposed decision concerning inclusion in Annex I

[REDACTED]

3.3 Rational for the postponement of the decision to

[REDACTED]

The information in sections 3.2 and 3.3 has been removed upon request by the European Commission as it relates to risk management recommendations or proposals.

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LEVEL 4

**Further information to permit a decision to be made,
or to support a review of the conditions and
restrictions associated with the proposed inclusion in
Annex I**

Bensulfuron Methyl

Rapporteur Member State	Month and year	Active Substance (Name)
Italy	May 2006	Bensulfuron Methyl

Level 4

4. Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I

4.1 Identity of the active substance

No further studies or information requested

4.2 Physical and chemical properties of the active substance

No further studies or information requested

4.3 Data on application and further information

No further studies or information requested

4.4 Classification, packaging and labelling

No further studies or information requested

4.5 Methods of analysis

Annex IIA 4.2.2 and IIA 4.2.3; Annex IIIA 5.2

Data requirement:

Given the revised definition of residue in

soil: AE F082671/parent, IN-J0290, IN-N5297, IN-D1R84, IN-R9419,

surface water: AE F082671/parent, IN-J0290, IN-N5297, IN-R9419 and

drinking/groundwater: AE F082671/parent, IN-N5297, IN-T5831, IN-DAT97

the applicant is requested to submit suitable analytical methods for the determination of these metabolites in their relative matrices.

4.6 Toxicology and metabolism

No further studies or information requested

4.7 Residue data

No further studies or information requested

4.8 Environmental fate and behaviour

IIA 7.1.1.1.1 Aerobic degradation in soil

Conduct flooded aerobic soil degradation study based on SETAC guideline 1.1 and as described for rice paddy soils in OECD Test Guideline 307 for aerobic and anaerobic transformation in soil.

4.9 Ecotoxicology

No further studies or information requested.

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