European Commission

Renewal Assessment Report of the Inclusion of the Active Substance in Annex I of the Regulation (EC) 1107/2009

Volume 1
Oxamyl
Active substance and Product data

Rapporteur Member State: Italia
Co-Rapporteur Member State: France

December 2017

Content

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December 2017	After Comments Co-Rapporteur	December 2017

TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

LEVEL 1

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

1.1 Context in which the draft assessment report was prepared

1.1.1 Purpose for which the draft assessment report was prepared

This renewal assessment report has been prepared in accordance with Commission Regulation (EC) No. 844/2012 of 18 September 2012 which sets out the provisions necessary for the renewal of actives substances as provided for in Regulation (EC) No. 1107/2009 and under consideration of Guidance Document SANCO/11114/2012.

The supplementary summary dossier for the active substance, Oxamyl, and the representative formulations Oxamyl 10SL and Oxamyl 10GR, was submitted for renewal of Active Approval in accordance with Commission Regulation Commission Regulation (EC) No. 844/2012 of 18 September 2012.

This dossier contains data and information to support a limited range of representative uses of the active substance for which it is intended to demonstrate that, for the two formulated products, the requirements of Regulation (EC) No. 1107/2009, Article 4 can be met.

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

1.1.3 EU Regulatory history for use in Plant Protection Products

Oxamyl was included in Annex I of Directive 91/414/EEC on 01 August 2006 by Commission Directive No 2006/16/EC of 07 February 2006. The inclusion Directive was subsequently repealed by Regulation (EU) No 540/2011 where oxamyl is listed as entry No 116. Annex I listing was extended to 31 January 2018 according to Commission regulation No 1136/2013 of 12 November 2013.

The Review Report (Oxamyl SANCO/10212/05 final) was finalized in the Standing Committee on the Food Chain and Animal Health on 06 March 2006. Endpoints agreed during first inclusion evaluation are provided in the EFSA Scientific Report (2005) 26, 1-78 (Appendix 1).

The Review Report concluded that plant protection products containing Oxamyl fulfilled the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EC. The following particular conditions were stated as requiring consideration at Member State level in relation to the granting of authorizations of plant protection products containing Oxamyl:

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxamyl, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2005 shall be taken into account. In this overall assessment, Member States were required to pay particular attention to the following areas:

- The protection of birds and mammals, earthworms, aquatic organisms, surface water, and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.

- The operator safety. Conditions of authorisation should include protective measures, where appropriate.

The approval was conditional to the submission of the following confirmatory information within two years from the approval Directive:

- Further studies to confirm the risk assessment for groundwater contamination in acidic soils, birds, mammals, and earthworms within two years from the approval Directive.

Data gaps mentioned in the review report (Oxamyl SANCO/10212/05 final dated on 06 March 2006) were the following:

- Additional studies to be submitted in order to ensure authorisations for use under certain conditions, *i.e.*:

    - the boiling point or temperature of decomposition;
    - the auto-flammability of the dry technical material;
    - the identity of impurities;
    - the assessment of the degradation of oxamyl at different soil pHs;
    - information on the number of granules available on the ground surface and release of the active substance from the granule.

The evaluation table was finalized on 15 December 2004. In addition to the data gaps mentioned above, in particular, the following points were recommended for evaluation at Member State level:

- Rotational crop residue trials ('cold studies')

In July 2008, DuPont submitted to the Rapporteur Member State, the other Member States, the Commission and the Authority the required confirmatory data, together with information addressing gaps identified in the review report.

On 17 June 2011 the Standing Committee on the Food Chain and Animal Health took note of the revision of the review report after the assessment of the above confirmatory data (SANCO/10212/05 final rev 1 dated on 17 June 2001). This assessment was carried out in line with the Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC. The Committee agreed that, on the basis of the current outcomes, the data gaps have been addressed or, where necessary, can be considered at Member States level. No further review by EFSA has been considered necessary.

The RMS issued the following addenda to the initial DAR:

- In May 2004 an addendum to Annex B (Part B9) was issued to address additional information on aquatic risk assessment.

- In June 2004 an addendum to Annex B (Part B2) was issued to address additional information on physical and chemical properties.

- In June 2004 an addendum to Annex B (Part B8) was issued to address additional information on environmental fate and behaviour.

- In October 2004 an addendum to Annex B (Part B6) was issued to address additional information on toxicology and metabolism, and ecotoxicology.

- In November 2004, a final addendum compiling the above for addenda.

- In May 2010, an addendum to Annex B (ecotoxicology) was issued to address post Annex I Inclusion confirmatory data on ecotoxicology.

- In May 2010, and addendum to Annex B was issued to address post Annex I Inclusion confirmatory data on environmental fate.

1.1.4 Evaluations carried out under other regulatory contexts

The RMS is not aware of any other relevant EU-evaluations of Oxamyl carried out in the framework of other relevant EU-legislation (e.g. biocides, flavourings, food additives, cosmetics).

Oxamyl was included in the Inventory of Evaluations performed by the Joint Meeting on Pesticide Residues (JMPR 2002).

Oxamyl was assessed in frame of EC Regulation (396/2005) where Regulation (EU) No 61/2014 of 24 January 2014 amended the maximum residue levels.

1.2 Applicant(s) information

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

Applicant:	DuPont de Nemours (Deutschland) GmbH
Address:	Hugenottenallee 173 – 175 D-63263 Neu-Isenburg Germany
Primary contact:	[redacted]
Address:	[redacted]
Telephone:	[redacted]
Email:	[redacted]
Alternate contact:	[redacted]
Address:	[redacted]
Telephone:	[redacted]
Email:	[redacted]

1.2.2 Producer or producers of the active substance

For further information please refer to the file of confidential information in Volume 4.

1.2.3 Information relating to the collective provision of dossiers

The RMS received an application for renewal of the approval of oxamyl only from DuPont de Nemours (Deutschland) GmbH. A collective provision of dossiers has therefore not been necessary.

1.3 Identity of the active substance

Oxamyl is a non-fumigant nematicide used for the control of a range of plant parasitic nematodes. Oxamyl is an existing active substance according to Directive 91/414/EEC, which was included into Annex I of 91/414 by Commission Directive 2006/16/EC of 7 February 2006 published on Official Journal of EU Community of 2 February 2006 and entered into force on 1 August 2006.

1.3.1 Common name proposed or ISO-accepted and synonyms

ISO common name: Oxamyl

1.3.2 Chemical name (IUPAC and CA nomenclature)

IUPAC: Methyl 2-(dimethylamino)-*N*-[(methylcarbamoyl)oxy]-2-oxoethanimidothioate

CA: Methyl 2-(dimethylamino)-N-methylamino)carbonyl]oxy]-2-oxoethanimidothioate

1.3.3 Producer's development code numbers

DPX-D1410

1.3.4 CAS, EC and CIPAC numbers

CAS number: 23135-22-0

CIPAC number: 342

EEC number: 245-445-3

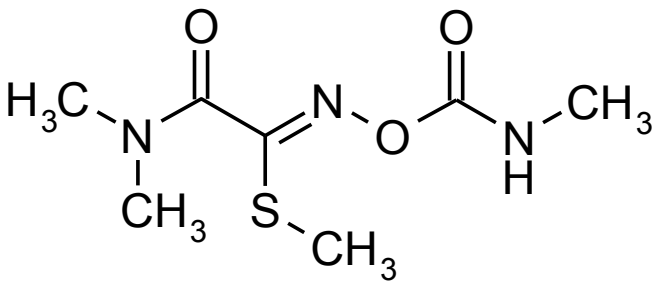
1.3.5 Molecular and structural formulae, molecular mass

Active substance

Molecular Formula: $C_7H_{13}O_3N_3S$

Molecular Mass: 219.3 g/mol

Figure1
Structural formula of active substance



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

For further information please refer to the file of confidential information in Volume 4.

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

Minimum purity is 926 g/kg (dry weight calculation on precipitated material).

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

1.3.8.1 Additives

For further information please refer to the file of confidential information in Volume 4.

1.3.8.2 Significant impurities

For further information please refer to the file of confidential information in Volume 4.

1.3.8.3 Relevant impurities

There are no relevant impurities

1.3.9 Analytical profile of batches

For further information please refer to the file of confidential information in Volume 4.

1.4 Information on the plant protection product

1.4.1 Applicant

DuPont de Nemours (Deutschland) GmbH
Hugenottenallee 173 – 175
D-63263 Neu-Isenburg
Germany

1.4.2 Producer of the plant protection product

For further information please refer to the file of confidential information in Volume 4.

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

1.4.3.1 Oxamyl 10GR

DuPont development code: DPX-D1410 10GR

For Oxamyl 10GR, the following trade names are considered: Vydate® 10G, Vydate® 10GR

1.4.3.2 Oxamyl 10 SL

DuPont Product: DPX-D1410 10SL

For Oxamyl 10SL, the following trade names are considered: Vydate® 10SL, Vydate® 10L

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

1.4.4.1 Composition of the plant protection product Oxamyl 10GR

Pure active substance

Content of pure active substance in the product:	**100 g/kg (10% w/w)**	
Limits: ±6	Min: 94.0 g/kg	Max: 106 g/kg

Technical active substance

Content of technical Concentrate (TK) in the product:	**238 g/kg (23.8% w/w)**	
Limits: ±6%	Min: 223.72 g/kg	Max: 252.28 g/kg

at a nominal purity of the TK of 42% w/w.

For further information please refer to the file of confidential information in Volume 4.

1.4.4.2 Composition of the plant protection product Oxamyl 10SL

Pure active substance

Content of pure active substance in the product:	**100 g/L (10% w/w)**	
Limits: ±6%	Min: 94.0 g/L	Max: 106.0 g/L

Technical active substance

Content of technical Concentrate (TK) in the product:	**104 g/l**	
Limits: ±6%	Min: 97.7 g/l	Max: 110.2 g/l

at a nominal purity of the TK of 10% w/w [96.2% pure active based on dry calculations].

For further information please refer to the file of confidential information in Volume 4.

1.4.4.3 Information on the active substances

See 1.4.4.1 and 1.4.4.2

1.4.4.4 Information on safeners, synergists and co-formulants

For further information please refer to the file of confidential information in Volume 4.

1.4.5 Type and code of the plant protection product

Granule (GR)

Soluble concentrate (SL)

1.4.6 Function

Nematicide

1.4.7 Field of use envisaged

Oxamyl is a non-fumigant nematicide used for the control of a range of plant parasitic nematodes.

Oxamyl 10GR is to be used in agricultural situations and under field conditions only.

Oxamyl 10SL is to be used in agricultural situations and under protected conditions (greenhouse) only.

1.4.8 Effects on harmful organisms

Oxamyl is systemic in plants. Uptake by plants also occurs when the substance (product) is applied to the soil system. In this case, oxamyl is absorbed by root of plants and translocated to leaves. Direct activity on nematode control occurs in this case as well as control of pests on above-ground plant material.

Oxamyl is used to control a wide range of important plant parasitic nematodes in a range of crops. Nematode pests that are controlled include *Meloidogyne* sp. (rootknot nematodes), *Globodera* and *Heterodera* sp. (cyst nematodes), *Trichodorus* and *Paratrichodorus* sp. (stubby root nematodes), *Radopholus similis* (burrowing nematode), *Belonalaimus longicaudatus* (sting nematode), *Hiplolaimus galeatus* (lance nematode), *Ditylenchus* sp. (stem and bulb nematodes), and *Pratylenchus penetrans* (root lesion nematode).

1.5 Detailed uses of the plant protection product (to be included for each preparation for which documentation was submitted)

1.5.1 Details of representative uses

The oxamyl containing products (oxamyl 10GR and oxamyl 10SL) are used at rates as shown in the following tables and control Meloidogyne sp. (rootknot nematodes), Globodera and Heterodera sp. (cyst nematodes), Trichodorus and Paratrichodorus sp. (stubby root nematodes), Radopholus similis (burrowing nematode), Belonalaimus longicaudatus (sting nematode), Hiplolaimus galeatus (lance nematode), Ditylenchus sp. (stem and bulb nematodes), and Pratylenchus penetrans (root lesion nematode).

Table 1 Representative Good Agricultural Practice (GAP) for Oxamyl 10GR—Representative uses

PPP (product name/code)	**Oxamyl 10GR (Vydate® 10G)**	**Formulation type:**	**GR**
active substance 1	**Oxamyl (DPX-D1410)**	**Conc. of as 1:**	**100 g/kg**
active substance 2		**Conc. of as 2:**	
safener **none**		**Conc. of safener:**	**n.a.**
synergist **none**		**Conc. of synergist:**	**n.a.**
Applicant:	**E. I. DuPont de Nemours and Company**	**professional use**	☒
Zone(s):	**Southern and Central Zones**	**non professional use**	☐

Verified by MS: n

1	2	3	4	5	6	7	8	10	11	12	13	14
					Application			**Application rate**				
Use No.	**Member state(s)**	**Crop and/ or situation (crop destination/ purpose of crop)**	**F G or I**	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Method/ Kind**	**Timing/ Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg product/ ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min/max**	**PHI (days)**	**Remarks: *e.g.* safener/synergist per ha *e.g.* recommended or mandatory tank mixtures**
1	Central Zone	Potato	F	Nematodes	In-furrow application/ Application to be made only with tractor mounted equipment	At planting (BBCH 00)	a) 1 b) 1	a) 10 b) 10	a) 1 b) 1	n.a.	90 days	
2	South Zone	Tobacco	F	Nematodes	In-furrow application/ Application to be made only with tractor mounted equipment	At trans-planting (BBCH 00)	a) 1 b) 1	a) 30 b) 30	a) 3 b) 3	n.a.	n.a.	
3	South Zone	Tobacco	F	Nematodes	Evenly soil incorporated to a depth of 10cm/ Application to be made only with tractor mounted equipment	Pre-planting (BBCH 00)	a) 1 b) 1	a) 42.5 - 55 b) 42.5 - 55	a) 4.25 - 5.5 b) 4.25 - 5.5	n.a.	n.a.	

Table 2 Representative Good Agricultural Practice (GAP) for Oxamyl 10SL—Representative uses

PPP (product name/code)	**Oxamyl 10SL (Vydate® 10L)**	**Formulation type:**	**SL**
active substance 1	**Oxamyl (DPX-D1410)**	**Conc. of as 1:**	**100 g/L**
active substance 2		**Conc. of as 2:**	
safener	**none**	**Conc. of safener:**	**n.a.**
synergist	**none**	**Conc. of synergist:**	**n.a.**
Applicant:	**E. I. DuPont de Nemours and Company**	**professional use**	☒
Zone(s):	**Interzonal**	**non professional use**	☐
Verified by MS: n			

1	2	3	4	5	6	7	8	10	11	12	13	14
				Pests or Group of pests controlled	**Application**			**Application rate**				
Use No.	**Member state(s)**	**Crop and/ or situation (crop destination/ purpose of crop)**	**F G or I**	**(additionally: developmental stages of the pest or pest group)**	**Method/ Kind**	**Timing/ Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**L product/ ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min/max**	**PHI (days)**	**Remarks: *e.g.* safener/synergist per ha *e.g.* recommended or mandatory tank mixtures**
1	Interzonal	Tomato	G	Nematodes	Drip irrigation	a.1) Immediately after transplant a.2) Starting with BBCH 11 (10-14 days after transplant application). Up to 42 days after transplant.	a.1) 1 a.2) 1-3 b) 4	a.1) 10-20 a.2) 10 b) 40-50	a.1) 1- 2 a.2) 1 b) 4-5	n.a.	a.1) n.a. a.2) 28	Apply up to 2 kg as/ha immediately after transplant. Followed by up to 3 appl. of 1 kg as/ha each starting with BBCH 11 (10-14 days after transplant application), up to 42 days after transplanting
2	Interzonal	Solarization: Soil bed preparation in greenhouses designated for the growing of: Tomato, Cucurbits (edible and inedible peel), Pepper, Aubergine, and plants nurseries of the above mentioned crops	G	Nematodes	Drip irrigation with transparent plastic foil covering soil	Before transplant on bare soil (June-September)	a) 1 b) 1	a) 55 b) 55	a) 5.5 b) 5.5	-	n.a.	Plant Back Interval (PBI) = 30days Application to bare soil covered with plastic foil to control soil nematodes before transplant

1.5.2 Further information on representative uses

1.5.2.1 Oxamyl 10GR

Oxamyl 10GR is applied to the soil with tractor-mounted equipment in a broadcast or in-furrow pattern, followed by soil incorporation when crops are planted or transplanted.

Maximum number of applications and their timing

On potato, Oxamyl 10GR is intended to be applied once in-furrow at planting stage (BBCH 00).

On tobacco, Oxamyl 10GR is intended to be applied once *via* in-furrow application at transplanting stage (BBCH 00). Also, on tobacco, at pre-planting stage (BBCH 00), one application of the product evenly soil incorporated to a depth of 5–10 cm is recommended.

For each application, development stage of the harmful organisms concerned

After application of Oxamyl 10GR, the enzyme inhibition results in paralysis of the nematode (nematostatic activity) when applied at the recommended dose rate for the crop, preventing feeding, and disrupting the nematode life cycle. Oxamyl also inhibits egg or cyst hatch in many nematode species.

Duration of protection afforded by the maximum number of applications

A single application is recommended in all crops (see Table 1).

Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

All rotational crops may be planted 30 days after last application on potato and tobacco.

Limitations on choice of succeeding crops

There are no limitations on the crops that can be grown following a crop treated with Oxamyl 10GR.

Description of damage to rotational crops

No crop damage due to the use of Oxamyl 10GR in re-cropping has been observed.

Proposed instructions for use

Oxamyl 10GR shall be used according to the instructions displayed one the proposed label.

1.5.2.2 Oxamyl 10SL

Oxamyl 10SL is applied to the soil via drip irrigation (see details above in Table 2), before transplant (solarisation use); or in the case of tomato, immediately after transplant, or starting with BBCH 11 (10–14 days *after transplant application).*

Maximum number of applications and their timing

On tomato, Oxamyl 10SL is intended to be applied once immediately after transplant; followed by up to three applications each starting with BBCH 11 (10–14 days after transplant application), up to 42 days after transplanting.

For the solarisation use, Oxamyl 10SL is applied once before transplant on bare soil (approximately between June and September).

For each application, development stage of the harmful organisms concerned

After application of Oxamyl 10SL, the enzyme inhibition results in paralysis of the nematode (nematostatic activity) when applied at the recommended dose rate for the crop, preventing feeding, and disrupting the nematode life cycle. Oxamyl also inhibits egg or cyst hatch in many nematode species.

Duration of protection afforded by the maximum number of applications

A single or split application is recommended

Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

30 days following protected crops (as illustrated in DuPont-16693 following application of Oxamyl 10SL at 6 kg a.s./ha; see the Oxamyl EU Renewal Dossier, Document M-CA, Section 6, DuPont-40933 EU)

Limitations on choice of succeeding crops

There are no limitations on the crops that can be grown following a crop treated with Oxamyl 10SL.

Description of damage to rotational crops

No crop damage due to the use of Oxamyl 10SL in re-cropping has been observed.

Proposed instructions for use

Oxamyl 10SL shall be used according to the instructions displayed on the proposed label.

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

None

Overview on authorisations in EU Member States

This information was extracted from DuPont system on July 18, 2014. Products approved and or exceptionally approved have been considered in the present table.

Country	Product	Crop	Formulation	Registration Status	Expiration Date
Belgium	Vydate 10 G	Brussels Sprouts	GR	Exceptional Approval	18-AUG-2017
Belgium	Vydate 10 G	Carrot	GR	Exceptional Approval	18-AUG-2017
Belgium	Vydate 10 G	Ornamentals	GR	Exceptional Approval	18-AUG-2017
Belgium	Vydate 10 G	Parsnips	GR	Exceptional Approval	18-AUG-2017
Belgium	Vydate 10 G	Potato	GR	Approved	18-AUG-2017
Belgium	Vydate 10 G	Potato (Seed Potato)	GR	Approved	18-AUG-2017

Belgium	Vydate 10 G	Salsify	GR	Exceptional Approval	18-AUG-2017
Belgium	Vydate CHL	Cucumber	EC	Approved	31-JUL-2017
Belgium	Vydate CHL	Eggplant / Aubergine	EC	Approved	31-JUL-2017
Belgium	Vydate CHL	Gherkin	EC	Approved	31-JUL-2017
Belgium	Vydate CHL	Marrow	EC	Approved	31-JUL-2017
Belgium	Vydate CHL	Ornamentals	EC	Exceptional Approval	31-JUL-2017
Belgium	Vydate CHL	Pepper	EC	Approved	31-JUL-2017
Belgium	Vydate CHL	Pepper, Bell	EC	Approved	31-JUL-2017
Belgium	Vydate CHL	Tomato	EC	Approved	31-JUL-2017
Bulgaria	Vydate 10 G	Carrot	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Eggplant / Aubergine	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Eggplant / Aubergine	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Potato	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Potato	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Potato	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Tobacco	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Tobacco	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Tomato	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 G	Tomato	GR	Approved	25-JAN-2023
Bulgaria	Vydate 10 L	Cucumber	SL	Approved	29-APR-2023
Bulgaria	Vydate 10 L	Cucumber	SL	Approved	29-APR-2023
Bulgaria	Vydate 10 L	Eggplant / Aubergine	SL	Approved	29-APR-2023
Bulgaria	Vydate 10 L	Eggplant / Aubergine	SL	Approved	29-APR-2023
Bulgaria	Vydate 10 L	Pepper	SL	Approved	29-APR-2023
Bulgaria	Vydate 10 L	Pepper	SL	Approved	29-APR-2023

Bulgaria	Vydate 10 L	Tomato	SL	Approved	29-APR-2023
Bulgaria	Vydate 10 L	Tomato	SL	Approved	29-APR-2023
Croatia	Vydate 10 L	Cucumber	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Eggplant / Aubergine	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Grapefruit	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Lemon	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Melon	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Orange	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Orange, Mandarin	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Pepper	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Tomato	SL	Approved	31-DEC-2023
Croatia	Vydate 10 L	Zucchini	SL	Approved	31-DEC-2023
Cyprus	Vydate 10 GR	Carrot	GR	Approved	30-JUN-2016
Cyprus	Vydate 10 GR	Eggplant / Aubergine	GR	Approved	30-JUN-2016
Cyprus	Vydate 10 GR	Eggplant / Aubergine	GR	Approved	30-JUN-2016
Cyprus	Vydate 10 GR	Potato	GR	Approved	30-JUN-2016
Cyprus	Vydate 10 GR	Potato	GR	Approved	30-JUN-2016
Cyprus	Vydate 10 GR	Tobacco	GR	Approved	30-JUN-2016
Cyprus	Vydate 10 GR	Tobacco	GR	Approved	30-JUN-2016

Cyprus	Vydate 10 GR	Tomato	GR	Approved	30-JUN-2016
Cyprus	Vydate 10 GR	Tomato	GR	Approved	30-JUN-2016
Cyprus	Vydate 10 SL	Banana	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Cucumber	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Cucumber	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Eggplant / Aubergine	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Eggplant / Aubergine	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Melon	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Melon	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Pepper	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Pepper	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Tomato	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Tomato	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Watermelon	SL	Approved	31-JUL-2016
Cyprus	Vydate 10 SL	Watermelon	SL	Approved	31-JUL-2016
Czech Republic	Vydate 10 G	Beet, Sugar	GR	Approved	31-JAN-2018
Czech Republic	Vydate 10 G	Brussels Sprouts	GR	Approved	31-JAN-2018
Czech Republic	Vydate 10 G	Carrot	GR	Approved	31-JAN-2018
Czech Republic	Vydate 10 G	Parsley	GR	Approved	31-JAN-2018
Czech Republic	Vydate 10 G	Parsnips	GR	Approved	31-JAN-2018
Czech Republic	Vydate 10 G	Potato	GR	Approved	31-JAN-2018

France	Vydate 10G	Carrot	GR	Approved	31-DEC-2020
France	Vydate 10G	Carrot	GR	Approved	31-DEC-2020
France	Vydate 10G	Corn / Maize, Field+Pop+Sweet (Seed Production Only)	GR	Approved	31-DEC-2020
France	Vydate 10G	Corn / Maize, Field+Pop+Sweet (Seed Production Only)	GR	Approved	31-DEC-2020
France	Vydate 10G	Corn / Maize, Field+Pop+Sweet (Seed Production Only)	GR	Approved	31-DEC-2020
France	Vydate 10G	Ornamentals	GR	Approved	31-DEC-2020
France	Vydate 10G	Potato	GR	Approved	31-DEC-2020
France	Vydate 10G	Potato	GR	Approved	31-DEC-2020
France	Vydate 10G	Salsify	GR	Approved	31-DEC-2020
France	Vydate 10G	Salsify	GR	Approved	31-DEC-2020
France	Vydate 10G	Tobacco	GR	Approved	31-DEC-2020
France	Vydate 10G	Tobacco	GR	Approved	31-DEC-2020
France	Vydate 10G	Tobacco	GR	Approved	31-DEC-2020
Greece	Vydate 10 GR	Carrot	GR	Approved	31-JUL-2016
Greece	Vydate 10 GR	Eggplant / Aubergine	GR	Approved	31-JUL-2016
Greece	Vydate 10 GR	Eggplant / Aubergine	GR	Approved	31-JUL-2016
Greece	Vydate 10 GR	Potato	GR	Approved	31-JUL-2016

Greece	Vydate 10 GR	Potato	GR	Approved	31-JUL-2016
Greece	Vydate 10 GR	Tomato	GR	Approved	31-JUL-2016
Greece	Vydate 10 GR	Tomato	GR	Approved	31-JUL-2016
Greece	Vydate 10 SL	Banana	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Cucumber	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Cucumber	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Eggplant / Aubergine	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Eggplant / Aubergine	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Melon	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Melon	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Pepper	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Pepper	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Tomato	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Tomato	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Watermelon	SL	Approved	31-JUL-2016
Greece	Vydate 10 SL	Watermelon	SL	Approved	31-JUL-2016
Greece	Vydate 5 GR	Carrot	GR	Approved	31-JUL-2016
Greece	Vydate 5 GR	Eggplant / Aubergine	GR	Approved	31-JUL-2016
Greece	Vydate 5 GR	Eggplant / Aubergine	GR	Approved	31-JUL-2016
Greece	Vydate 5 GR	Potato	GR	Approved	31-JUL-2016
Greece	Vydate 5 GR	Potato	GR	Approved	31-JUL-2016

Greece	Vydate 5 GR	Tobacco	GR	Approved	31-JUL-2016
Greece	Vydate 5 GR	Tobacco	GR	Approved	31-JUL-2016
Greece	Vydate 5 GR	Tomato	GR	Approved	31-JUL-2016
Greece	Vydate 5 GR	Tomato	GR	Approved	31-JUL-2016
Hungary	Vydate 10 G	Carrot	GR	Approved	31-JUL-2016
Hungary	Vydate 10 G	Parsley	GR	Approved	31-JUL-2016
Hungary	Vydate 10 G	Potato	GR	Approved	31-JUL-2016
Hungary	Vydate 10 L	Cucumber	SL	Approved	31-JUL-2016
Hungary	Vydate 10 L	Eggplant / Aubergine	SL	Approved	31-JUL-2016
Hungary	Vydate 10 L	Muskmelon	SL	Approved	31-JUL-2016
Hungary	Vydate 10 L	Pepper	SL	Approved	31-JUL-2016
Hungary	Vydate 10 L	Tomato	SL	Approved	31-JUL-2016
Hungary	Vydate 10 L	Watermelon	SL	Approved	31-JUL-2016
Ireland	Vydate 10 G	Beet, Fodder	GR	Approved	
Ireland	Vydate 10 G	Beet, Sugar	GR	Approved	
Ireland	Vydate 10 G	Carrot	GR	Approved	
Ireland	Vydate 10 G	Parsnips	GR	Approved	
Ireland	Vydate 10 G	Potato	GR	Approved	
Italy	Vydate 10 L	Cucumber	SL	Approved	31-JAN-2018
Italy	Vydate 10 L	Eggplant / Aubergine	SL	Approved	31-JAN-2018
Italy	Vydate 10 L	Melon	SL	Approved	31-JAN-2018
Italy	Vydate 10 L	Pepper	SL	Approved	31-JAN-2018
Italy	Vydate 10 L	Tobacco	SL	Approved	31-JAN-2018
Italy	Vydate 10 L	Tomato	SL	Approved	31-JAN-2018
Italy	Vydate 10 L	Watermelon	SL	Approved	31-JAN-2018
Italy	Vydate 10 L	Zucchini	SL	Approved	31-JAN-2018
Italy	Vydate 5G	Beet, Sugar	GR	Approved	31-JAN-2018
Italy	Vydate 5G	Carrot	GR	Approved	31-JAN-2018

Italy	Vydate 5G	Potato	GR	Approved	31-JAN-2018
Italy	Vydate 5G	Potato	GR	Approved	31-JAN-2018
Italy	Vydate 5G	Tobacco	GR	Approved	31-JAN-2018
Italy	Vydate 5G	Tomato	GR	Approved	31-JAN-2018
Italy	Vydate 5G	Tomato	GR	Approved	31-JAN-2018
Malta	Vydate 10 L	Cucumber	SL	Approved	30-SEP-2016
Malta	Vydate 10 L	Eggplant / Aubergine	SL	Approved	30-SEP-2016
Malta	Vydate 10 L	Melon	SL	Approved	30-SEP-2016
Malta	Vydate 10 L	Pepper	SL	Approved	30-SEP-2016
Malta	Vydate 10 L	Tomato	SL	Approved	30-SEP-2016
Malta	Vydate 10 L	Watermelon	SL	Approved	30-SEP-2016
Malta	Vydate 10 L	Zucchini	SL	Approved	30-SEP-2016
Malta	Vydate 5G	Beet, Sugar	GR	Approved	10-DEC-2014
Malta	Vydate 5G	Carrot	GR	Approved	10-DEC-2014
Malta	Vydate 5G	Potato	GR	Approved	10-DEC-2014
Malta	Vydate 5G	Potato	GR	Approved	10-DEC-2014
Malta	Vydate 5G	Tomato	GR	Approved	10-DEC-2014
Malta	Vydate 5G	Tomato	GR	Approved	10-DEC-2014
Netherlands	Vydate 10 G	Beet	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Beet, Fodder	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Beet, Sugar	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Brussels Sprouts	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Carrot	GR	Approved	01-APR-2020

Netherlands	Vydate 10 G	Carrot	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Chicory	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Flowers	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Flowers (Seed Production)	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Flowers (Seed Production)	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	House Plants - Indoor and Outdoor	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Lilium	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Nursery Stock	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Onion	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Potato	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Potato	GR	Approved	01-APR-2020
Netherlands	Vydate 10 G	Strawberry	GR	Approved	01-APR-2020
Netherlands	Vydate 10L	Brussels Sprouts	SL	Under Development	
Netherlands	Vydate 10L	Carrot	SL	Under Development	
Netherlands	Vydate 10L	Carrot	SL	Under Development	
Netherlands	Vydate 10L	Flowers	SL	Under Development	
Netherlands	Vydate 10L	Flowers	SL	Under Development	
Netherlands	Vydate 10L	Flowers	SL	Under Development	
Netherlands	Vydate 10L	Flowers	SL	Under Development	
Netherlands	Vydate 10L	Flowers	SL	Under Development	
Netherlands	Vydate 10L	Flowers	SL	Under Development	
Netherlands	Vydate 10L	Flowers (Seed Production)	SL	Under Development	
Netherlands	Vydate 10L	Flowers (Seed	SL	Under Development	

		Production)			
Netherlands	Vydate 10L	House Plants - Indoor and Outdoor	SL	Under Development	
Netherlands	Vydate 10L	House Plants - Indoor and Outdoor	SL	Under Development	
Netherlands	Vydate 10L	Lilium	SL	Under Development	
Netherlands	Vydate 10L	Nursery Stock	SL	Under Development	
Netherlands	Vydate 10L	Nursery Stock	SL	Under Development	
Netherlands	Vydate 10L	Potato	SL	Under Development	
Netherlands	Vydate 10L	Potato	SL	Under Development	
Netherlands	Vydate 10L	Strawberry	SL	Under Development	
Poland	Vydate 10 G	Beet, Sugar	GR	Approved	01-APR-2020
Poland	Vydate 10 G	Carrot	GR	Approved	01-APR-2020
Poland	Vydate 10 G	Potato	GR	Approved	01-APR-2020
Poland	Vydate 10 G	Strawberry (Plant Production Only)	GR	Approved	01-APR-2020
Portugal	Vydate 10 L	Banana	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Cucumber	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Cucumber	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Eggplant / Aubergine	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Eggplant / Aubergine	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Melon	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Melon	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Pepper	SL	Approved	11-MAR-2023

Portugal	Vydate 10 L	Pepper	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Tobacco	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Tomato	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Tomato	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Watermelon	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Watermelon	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Zucchini	SL	Approved	11-MAR-2023
Portugal	Vydate 10 L	Zucchini	SL	Approved	11-MAR-2023
Portugal	Vydate 10G	Carrot	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Eggplant / Aubergine	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Eggplant / Aubergine	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Pepper	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Pepper	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Potato	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Tobacco	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Tobacco	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Tomato	GR	Approved	02-NOV-2022
Portugal	Vydate 10G	Tomato	GR	Approved	02-NOV-2022
Romania	Vydate 10 G	Beet, Sugar	GR	Approved	08-DEC-2015

Romania	Vydate 10 G	Cucumber	GR	Approved	08-DEC-2015
Romania	Vydate 10 G	Cucumber	GR	Approved	08-DEC-2015
Romania	Vydate 10 G	Garlic	GR	Approved	08-DEC-2015
Romania	Vydate 10 G	Pepper	GR	Approved	08-DEC-2015
Romania	Vydate 10 G	Potato	GR	Approved	08-DEC-2015
Romania	Vydate 10 G	Potato	GR	Approved	08-DEC-2015
Romania	Vydate 10 G	Potato	GR	Approved	08-DEC-2015
Romania	Vydate 10 G	Tomato	GR	Approved	08-DEC-2015
Romania	Vydate 10 G	Tomato	GR	Approved	08-DEC-2015
Romania	Vydate 10 L	Cucumber	SL	Approved	16-DEC-2019
Romania	Vydate 10 L	Pepper	SL	Approved	16-DEC-2019
Romania	Vydate 10 L	Tomato	SL	Approved	16-DEC-2019
Spain	Vydate 10 G	Potato	GR	Approved	31-JUL-2016
Spain	Vydate 10 G	Tobacco	GR	Approved	31-JUL-2016
Spain	Vydate 10 L	Banana	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Cucumber	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Eggplant / Aubergine	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Gherkin	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Grapefruit	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Lemon	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Lime	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Melon	SL	Approved	31-JUL-2016

Spain	Vydate 10 L	Nursery Stock	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Nursery Stock	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Orange	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Ornamentals	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Pamelo / Pomelos	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Pepper	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Tomato	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Watermelon	SL	Approved	31-JUL-2016
Spain	Vydate 10 L	Zucchini	SL	Approved	31-JUL-2016
Spain	Vydate P	Banana	SL	Approved	09-MAR-2016
United Kingdom	Vydate 10 G	Beet, Sugar	GR	Approved	31-DEC-2016
United Kingdom	Vydate 10 G	Carrot	GR	Approved	31-DEC-2016
United Kingdom	Vydate 10 G	Parsnips	GR	Approved	31-DEC-2016
United Kingdom	Vydate 10 G	Potato	GR	Approved	31-DEC-2016

LEVEL 2

2 Summary of active substance hazard and of product risk assessment

2.1 Identity

2.1.1 Summary of identity

Oxamyl is a non-fumigant nematicide used for the control of a range of plant parasitic nematodes.

Oxamyl is not a chiral molecule and thus the technical material used in regulatory testing is not a racemic mixture or a resolved isomer of a chiral molecule.

Manufacturing process and data on characterization of technical material were provided and are considered adequate to confirm the specifications. There are no relevant impurities reported. Data were generated based on actual full scale productions.

For further information please refer to the file of confidential information in Volume 4.

2.2 Physical and chemical properties

2.2.1 Summary of physical and chemical properties of the active substance

The pure active substance of oxamyl, which is never isolated, is a white, crystalline solid that melts at 99.2 °C. Oxamyl does not exhibit a pKa and thus would not be expected to ionise in the relevant environmental pH range. The aqueous solubility of oxamyl is 148.1 g/L and is not dependent upon pH. The vapour pressure (1.80×10^{-5} Pa at 20°C) and the Henry's Law Constant (2.7×10^{-8} Pa m^3/mol at 20°C) indicate that volatilisation is not a significant route of dissipation for oxamyl. The oxamyl technical is a concentrate, stabilized as manufactured at 42% or 10% oxamyl (42TK and 10TK), which are used for the formulation of Oxamyl 10GR and Oxamyl 10SL. Oxamyl 42TK exhibits a flash point of 57.4°C and an auto-ignition temperature of 303°C due to the presence of cyclohexanone as a solvent. This manufactured technical concentrates were demonstrated to be safe with respect to explosivity and oxidising properties.

All data requirements were met by data provided and findings are considered appropriate. No further data are required.

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

2.2.2.1 Oxamyl 10GR

Oxamyl 10GR is non-flammable, non-explosive, and not an oxidizer. The pH of a 1% concentration of the preparation in water was consistently measured between 6.5 and 7.6 pH units. The preparation was tested for dustiness in accordance with CIPAC Method MT 171 and found to be "essentially dust free."

The pure active substance content of Oxamyl 10GR, as manufactured was 9.86%. The physical and chemical properties of the preparation were measured using CIPAC Methods or other accepted methods. All physical and chemical properties 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. The preparation was stored at a temperature of 54°C for a period of 2 weeks. Based on storage stability data provided, it can reasonably be assumed that Oxamyl 10GR will be stable under normal storage conditions for a minimum of 2 years.

Oxamyl 10GR is applied to the soil in a broadcast or in-furrow pattern, followed by soil incorporation when crops are planted or transplanted. Equipment cleanout is easily accomplished using standard wash out procedures.

The plant protection product is a non-dusty, dry flowable granule that can easily be recovered (scooped up using a shovel) if spilled.

2.2.2.2 Oxamyl 10SL

Oxamyl 10SL is non-flammable, non-explosive, and not an oxidizer. The pH of a 1% concentration of the preparation in water was consistently measured between 3.5 and 4.1 pH units. The pH of undiluted Oxamyl 10SL was 3.3.

The pure active substance content of Oxamyl 10SL, as manufactured was 10.39%. The physical and chemical properties of the preparation were measured using CIPAC Methods. All physical and chemical properties 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. The preparation was stored at a temperature of 54°C for a period of 2 weeks and for a period of 2 years at ambient temperature. The storage data have clearly demonstrated that Oxamyl 10SL is stable under normal storage conditions for a minimum of two years in an HDPE container.

Oxamyl 10SL product can be conveniently measured using a calibrated volumetric measuring guide and easily diluted in water. It can be applied by drip irrigation pipelines. Equipment cleanout is easily accomplished using standard wash out procedures.

The plant protection product is a soluble concentrate that can easily be recovered (soaked up with inert absorbent material). If liquid has been spilt in large quantities, it can be cleaned up promptly by scoop or vacuum.

No further data are required.

2.3 Data on application and efficacy

2.3.1 Summary of effectiveness

Oxamyl is used to control a wide range of important plant parasitic nematodes in a range of crops. Nematode pests that are controlled include *Meloidogyne* sp. (rootknot nematodes), *Globodera* and H*eterodera* sp. (cyst nematodes), *Trichodorus* and *Paratrichodorus* sp. (stubby root nematodes), *Radopholus similis* (burrowing nematode), *Belonalaimus longicaudatus* (sting nematode), *Hiplolaimus galeatus* (lance nematode), *Ditylenchus* sp. (stem and bulb nematodes), and *Pratylenchus penetrans* (root lesion nematode).

Oxamyl is systemic in plants. Uptake by plants also occurs when the substance (product) is applied to the soil system. In this case, oxamyl is absorbed by root of plants and translocated to leaves. Direct activity on nematode control occurs in this case as well as control of pests on above-ground plant material.

Oxamyl contained in product Oxamyl 10GR and Oxamyl 10SL has been tested in field trials which demonstrated efficacious activity. The products have been registered in many EU countries based on detailed national assessments of the efficacy package in compliance with Regulation (EC) No 545/2011 and according to the Uniform Principles (Regulation (EC) No 546/2011), with which Member States authorities were satisfied.

2.3.2 Summary of information on the development of resistance

Oxamyl is classified as an IRAC (Insecticide Resistance Action Committee) Group 1A Nematicide and Insecticide (acetylcholine esterase inhibitor). Based on historical use data, it is expected that the risk of development of resistance in plant parasitic nematodes is low.

The development of resistance cannot be predicted, and local advisors should be consulted for detailed recommendations. Resistance of nematodes to oxamyl has not been found when applied as granular formulation for soil incorporation in the UK or other countries. This is unlikely, as the product is only applied once per crop and with crop rotation would only be applied to the same soil every 4–5 years.

Good Agricultural Practices and Good Plant Protection Practices should be followed in the management strategy. The key elements for Resistance Management are:

- Alternate compounds of different chemical classes. Oxamyl is a carbamate and can be effectively alternated with pyrethroids and organophosphates.
- When in a tank mixture, ensure that compounds mixed are not at all of the same chemical class.
- Monitor the insect population, and apply oxamyl when locally determined economic thresholds are reached. When used as a liquid plant protection product for drip irrigation scenarios, more than one application may be necessary.

Follow label recommendations for rates and spray intervals. Because of oxamyl´s mode of action and short persistence (thus reducing selection pressure), oxamyl has been found to be a valuable tool in resistance management programmes.

2.3.3 Summary of adverse effects on treated crops

Oxamyl containing products used in agriculture *via* broadcast or in-furrow application and soil incorporation prior to or at (trans)planting or sowing, and *via* drip irrigation in fruiting vegetables and various field crops have been proven to be safe to the target crops at the established product label rates.

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

For efficacy-related elements, only limited information was provided to address the requirements of Article 4(3) of Regulation (EC) No 1107/2009. Detailed consideration of efficacy will occur in the subsequent product authorisation process when a full biological assessment dossier will be available for evaluation. Therefore, only limited efficacy information was provided under the appropriate headings in line with the relevant guidance for renewals - Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 Appendix II (SANCO/2012/11251).

2.4 Further information

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

While handling oxamyl, Oxamyl 10GR, and Oxamyl 10SL, it is required to wear approved personal protective equipment (gloves, coverall, mask, and goggles) and to provide adequate ventilation.

Oxamyl is not labelled for general public use but for professional users. Therefore, storage is recommended within a specialised and dedicated area (warehouse).

In case of fire, water spray, foam, dry chemical, carbon dioxide (CO_2) may be used. Due to a risk of contamination, a high volume water jet should not be used. Carbon dioxide (CO_2) and nitrogen oxides (NOx) are hazardous decomposition products formed under fire conditions.

Spillage water must be contained and disposed of according to local rules in order to avoid contamination of the environment.

2.4.2 Summary of procedures for destruction or decontamination

Solids: Sweep up or vacuum up spillage, and collect in suitable container for disposal. If solid has been spilt in large quantities, avoid dust formation and knock down dust with water spray jet. Prevent further leakage or spillage. Contain spillage, pick up with an electrically protected vacuum cleaner or by wet-brushing, and transfer to a container for disposal according to local/national regulations.

Liquids: Soak up with sawdust, sand, oil dry, or other absorbent material. Dispose of in an approved container. If liquid has been spilt in large quantities, clean up promptly by scoop or vacuum.

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

2.4.3 Summary of emergency measures in case of an accident

Clean-up methods—small spillage: Neutralise with sodium hydroxide and allow to stand for 4 hours. Soak up with inert absorbent material. Sweep up or vacuum up spillage, and collect in suitable container for disposal.

Clean-up methods—large spillage: Prevent further leakage or spillage. Contain spillage, soak up with non-combustible absorbent material (*e.g.*, sand, earth, diatomaceous earth, vermiculite), and transfer to a container for disposal according to local/ national regulations. Neutralise with sodium hydroxide, and allow to stand for 4 hours. Large spills should be collected mechanically (remove by pumping) for disposal. Collect leaking liquid in sealable (metal/plastic) containers. Collect and contain contaminated absorbent and dike material for disposal.

Waste treatment methods

Product: In accordance with local and national regulations, the product must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities. The product should not be allowed to enter drains, water courses, or the soil.

Methods of analysis

Matrix	Reference and report	Separation/ Quantitation	Limit of determination (mg/kg)	Comments
Dry, watery, oily, acidic, and difficult to analyse crops	Lissemore, Harris and Patterson, 2014 DuPont-41730	QuECHERS MRM HPLC/MS/MS	0.01	QuECHERS MRM
Meat (bovine), fat (bovine), liver (bovine), milk, eggs	Lissemore, Harris and Patterson, 2014 DuPont-41763	QuECHERS MRM HPLC/MS/MS	0.01	QuECHERS MRM
Soil	Henze and Klems, 2014 DuPont-38689	HPLC-MS/MS	0.001	DuPont single analyte method
Water	Hill, Maliszewski and Stry, 2001 DuPont-5677	HPLC-MS/MS	0.0001 mg/L	DuPont single analyte method
Air	Bacher, 2000, DuPont-4564	HPLC-MS/MS	0.05 $\mu g/m^3$	DuPont single analyte method
Body fluids and tissues	Klems, 2015 DuPont-38598 Rev. No. 1	HPLC-MS/MS	0.05 mg/L	DuPont single analyte method

2.4.4 Methods used for the generation of pre-authorisation data

2.4.5 Methods for post control and monitoring purposes

A new method for assay of oxamyl as manufactured is submitted in order to meet current requirements. The analytical method for determination of oxamyl (DPX-D1410) in technical grade oxamyl and end-use products has been validated.

The method involves dissolution by ultrasonication of oxamyl in a solution of 5% methanol and 95% water adjusted to pH 3.0 with H_3PO_4. Analysis was done by reversed-phase liquid chromatography (HPLC) and ultra-high pressure liquid chromatography (UPLC), with quantitation by ultraviolet absorbance at 240 nm.

Details regarding the specificity of the method are claimed as confidential according to Article 63 of Regulation EC 1107/2009, Council Directive 2003/4/EC and are included Volume 4

The method was successfully evaluated and meets the EU criteria with respect to linearity, precision (repeatability), accuracy (recovery), and specificity. The method requires instrumentation commonly available in most well equipped analytical laboratories. No hazardous reagents are required. Therefore, this method is suitable for enforcement purposes.

There is a CIPAC method for oxamyl, FAO specification 342/TK (April, 2008). The analytical method for determination of oxamyl (including identity tests) is based on reversed-phase HPLC with UV detection at 240 nm and internal standardization with acetanilide. The method was adopted by CIPAC with provisional status in 2006 and full CIPAC method status in 2007. DuPont and CIPAC have noted that the method can also be used with external standardization. The method is applicable for technical concentrate, granules, and soluble concentrates.

2.5 Effects on human and animal health

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

Elimination	After single doses of [1-^{14}C]oxamyl (1 mg/kg bw) to rats, the majority of the dose was eliminated in the urine. Faeces and expired air were minor elimination routes.
Clearance	The highest concentration of radioactivity was found in whole blood (approximately 0.1 µg equivalent/g) and the following tissues (approximately 0.04 to 0.09 µg equivalent/g): heart, liver, kidney, lungs, spleen, and the gastro-intestinal tract. Concentrations in all other tissues were approximately 0.01 to 0.03 µg equivalent/g. There were no significant differences in tissue concentrations between males and females.
Metabolite profile	The major urinary metabolite in oxamyl and IN-A2213 dosed rats was the IN-A2213 glucuronide. Metabolism was characterized by hydrolysis of parent oxamyl to IN−A2213 or enzymatic conversion *via* the N,N-dimethyl-carbonocyanidic amide (IN−N0079) to N,N'-dimethyloxamic acid (IN-D2708) and N-methyloxamic acid (IN−KP523). Minor unidentified metabolites were considered to be conjugates of demethylated compounds (*e.g.*, IN-L2953) or IN-D2708. The major route of oxamyl biotransformation was hydrolysis to IN-A2213, then conjugation.

2.5.2 Summary of acute toxicity

Oxamyl technical:

Oxamyl has high acute oral and inhalation toxicity, but relatively low acute dermal toxicity. High purity oxamyl was not irritating to either the skin or eyes of rabbits. Toxicity precluded testing of pure oxamyl for skin sensitisation in guinea pigs by both the Maximisation and Buehler methods when the test substance was administered at doses recommended by the test guidelines. However, negative results were obtained in a study with oxamyl technical 42 (TK), which represented the approximate maximum concentration that could be evaluated without significant clinical signs of toxicity or mortality. Oxamyl was determined not to have the potential to be phototoxic.

Table 3 Summary of acute toxicity studies with oxamyl (a.s.)

Type of study	Purity	Species	Result	Reference[a]
Acute oral LD_{50}	98.1%	Rat	LD_{50} 2.5 mg/kg bw (female)	DuPont-26931
Acute dermal LD_{50}	97.1%	Rabbit	LD_{50} 5027 mg/kg bw (male) LD_{50} >5000 mg/kg bw (female)	HLR 114-88
Acute inhalation LC_{50} (4 hr)	98.1%	Rat	LC_{50} 56 mg/m^3 (equivalent to 0.056 mg/L)	DuPont-6331
Acute skin irritation	98.1%	Rabbit	Not irritating	DuPont-7060
Acute eye irritation	98.2%	Rabbit	Not irritating	DuPont-7059
Skin sensitisation	96.9%	Guinea pig	Study discontinued due to toxicity	DuPont-3021
Skin sensitisation	42%[b]	Guinea pig	Not a sensitiser	HLR 179-88
Phototoxicity	99.1%	Mouse fibroblast cell line, Balb/3T3, clone A31	Not phototoxic	DuPont-42100

[a] Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU

[b] Oxamyl technical 42TK (42% a.s. in cyclohexanone and water)

Oxamyl 10GR:

Oxamyl 10GR was highly toxic by the oral route of exposure with an LD_{50} of 34 mg/kg bw. It was also found to be toxic by the inhalation route with an LC_{50} of 0.68 mg/L. In contrast, by the dermal route of exposure, it was not toxic, as the LD_{50} was found to be >5000 mg/kg bw. Oxamyl 10GR was not irritating to the eyes or skin of

rabbits and was found not to be a sensitiser in a modified Buehler study, which was conducted in lieu of the Guinea Pig Maximization study, as the material is highly toxic if dosed systemically.

Table 4 Summary of acute toxicity data for Oxamyl 10GR

Type of study	Species	Results	Reference[a]
Acute oral LD_{50}	Rat	LD_{50} = 34 mg/kg	DuPont-2703
Acute dermal LD_{50}	Rat	LD_{50} = >5000 mg/kg mg/kg	DuPont-2810
Acute inhalation LC_{50} (4h)	Rat	LC_{50} = 0.68 mg/L mg/L	DuPont-1987
Skin irritation	Rabbit	Not irritating	DuPont-2453
Eye irritation	Rabbit	Not irritating	DuPont-2640
Skin sensitisation (Buehler test)	Guinea Pig	Not sensitising	DuPont-1953

[a]Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 7, DuPont-40951 EU

In accordance with Regulation (EC) No. 1272/2008, classification of Oxamyl 10GR is required for acute oral and inhalation toxicity. Acute oral Category 2 is applicable in accordance to Annex I - Part 3 - Points 3.1.3 to 3.1.3.6.2.3 of Regulation (EC) No. 1272/2008 and its corresponding ATPs. Acute inhalation Category 3 is applicable in accordance to Annex I - Part 3 Points 3.1.3 to 3.1.3.6.2.3 of Regulation (EC) No. 1272/2008 and its corresponding ATPs. Therefore, hazard statements H300 Fatal if swallowed and H331 Toxic if inhaled apply to Oxamyl 10GR. Classification for acute dermal, skin and eye irritation, and dermal sensitisation is not required.

Oxamyl 10SL:

Oxamyl 10SL was highly toxic by the oral route of exposure with an LD_{50} of 39 mg/kg bw. It was also found to be toxic by the inhalation route with an LC_{50} of 0.62 mg/L. In contrast, by the dermal route of exposure, it was not toxic, as the LD_{50} was found to be >5000 mg/kg bw. Oxamyl 10SL was not irritating to the eyes or skin of rabbits and was found not to be a sensitiser in a modified Buehler study, which was conducted in lieu of the Guinea Pig Maximization study as the material is highly toxic if dosed systemically.

Table 5 Summary of acute toxicity data for Oxamyl 10SL

Type of study	Species	Results	Reference[a]
Acute oral LD_{50}	Rat	LD_{50} = 39 mg/kg	DuPont-2140
Acute dermal LD_{50}	Rat	LD_{50} =>5000 mg/kg	DuPont-2130
Acute inhalation LC_{50} (4h)	Rat	LC_{50} = 0.62 mg/L	HL-1998-01611
Skin irritation	Rabbit	Not irritating	DuPont-2024
Eye irritation	Rabbit	Not irritating	DuPont-2040
Skin sensitisation (Buehler test)	Guinea Pig	Not sensitising	DuPont-2016

[a]Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 7, DuPont-42127 EU

In accordance with Regulation (EC) No. 1272/2008, classification of Oxamyl 10SL for acute oral and inhalation toxicity is required. Acute oral Category 2 is applicable in accordance to Annex I - Part 3 - Points 3.1.3 to 3.1.3.6.2.3 of Regulation (EC) No. 1272/2008 and its corresponding ATPs. Acute inhalation Category 3 is applicable in accordance to Annex I - Part 3 Points 3.1.3 to 3.1.3.6.2.3 of Regulation (EC) No. 1272/2008 and its corresponding ATPs. Therefore, hazard statements, H300 Fatal if swallowed and H331 Toxic if inhaled apply to Oxamyl 10SL. Classification for acute dermal, skin and eye irritation, and dermal sensitisation is not required.

2.5.3 Summary of short-term toxicity

Oxamyl has been evaluated in several short-term toxicity studies that have included 90-day feeding studies in rats and dogs, one-year feeding studies in dogs, and short-term dermal exposure studies in rabbits.

Table 6 Summary of short-term toxicity studies (relied upon) with oxamyl

Type of study	Species	Dose range tested	NOAEL	LOAEL	Target organ(s) and effects	Reference[a]

Table 6 Summary of short-term toxicity studies (relied upon) with oxamyl

Type of study	Species	Dose range tested	NOAEL	LOAEL	Target organ(s) and effects	Reference[a]
oral, 13 weeks	rat	0, 50, 100, 500/150 ppm (equivalent to 0, 3.9, 8.4, 14.6 mg/kg bw/day for males and 0, 4.3, 9.2, 14 mg/kg bw/day for females)	50 ppm (3.9 and 4.3 mg/kg bw/day, males and females, respectively)	100 ppm (8.4 and 9.2 mg/kg bw/day males and females, respectively)	↓ body weight gain, urine blood, ↓ absolute organ weight	HLR 308-69
oral, 13 weeks	dog	0, 50, 100, 150 ppm (equivalent to 0, 1.5, 2.9, 5.0 mg/kg bw/day for males and 0, 1.3, 2.6, 4.2 mg/kg bw/day for females)	>150 (HDT)[b] (>4.2 mg/kg bw/day)	>150 (HDT)[b] (>4.2 mg/kg bw/day)	No treatment-related effects	HLO 328-69
oral, 12 months	dog	0, 50, 150, 250 ppm (equivalent to 0, 1.56, 4.60, 8.0 mg/kg bw/day for males, and 0, 1.46, 4.50, 7.84 mg/kg bw/day for females)	<50 ppm (male)[c] (<1.56 mg/kg bw/day) 50 ppm (female) (1.46 mg/kg bw/day)	<50 ppm (male) (<1.56 mg/kg bw/day) 100 ppm (female) (4.5 mg/kg bw/day)	↓ plasma and brain cholinesterase activity among males and clinical signs among females	HLR 381-90
oral, 12 months	dog	0, 12.5, 20, 35, 50 ppm (males only) (equivalent to 0, 0.372, 0.577, 0.93, 1.364 mg/kg bw/day)	50 ppm (HDT)[c] (1.36 mg/kg bw/day) (males only)	>50 ppm (HDT) (1.36 mg/kg bw/day) (males only)	No treatment-related effects	HLO 555-90
dermal, 21 days	rabbit	0, 2.5, 50, 250 mg/kg bw/day (occlusive, non-porous dressing)	2.5 mg/kg bw/day	50 mg/kg bw/day	↓ plasma, erythrocyte and brain cholinesterase activity	HLR 523-88
dermal, 21 days	rabbit	0, 25, 40, 50, 75 mg/kg bw/day (porous, semi-occlusive dressing)	50 mg/kg bw/day	75 mg/kg bw/day	↓ plasma, erythrocyte & brain cholinesterase activity among females	DuPont-1599

[a] Summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU

[b] HDT = Highest dose tested.

[c] 50 ppm is a threshold dose; therefore, the NOEL for male dogs is based on the daily intake value of 1.36 mg/kg bw/day established in the second 12-month feeding study (Dickrell, 1991 [HLO 555-90]).

In a 13-week rat study, decreased body weight gain; decreased kidney, heart, thymus, spleen, liver, and lung weights; and increased stomach weights were noted in males and/or females at the mid- and/or high-dose level. At the high dose, clinical signs of toxicity (fasciculations, ruffled fur, mild diarrhoea, bulging eyes, and lacrimation), decreased food consumption, and an increased incidence of protein and blood in the urine were observed. In a 13-week dog study, no treatment-related effects were noted at any dose level up to the highest dose tested of 150 ppm. The results of one oral 12-month dog study showed effects on body weight, body weight gain, food consumption and food efficiency, and clinical signs of toxicity related to cholinesterase inhibition in males and/or females at the mid- and high-dose levels (150 and 250 ppm, respectively). Body weight effects and plasma and brain cholinesterase inhibition were also noted in males at the low dose (50 ppm; equivalent to 1.56

mg/kg bw/day). In a second oral 12-month study specifically designed to establish a NOEL in male dogs, no treatment-related findings, including cholinesterase inhibition were noted at doses up to 50 ppm (equivalent to 1.36 mg/kg bw/day). Based on the results of these two studies, 50 ppm is considered a threshold dose for male dogs. Although effects were observed in the first study when male dogs consumed a diet of 50 ppm at 1.56 mg/kg bw/day, no toxicity was observed in the second study when male dogs consumed a similar diet at 1.36 mg/kg bw/day. Therefore, the NOEL in dogs is considered to be 1.36 mg/kg bw/day for males and 1.46 mg/kg bw/day for females (the latter based on results of the first 1-year dog study).

In a 21-day dermal toxicity study in rabbits, plasma, RBC, and/or brain cholinesterase activities were decreased at the mid- and high-doses (50 and 250 mg/kg bw/day, respectively). Mild hyperglycemia and an accumulation of an eosinophilic material in the duodenal submucosa were also noted at the high dose. A second 21-day study was conducted to more precisely define the NOEL in rabbits by the dermal route of exposure. In this study, plasma, RBC, and brain cholinesterase activities were decreased in females at the high dose of 75 mg/kg bw/day. No treatment-related decreases in plasma, RBC, and brain cholinesterase activities were noted in females at dose levels of 50 mg/kg bw/day and below and in males at any dose level (up to 75 mg/kg bw/day). In the second study, no treatment-related effects were noted in males and females at 50 mg/kg bw/day, unlike the first study. The reason for the disparity of effects between the two studies is considered to be due to the differences in the wrapping procedures. In the second study, the test sites were wrapped with a porous, semi-occlusive (gauze) wrap. In the first study, the test sites were wrapped with an impervious (plastic film) wrap, which would have enhanced test substance absorption. Therefore, it is not unexpected that effects on cholinesterase activity occurred at lower dose levels in the first study compared with the second study. For the purposes of assessing the risk to operators and workers, the second 21-day dermal toxicity study more closely resembles actual dermal exposure conditions.

Thus, the relevant oral NOAEL was an overall NOAEL for the one year dog studies of 0.93 mg/kg bw/day (*i.e.*, 35 ppm), based on clinical signs and tremors and cholinesterase inhibition at 1.46 mg/kg bw/day, observed.

Short-term toxicity studies on the formulated product are not required according EC Regulation 1107/2009.

2.5.4 Summary of genotoxicity

The mutagenic and DNA damaging potential of oxamyl was studied in several *in vitro* test systems using bacterial and mammalian cells. Oxamyl did not show any evidence of gene mutations, chromosome aberrations, or DNA damage and repair. Additionally, an *in vivo* test for chromosome damage in mice produced negative results. Based on these data, oxamyl does not pose a mutagenic or genotoxic concern.

Table 7 Summary of *in vitro* and *in vivo* genotoxicity studies with oxamyl

Type of study	Organism/Cells	Concentration range tested	Result	Reference[a]
Gene mutation assays				
Reverse mutation	*Salmonella typhimurium Escherichia coli*	5–5000 μg/plate (+/-S9)	Negative	DuPont-3084
Mammalian cell gene mutation	Chinese hamster ovary cells	50–500 μg/mL (-S9) 150–400 μg/mL (+S9)	Negative	DuPont-2937
Chromosome aberration assay				
In vitro cytogenetics	human peripheral blood lymphocytes	10–600 μg/mL (-S9) 50–800 μg/mL (+S9)	Negative	DuPont-2936
DNA damage and repair assay				
In vitro UDS	rat primary hepatocytes	1×10^{-5}–10 mM (0.002–2193 μg/mL)	Negative	HLR 719-82, Revision No. 1
***In vivo* cytogenetics assay**				
In vivo micronucleus	mouse	1, 2, 3 mg/kg bw	Negative	DuPont-10618

[a] Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU

2.5.5 Summary of long-term toxicity and carcinogenicity

Oxamyl showed no evidence of oncogenicity in the long-term rat and mouse studies. The overall weight of the evidence suggests that oxamyl does not present a concern for carcinogenicity.

Oxamyl did not exhibit evidence of cumulative toxicity in chronic toxicity studies in rats, mice, or dogs. In one chronic toxicity/oncogenicity study in rats, decreased body weights, body weight gains, and food efficiency were noted in males and females at the mid- and high-doses. In addition, plasma cholinesterase activity was inhibited in males at several sampling intervals and in females at one month at the mid- and high-doses. In another long-term rat study, decreased body weight was noted in males and females at the mid- and high-doses. Blood cholinesterase activity was decreased in males and females at the high-dose level. In a mouse oncogenicity study, decreased body weight and food consumption, increased RBC count, and decreased corpuscular haemoglobin concentration levels were observed at the high-dose level. In a two-year study in dogs, increased alkaline phosphatase and cholesterol levels were noted at the high-dose level.

Based on the results of chronic feeding studies in rats and mice, oxamyl is not a carcinogen, and the lowest NOAEL of approximately 1.97 mg/kg/day is based on lower body weights and body weight gain as well as plasma cholinesterase inhibition observed with dietary administration of 4.19 mg/kg bw/day and higher in rats.

Table 8 Summary of chronic toxicity studies for oxamyl

Type of study	Dose range tested	NOAEL		LOAEL		Target organ(s) and effects	Reference[a]
		ppm	mg/kg/d	ppm	mg/kg/d		
Oral (Feeding), 2-year Rat	0, 25, 50, 100, 150 ppm (equivalent to 0, 0.992, 1.97, 4.19, 6.99 mg/kg bw/day for males and 0, 1.32, 2.69, 6.73, 11.1 mg/kg bw/day for females)	50	m: 1.97 f: 2.69	100	m: 4.19 f: 6.73	Lower body weight, lower body weight gain and plasma cholinesterase inhibition at 100 ppm and higher	HLR 278-91
Oral (Feeding), 2-year Mouse	0, 25, 50, 100/75 ppm (equivalent to 4.2, 8.7, 13.5 mg/kg bw/day for males and 5.2, 10.8, 16.8 mg/kg bw/day for females)	25	m: 4.2 f: 5.2	50	m: 8.7 f: 10.8	Decreased body weights	HLO 252-81

[a]Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU

2.5.6 Summary of reproductive toxicity

A two-generation rat reproduction study conducted with oxamyl did not reveal evidence of reproductive toxicity. Parental toxicity consisted of decreased body weight, body weight gain, and food consumption in males and females of both generations at the mid- and high-dose levels (75 and 150 ppm, respectively). A statistically significant increase in the incidence of alopecia was noted in F_1 females at the mid- and high-dose during the premating and gestation periods, and an increased incidence of hyperactivity was noted in F_1 males and females (statistically significant in males) at the high dose. No treatment-related reproductive effects were noted; however, pup toxicity (decreased viability and decreased body weight) occurred at the same dose levels causing parental toxicity. A three-generation rat reproductive study with oxamyl was conducted as part of a chronic toxicity study. No treatment-related reproductive effects were noted. Parental toxicity consisted of decreased body weight in males and females at the mid- and high-dose levels of 100 and 150 ppm, respectively, and decreased food consumption and blood cholinesterase activity in males and females at the high dose. Slightly decreased weanling weight was observed at 100 and 150 ppm but was reversible when pups were transferred to control diet. A reproductive toxicity assessment was conducted on a small subset of rats from a 90-day toxicity study. In this non-guideline study, no significant differences between the control and test groups with respect to reproduction and lactation performance were noted. Body weights of weanlings at all dietary levels (from 50 to 150 ppm) in both the F_{1a} and F_{1b} generations were decreased. Oxamyl showed no evidence of developmental toxicity in the rat and rabbit developmental studies. In the rabbit developmental study, maternal toxicity consisted of decreased body weight gain during the treatment period at the mid- and high-dose levels (2 and 4 mg/kg bw/day, respectively). Slightly decreased foetal viability was noted at the high dose, but this finding was not statistically significant. In the rat developmental study in which oxamyl was administered as a bolus dose by gavage, maternal toxicity consisted of transient tremors and decreased body weight changes and food consumption at the two highest dose levels (0.8 and 1.5 mg/kg bw/day, respectively). Statistically significant decreases in foetal body weight were noted at dose levels of ≥0.5 mg/kg bw/day, but the slightly reduced foetal body weight for the 0.5 mg/kg bw/day group was within the laboratory's historical control range and is not regarded as adverse. Therefore, an appropriate foetal NOEL for this study is 0.5 mg/kg bw/day, which is the same as the NOEL for maternal toxicity. In a rat developmental study in which oxamyl was administered by diet, significantly less maternal toxicity was observed, primarily consisting of effects on body weight and nutritional parameters at 100, 150, and 300 ppm (8.2, 11.6, and 20.5 mg/kg bw/day, respectively). No effects were observed on the reproductive outcome or in the foetuses. The NOEL in this study is 50 ppm (4.5 mg/kg bw/day), approximately 10-fold greater than the NOEL obtained in the rat developmental study when oxamyl was administered by gavage.

Oxamyl is therefore, not considered to be uniquely toxic to the conceptus and is not considered to have any unique toxicity to the reproductive system.

Table 9 Summary of reproduction and developmental studies for oxamyl

Type of study	Species	Doses/ concentra-tions tested	NOAEL	LOAEL	Target organ(s) and effects	Reference [a]
Two-generation reproduction	rat	0, 25, 75, 150 ppm	Parental: 25 ppm (1.43 mg/kg bw/day) Pup: 25 ppm Reproductive: ≥150 ppm (HDT)[b] (≥12.2 mg/kg bw/day)	Parental: 75 ppm (4.22 mg/kg bw/day) Pup: 75 ppm Reproductive: >150 ppm (HDT)[b] (>12.2 mg/kg bw/day)	↓ parental body weight/body weight gain, food consumption & efficiency ↓ pup body weight	HLR 423-90
Three-generation reproduction	rat	0, 50, 100, 150 ppm	Parental: 50 ppm (2.5 mg/kg bw/day[c]) Pup: 50 ppm Reproductive: ≥150 ppm (HDT) (≥7.5 mg/kg bw/day[c])	Parental: 100 ppm (4.9 mg/kg bw/day[c]) Pup: 100 ppm Reproductive: >150 ppm (HDT) (>7.5 mg/kg bw/day[c])	↓ parental body weight ↓ pup body weight ↓ litter size	HLR 37-72
Teratology —gavage	rabbit	0, 1, 2, 4 mg/kg bw/day	Maternal: 1 mg/kg bw/day Foetal: 2 mg/kg bw/day Developmental: ≥4 mg/kg bw/day (HDT)	Maternal: 2 mg/kg bw/day Foetal: 4 mg/kg bw/day Developmental: >4 mg/kg bw/day (HDT)	↓ maternal body weight gain ↑ resorptions	HLO 0801-80
Teratology —gavage	rat	0, 0.2, 0.5, 0.8, 1.5 mg/kg bw/day	Maternal: 0.5 mg/kg bw/day Foetal: 0.5 mg/kg bw/day Developmental: ≥1.5 mg/kg bw/day (HDT)	Maternal: 0.8 mg/kg bw/day Foetal: 0.8 mg/kg bw/day Developmental: >1.5 mg/kg bw/day (HDT)	↓ maternal body weight gain; clinical signs ↓ foetal body weight	HLR 473-88
Teratology —diet	rat	0, 50, 100, 150, 300 ppm (0, 4.5, 8.2, 11.6, 20.5 mg/kg bw/day)	Maternal: 50 ppm (4.5 mg/kg bw/day) Foetal and Developmental: ≥300 ppm (≥20.5 mg/kg bw/day) (HDT)	Maternal: 100 ppm (8.2 mg/kg bw/day) Foetal and Developmental>300 ppm (>20.5 mg/kg bw/day) (HDT)	↓ maternal body weight gain	HLR 5-71

[a] Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU

[b] HDT = Highest dose tested.

[c] Calculated using standard conversion method (ppm × 0.05 mg/kg bw/day).

2.5.7 Summary of neurotoxicity

A single oral dose study in human volunteers was conducted with oxamyl. In this study, a statistically significant and biologically relevant increase in saliva secretion was noted at the highest dose level of 0.15 mg/kg bw one hour following dose administration. In addition, statistically significant and biologically relevant decreases in plasma and RBC cholinesterase activities were observed at 0.15 mg/kg bw with the period of maximum depression occurring at 45 and 60 minutes for plasma cholinesterase activity and from 30 to 60 minutes for RBC cholinesterase activity. Plasma and RBC cholinesterase activities returned to baseline values within 4 and 3 hours, respectively, following administration of oxamyl. No adverse treatment-related effects were noted on ECG, vital signs, haematology and clinical chemistry parameters (including plasma and RBC cholinesterase), urinalysis, or clinical signs at dose levels of 0.09 mg/kg bw and lower. Acute and subchronic neurotoxicity studies in rats were conducted with oxamyl. In the acute neurotoxicity study, treatment-related clinical signs related to cholinesterase inhibition were noted in male and females at the mid- and high-dose levels (1 and 2 mg/kg bw for males and 0.75 and 1.5 mg/kg bw for females, respectively). Decreased body weight gain was noted in males at the mid- and high-dose and in females at the high dose. Plasma, RBC, and brain cholinesterase inhibition was noted in males and females at the mid- and high-dose levels on Day 1. No treatment-related neuropathological findings were observed. In the subchronic neurotoxicity rat study, treatment-related clinical signs of toxicity related to cholinesterase inhibition were noted in males and females at ≥100 ppm. Decreased body weight, body weight gain, food consumption, and food efficiency were also noted at doses ≥100 ppm. Plasma, RBC, and brain cholinesterase inhibition was noted in males and females at 250 ppm. No treatment-related neuropathological findings were noted.

A reversibility study was conducted with oxamyl. The objective of this study was to determine the length of time needed for recovery from inhibition of cholinesterase activity following an acute oral exposure to oxamyl at a concentration of 1.0 mg/kg bw. Clinical signs (predominantly tremors) were noted, and plasma, RBC, and brain cholinesterase activities were decreased within 30 minutes of dosing with recovery occurring within 2 hours post dosing. In a subacute study in which rats were administered oxamyl at a concentration of 2.4 mg/kg bw/day five times per week for two weeks, mild fasciculations, slight pallor, salivation, and body weight loss were noted. A 4-hour inhalation study was conducted in which marginal effects on RBC and brain cholinesterase activities were induced at 0.0049 mg/L, the lowest concentration evaluated.

Table 10 Summary of neurotoxicity studies for oxamyl

Type of study	Dose range tested	NOAEL		LOAEL		Target organ(s) and effects	Reference[a]
		ppm	mg/kg/d	ppm	mg/kg/d		
Oral, acute Human	0, 0.005, 0.015, 0.03, 0.06, 0.09, 0.15 mg/kg bw (males)	—	0.09	—	0.15	Acetylcholinesterase inhibition and increased saliva	HLO-1998-01505
Acute neurotoxicity (gavage) Rat	0, 0.1, 1.0, 2.0 mg/kg bw (males) 0, 0.1, 0.75, 1.5 mg/kg bw (females)	—	m: 0.1 f: 0.1	—	m: 1.0 f: 0.75	Acetylcholinesterase inhibition, decreased body weight and food consumption	HLR 1118-96
Subchronic neurotoxicity (Feeding), 90-d Rat	0, 10, 100/30, 300/250 ppm (equivalent to 0, 0.55, 1.69, 15.3 mg/kg bw/day for males and 0, 0.67, 2.03, 20.3 mg/kg bw/day for females)	30	m: 1.69 f: 2.03	100	m: 1.69 f: 2.03	Acetylcholinesterase inhibition and clinical signs	HL-1998-00708
Oral, reversibility study (gavage) Rat	0 and 1 mg/kg bw	Not applicable				Acetylcholinesterase inhibition and tremors, recovery complete within 2 hrs post-dosing	HL-1997-00641
Acute inhalation neurotoxicity Rat	0, 0.0049, and 0.024 mg/L	<0.0049 mg/L		0.0049 mg/L		Acetylcholinesterase inhibition	DuPont-4383, Revision No. 1

[a]Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU

2.5.8 Summary of further toxicological studies on the active substance

No additional studies were required or submitted.

2.5.9 Summary of toxicological data on impurities and metabolites

The principal metabolites of oxamyl found in plants, soil, water, and/or sediment are INA2213, IN-N0079, IN-D2708, IN-T2921, and IN-L2953. These metabolites, with the exception of IN-T2921, have been observed in their free or conjugated forms in metabolism studies performed in rats and mice. IN-T2921 was not detected in either the rat or the mouse; however, this metabolite is a proposed intermediate in the formation of IN-D2708 from IN-N0079 and was identified in goat rumen fluid.

IN-A2213 was investigated in an acute oral study in which the approximate lethal dose (acute) was the maximum dose tested, 11000 mg/kg bw. Mortality was also recorded at 2200 mg/kg bw/day in a subacute study as well as histopathological changes. These were reversed at the lower dose of 1000 mg/kg bw/day. Clinical signs of toxicity and body weight loss were recorded at both doses levels. The acute oral LD_{50} for IN-L2953 was 6675 mg/kg bw with clinical signs of toxicity including tremors and body weight loss recorded at lower doses. The toxicity of IN-N0079 was investigated in acute, 10-dose, and 90-day oral studies. The approximate lethal dose (acute) was 450 mg/kg bw and was associated with clinical signs of toxicity such as abnormal posture, salivation, hyper-responsiveness to noise, and body weight loss. The latter finding was also recorded in the subacute and subchronic studies. Other findings in these studies include organ weight perturbations, reversible spleen, thymus and bone marrow atrophy, and cytoplasmic de-vacuolation of centrilobular hepatocytes (subacute) and clinical

signs of toxicity, decreased body weight gain, haematology, clinical chemistry and urinalysis effects, and decreased F1 pup body weight (subchronic). IN-N0079 was not mutagenic when investigated using the Ames test with and without metabolic activation. The acute oral LD_{50} for IN-D2708 was 3540 mg/kg bw with clinical signs of toxicity including irregular respiration, abnormal posture and weakness, and body weight loss recorded at lower doses.

Table 11 Summary of studies conducted with oxamyl metabolites

Type of study	Test substance	Test system	Concentration/Dose range tested	Result	Reference[a]
Acute oral (ALD)	IN-A2213	Male rats	90–11000 mg/kg bw	ALD = 11000 mg/kg bw	HLR 300-68
10-dose subacute oral	IN-A2213	Male rats	1100 and 2200 mg/kg bw/day	Mortality, histopathological changes at 2200 mg/kg bw/day; histopathological changes at 1000 mg/kg bw/day; clinical signs and body weight loss	HLR 228-71
Oral LD_{50} study	IN-L2953	Male rats	4000–7000 mg/kg bw	LD_{50} = 6675 mg/kg bw (6370–6990 mg/kg bw); clinical signs at all doses; tremors at 6000 mg/kg bw; ↓bw	HLR 126-73
Acute oral study (ALD)	IN-N0079	Male rats	90–1000 mg/kg bw	ALD = 450 mg/kg bw; abnormal posture, salivation, hyper-responsiveness to noise, weight loss at lethal doses.	HLR 585-74
10-dose subacute oral study	IN-N0079	Male rats	90 mg/kg bw/day	↓ bw/bw gain; ↓abs. liver and kidney wt., ↓ rel. spleen and thymus wt., ↑ rel. testes wt.; reversed spleen, thymus and bone marrow atrophy; partially reversed cytoplasmic de-vacuolation of centrilobular hepatocytes	HLR 390-76
90-day oral study	IN-N0079	Rat	0, 4.0, 11.4, 34.3 mg/kg bw/day ♂; 0, 4.2, 12.6, 35.7 mg/kg bw/day ♀	Clinical signs; ↓ bw gain; haematology, clinical chemistry and urinalysis effects; ↓ bw F1 pups	HLR 630-76
Ames study	IN-N0079	(*S.typhimurium*)	250–10,000 µg/plate ±S9	No increase in revertants	HLR 284-78
Oral LD_{50} study	IN-D2708	Male rats	2500 and 5000 mg/kg bw	LD_{50} = 3540 mg/kg bw; Clinical signs including irregular respiration, abnormal posture and weakness; ↓ bw	HLR 399-72

[a]Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU

Summary of endocrine disrupting properties

The potential of oxamyl to induce adverse effects on components of the endocrine system has been assessed in short-term and long-term feeding studies, in a multi-generation reproduction study, and in developmental toxicity studies in rats and rabbits. In these studies, there was no evidence to suggest that oxamyl directly interferes with the function of the oestrogen, androgen, or thyroid pathways. No effects on fertility, reproduction, development, sexual maturation, or reproductive organ toxicity were noted. There was no specific target organ toxicity indicative of interaction with the endocrine system. Further, a full battery of studies presented below designed to specifically address the effects of oxamyl on the endocrine system have been undertaken as part of the Test Order received by DuPont requiring testing of oxamyl in the Tier 1 U.S. EPA Endocrine Disruptor Screening Program (EDSP). The results of these studies are summarized below and confirm the absence of any interaction by oxamyl with the estrogen, androgen, or thyroid systems. Therefore, it can be concluded that oxamyl does exert effects on the endocrine system.

Table 12 Summary of endocrine studies with oxamyl

Type of study	Species	Concentration range tested	Result	Reference[a]
Intact male juvenile/ peripubertal male rat	juvenile/ peripubertal male Crl:CD(SD) rats	0.25 and 0.5 mg/kg/day	Negative	DuPont-33933
Intact female juvenile/ peripubertal male rat	juvenile/ peripubertal female Crl:CD(SD) rats	0.25 and 0.5 mg/kg/day	Negative	DuPont-33934
Aromatase inhibition assay	human recombinant microsomes	1.0×10^{-10} M to 1.0×10^{-3} M	Negative	DuPont-32072
Estrogen receptor transcriptional assay	hERα-HeLa-9903 cell line	$1 \times 10^{-6.8}$ M to $1 \times 10^{-3.3}$ M	Negative	DuPont-32073, Revision No. 1
ER binding assay	estrogen receptors in rat uterine cytosol	1.0×10^{-10} to 1.0×10^{-3} M	Negative	DuPont-32074
Uterotrophic assay	ovariectomised adult Crl:CD(SD) rats	0, 0.1, 0.25, or 0.5 mg/kg/day	Negative	DuPont-32075
Hershberger assay	young adult castrated Crl:CD(SD) rats	0, 0.1, 0.25, or 0.5 mg/kg/day	Negative	DuPont-32076
Steroidogenesis assay	human cell line, H295R	100, 10, 1, 0.1, 0.01, 0.001, and 0.0001 μM	Negative	DuPont-32077
AR binding assay	rat prostate cytosol	1.0×10^{-10} to 1.0×10^{-3} M	Negative	DuPont-32153

[a]Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU

2.5.10 Summary of medical data and information

The manufacturing sites of oxamyl technical and the representative formulations are considered confidential information and are reported in Volume 4. During the past 14 years there have been no incidents or accidents involving oxamyl that have been reported at the formulations sites of the finished product.

The risk of inhaling oxamyl is very well managed and minimised by the wearing of protective respiratory equipment. To minimise dermal exposure, protective clothing, *e.g.*, Tyvek coverall and nitrile gloves are worn.

Fume hoods have been installed in the work areas where oxamyl-containing material is loaded for the manufacturing of Oxamyl 10GR, and local air monitoring, which is carried out on a routine basis, has shown that the AEL is not exceeded. The AEL at the facility is 0.5 mg/m^3 (8-hour time weighted average) and 1.0 mg/m^3

(15 minute time weighted average). To prevent exposure of plant personnel, periodic inspection of process equipment is routinely undertaken. Additional protective measures include air monitoring for dust and solvent at the workplaces with the highest potential for exposure.

As reported for the Oxamyl 10GR formulation, there are no records of accidents involving workers involved in the final packaging or handling of Oxamyl 10SL. As with Oxamyl 10GR, the appropriate personal protective equipment, including ventilation and local air monitoring procedures, are in place in work areas to prevent accidental exposure. Periodically and routinely, inspection of the process equipment is conducted.

At both manufacturing locations, there were established procedures to ensure that in the event of an accidental exposure to oxamyl, appropriate medical treatment would be given and the accident recorded.

The notifier reports that an accident occurred recently (November 2014) at the site where the synthesis of oxamyl is made involving a fatal exposure of some workers to a raw material used for the synthesis of carbamates. This incident is not linked directly to exposure of finished product, and investigation is ongoing to correct the mechanical and procedural problems that resulted in the incident.

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

The EU Commission has established the ADI, AOEL, and ARfD for oxamyl at 0.001 mg/kg bw/day. This is based on an acute neurotoxicity study in the rat. The NOAEL of 0.1 mg/kg bw/day was used as the point of departure and an assessment factor of 100 (a 10 for interspecies differences and a 10 for intraspecies differences) was applied (EFSA, 2005).

The values set by the WHO for JMPR differ from those set by the EU since EU policy was to not accept data from studies in humans as the basis of setting health-based guidance values for plant protection products. However, there is new guidance that indicates human data should at least be considered in the development of assessment factors for the derivation of reference values (COMMISSION REGULATION [EU] No 283/2013).

Therefore, the results of the acute rat neurotoxicity study where treatment-related cholinesterase inhibition were noted in males and females at the mid- and high-dose levels (1 and 2 mg/kg bw for males and 0.75 and 1.5 mg/kg bw for females, respectively) and a NOAEL of 0.1 mg/kg bw/day was established represents the most sensitive effect in animals. For the EU, this represents the most conservative point of departure, since human data cannot be considered for direct use in the risk assessment. However, because the human data exist and due to the lower NOAEL that was established of 0.09 mg/kg bw, these data can be used to decrease the uncertainty in the risk assessment for extrapolation of rat to human.

Interspecies assessment factors help increase the confidence in safety assessment by providing a means to account for uncertainties. The most sensitive endpoint in all species is acute neurotoxicity observed due to inhibition of acetylcholinesterase. Therefore, an assessment factor of 10x is sufficient for this risk assessment due to the fact that human data exist and corroborate the most sensitive endpoint in the rat.

Endpoint Basis: Rat acute neurotox 0.1 mg/kg bw (current)

Inter/intra species assessment factor 10x

Proposed new ARfD/ADI/AOEL = 0.01 mg/kg bw

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

Please refer to Section 2.5.11 above.

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

Please refer to Section 2.5.11 above.

2.5.14 Summary of product exposure and risk assessment

Operator exposure

Operator exposure was evaluated according to German model and UK POEM model for the representative uses proposed.

Oxamyl 10GR:

In lieu of an appropriate model for estimating potential exposure during application of granular formulations into or onto the soil, an operator exposure study was provided. Inhalation and dermal exposure to oxamyl was determined during loading and during in row application of Oxamyl 10GR at a rate of 1 kg a.s./ha while planting potatoes. The study results represent operators wearing long pants and long sleeve shirt and protective gloves for handling the product. Based on observation of the workers, the highest potential for inhalation exposure to oxamyl was during the task of loading. The highest actual exposure was to the hands during application, which, based on observations made during the conduct of the study, likely occurred during adjusting of equipment and/or activities related to planting the crop. The highest individual operator exposure was 0.143 mg/person/day by the dermal route and 0.0132 mg/person/day by the inhalation route.

For the purposes of assessing risk to operators, a systemic AOEL of 0.01 mg/kg bw/day was established for oxamyl based on the NOAEL of 0.1 mg/kg bw where cholinesterase inhibition and decreased body weight were observed at doses >0.1 mg/kg bw from a rat acute neurotoxicity study. A 10-fold safety factor is proposed based on the observations from human studies that indicate the human LOAEL for cholinesterase inhibition is 0.15 mg/kg bw. A dermal penetration factor of 0.04% was established for the granule formulation based on the result of a *in vitro* study results. 100% absorption of potentially inhaled active substance was assumed.

Worst case exposure from the exposure study:

([0.143 mg/person/day × 0.0004] + 0.0132 mg/person/day)/60 kg/person = 0.00022 mg/kg/day, or 2.2% of the systemic AOEL.

Worst case estimate based on proposed critical GAP of 5.5 kg a.s./ha is estimated by extrapolating the study results:

5.5 × 2.2% of AOEL = 12% of AOEL

This is a reasonable extrapolation, since it is based on a product-specific study. In addition, the vast majority of the systemic dose resulted from inhalation exposure, and it is generally accepted that more exposure would be anticipated form opening and transferring the contents of more product containers.

Exposure to Oxamyl 10GR during loading and application does not involve a significant risk to the health of operators, assuming the use of proper work clothing (long pants and long sleeve shirt) and the use of protective gloves when handling the product or contacting contaminated surfaces.

Oxamyl 10SL:

A systemic AOEL of 0.01 mg/kg bw/day was established for oxamyl based on the NOAEL of 0.1 mg/kg bw where cholinesterase inhibition and decreased body weight were observed at doses >0.1 mg/kg bw from a rat acute neurotoxicity study with a 10-fold safety factor proposed based on the observations from human studies that indicate the human LOAEL for cholinesterase inhibition is 0.15 mg/kg b.w. A dermal penetration factor of 0.2% was established for the Oxamyl 10SL formulation based on the result of an *in vivo* dermal absorption study with a correction based on *in vitro* results. For the liquid formulation (Oxamyl 10SL) the dermal absorption is 0.2%, based on *in vivo* rat study (systemic absorption up to 66 h post exposure *ca*. 0.6%) and *in vitro* human/rat study (penetration rate *ca.* 1:3). A default assumption of 100% retention and absorption of inhaled product was

used to model exposure by inhalation. Exposure estimates were calculated using the maximum use rate. The estimates of total oxamyl exposure (expressed as the systemically absorbed dose) predicted by the German model and UK model were calculated as a proportion of the proposed systemic AOEL and are summarised in the table below.

Operator exposure as a proportion of the AOEL–no protective clothing or equipment used

Exposure to Oxamyl 10SL during loading, and application does not involve a significant risk to the health of operators according to both the German model and UK POEM, assuming personal protective equipment is not used.

Operator exposure as a proportion of the AOEL – no protective clothing or equipment used – assuming dermal absorption of 0.8%

Application method	Operator total systemic exposure (mg/kg bw/day)		% of AOEL	
	German model	UK model	German model	UK model
Drip irrigation - solarization	0.0016	0.0015	16	15

The calculations show that the estimated exposure is less than the AOEL using both the German model and the UK POEM.

Oxamyl 10SL is a soluble liquid concentrate containing a nominal concentration of 100 g oxamyl a.s./L which is packaged in five-litre containers. For the current use this product is applied *via* a drip irrigation system. Since this application method does not generate a spray, typical applicator exposure *via* airborne droplets is not a source of exposure.

Once the concentrated product is loaded it is introduced directly to the soil by drip irrigation. Therefore, contaminated plant surfaces are also not of concern as an exposure source. Adequate PPE must be used to prevent exposure during adjustments for repairs to equipment.

The margins of safety for operators to Oxamyl 10SL exposures were determined with the UK and German models. Calculations of operator exposure were based on the assumption that operators wore no personal protective clothing or equipment.

Additional assumptions/data utilised in the models are as follows:

Area treated in one day:	1 ha
Application rate (maximum):	5.5 kg a.s./ha
Packaging:	5 L container
Application volume:	Drip irrigation – applied with irrigation water

Exposure to Oxamyl 10SL during loading, and application does not involve a significant risk to the health of operators according to both the German model and UK POEM, assuming personal protective equipment is not used.

B..1.1 6.5.2 Bystander and resident exposure

The very low vapour pressure and high water solubility of oxamyl preclude significant vapour concentration, and its nature of application technique will result in no generation of spray droplets; therefore, no inhalation or dermal exposure to bystanders and residents is anticipated.

B..1.2 6.5.3 Workers

Since Oxamyl 10GR and Oxamyl 10SL are applied directly to soil at planting time, and there is negligible likelihood of worker exposure by contact with crop foliage, estimating exposure based on soil residue rather than foliar residue is presented here.

Oxamyl 10GR:

In line with the approach in the EUROPOEM II report, the concentration of active substance in soil (0.0055 mg/cm³) is based on the maximum broadcast application rate of 5500 g of oxamyl/ha (55 kg of 100 g a.s./kg formulated product) and assuming it is uniformly distributed in the soil to a depth of 10 cm. This is the worst-case soil concentration; equivalent to 5.5 g a.s./m³ or 0.0055 mg a.s./cm³. Adherence of soil to skin (0.00029 cm³/cm²) is based on the EUROPOEM cited value of 0.44 mg soil/cm² of skin surface area and assumed soil bulk density of 1.5 g/cm³. Exposed skin surface area (820 cm²) is based on the surface area of the hands assumed to be 820 cm². Percent of soil residue transferred to skin (100%) is assumed to be 100% as a conservative figure.

PDE = 0.0055 mg/cm³ × 0.00029 cm³/cm²/day × 820 cm² × 1 = 0.0013 mg a.s./day

Assuming 60 kg body weight and 0.04% dermal absorption gives a systemic dose equivalent to <1% of the AOEL of 0.01 mg/kg/day.

This is a conservative assessment, since residue transfer to skin is assumed to be 100%. In addition, oxamyl degrades in soil, and the application is made at planting time when no re-entry work is likely to occur for some time.

Oxamyl 10SL:

The concentration of active substance in soil (0.0055 mg/cm³) is based on the maximum drip irrigation application rate of 5500 g of oxamyl/ha (55 L of 100 g a.s./L formulated product) and assuming it is uniformly distributed in the soil to a depth of 10 cm. This is the worst-case soil concentration; equivalent to 5.5 g a.s./m^3 or 0.0055 mg a.s./cm^3. Adherence of soil to skin (0.00029 cm³/cm²) is based on the EUROPOEM cited value of 0.44 mg soil/cm² of skin surface area and assumed soil bulk density of 1.5 g/cm^3. SA is based on the surface area of the hands assumed to be 820 cm^2. Exposed skin surface area (820 cm²) is assumed to be 100% as a conservative figure.

PDE = 0.0055 mg/cm^3 × 0.00029 cm^3/cm²/day × 820 cm^2 × 1 = 0.0013 mg a.s./day

Assuming 60 kg body weight and 0.2% dermal absorption gives a systemic dose equivalent to <1% of the AOEL of 0.01 mg/kg/day.

This is a conservative assessment since residue transfer to skin is assumed to be 100%. In addition, oxamyl degrades in soil, and the application is made at pre planting time and with soil covered by a uniform transparent plastic film when no re-entry work is likely to occur for some time in order to reach the efficacy of the solarisation practice.

2.6 Residues

2.6.1 Summary of storage stability of residues

Oxamyl residues in representative watery, acidic, sugary, starchy, and oily fruit and vegetable matrices (potato tuber, sugar beet root, leaf lettuce, tomato, and orange peel) are stable when stored frozen at -18 ± 5°C for at least 24 months, a period which exceeds the longest time period for which samples were stored in the course of the residue trial studies. This supports residue data generated in crop matrices during the magnitude and decline of residue studies, processing studies, and field crop rotation studies. Crop samples from the storage stability study and the field studies were stored under similar conditions, extracted, and analysed following the procedures described in the analytical method reports DuPont-3702, DuPont-4722, and DuPont-11125,

analytical methods for the quantitation of oxamyl in various crop matrices and their processed fractions (summarised in the Oxamyl Volume 3 B5)

Oxamyl residues in dried tobacco leaves are stable for periods of storage at -20°C for at least 6 months, a period which exceeds the longest time period for which tobacco samples were stored in the course of the residue trial study. Likewise, oxamyl residues in whole oranges are stable for periods of storage at -20°C for at least 12 months.

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

The comparative metabolism of ^{14}C-oxamyl in plants was studied in diverse crops *via* direct foliage, fruit, or soil applications under laboratory and/or field settings. Metabolism of oxamyl in plants included hydrolysis of the methylcarbamoyl group to yield the non-insecticidal oxamyl oxime (IN-A2213). IN-A2213 was demethylated before or after glucose conjugation to give IN-L2953 and/or its glucose conjugate. Conjugation of the glucosides of IN-A2213 and IN-L2953 with additional sugar residues was also observed. IN-A2213 (or oxamyl) may also be metabolised to IN-N0079, which is metabolised to IN-D2708 and ultimately incorporated into plant natural products. (For details on the metabolite structures please refer to Appendix 1.

The major metabolic pathways in plants and animals were similar. Oxamyl was rapidly absorbed, extensively metabolised, and excreted in livestock. The major metabolites found in both lactating goats and laying hens were thiocyanate and radioactivity resulting from incorporation of the radioactivity into natural components (such as lactose). The metabolism of oxamyl proceeded rapidly in livestock animals with the formation of IN-A2213 by hydrolysis of the carbamate moiety. IN-A2213 (or oxamyl) was converted to IN-N0079, which was then degraded to cyanide. Cyanide was rapidly detoxified by the conversion to thiocyanate.

All metabolism studies were conducted using [1-^{14}C]oxamyl. The radiolabel in the 1-position is the most stable in the molecule and is appropriate for metabolism studies.

2.6.3 Definition of the residue

Proposed residue definition (crop)

Metabolism of [1-^{14}C]oxamyl was investigated in two GLP studies in potatoes and tomatoes following soil and/or foliar treatment regimes. These metabolism studies with representative root/tuber vegetables (potatoes) and fruit/fruiting vegetables (tomatoes) along with supplementary information from earlier studies in tobacco, peanuts, apples, and oranges demonstrate an overall consistent route of metabolism across all studied crops/crop groups regardless of the treatment regime.

Oxamyl was readily metabolised in plants *via* IN-A2213 and IN-N7009 to IN-D2708. IN-A2213 was conjugated with glucose to IN-QKT34 and demethylated to IN-L2953. IN-L2953 was further metabolised to IN-KP532. Oxamyl was ultimately incorporation into plant natural products (*e.g.*, glucose) and components characterized as highly polar likely resulting from more extensive metabolism of the 3 carbon (IN-KV998 and IN-KP532) or 4 carbon (IN-T2921 and IN-D2708) containing metabolites, and reincorporation of ^{14}C carbon dioxide into plant natural products.

It is generally recognised that carbamate insecticides lose their biological activity upon cleavage of the carbamate moiety. Oxamyl, like other methyl carbamate insecticides, inhibits acetylcholinesterase (AChE) in the nervous system. AChE hydrolyses oxamyl's carbamate ester resulting in carbamylation and inhibition of the AChE enzyme. Therefore, oxamyl metabolites in which the carbamate ester moiety has been either hydrolysed or metabolically degraded are not expected to be toxicologically active by this mechanism. According to metabolism studies conducted with [1-^{14}C]oxamyl in plants and toxicology studies on oxamyl and five principal metabolites (IN-A2213, IN-N0079, IN-D2708, IN-T2921, and IN-L2953; none containing the carbamate moiety) and as stated in the Reasoned Opinion from EFSA following the Article 12 Review, the parent oxamyl is the only relevant substance included in the definition of the residue for enforcement and risk assessment in commodities of plant origin. This definition was pending one additional metabolism study investigating the nature of residues in fruits and fruiting vegetables following drip irrigation.

Parent oxamyl is deemed to be the only residue for enforcement and risk assessment in commodities of plant origin.

Proposed residue definition (food of animal origin)

There are no significant terminal residues in milk, eggs, or meat anticipated; therefore, no residue definition is required. For purposes of monitoring and risk assessment, the EU residue definition in plant and livestock (food) matrices is defined as oxamyl.

2.6.4 Summary of residue trials in plants and identification of critical GAP

The renewal representative use for potatoes is in the CEU Regulatory zone. Oxamyl 10GR is applied in furrow, at the rate of 1.0 kg a.s./ha, at planting (BBCH 00) with an 90-d (12-week) PHI specified.

In total, sixteen residue trials (8 NEU; 8 SEU) were conducted.

With Oxamyl 10GR, ten magnitude of residue trials were conducted. Oxamyl 10GR was applied once *via* granular soil application at planting to main variety potatoes at a target application rate of 55.0 kg formulated product (fp)/ha (5.5 kg a.s./ha), trial no. 1, 3-8, and 10. Oxamyl 10GR was applied to early variety potatoes at a target application rate of 40.0 kg formulated product (fp)/ha (4.0 kg a.s./ha), trial no. 2 and 9.

With Oxamyl 5GR (a comparable formulation of Oxamyl 10GR), magnitudes of residue trials in southern Europe were conducted. Oxamyl 5GR was applied by in-furrow application with incorporation into the soil before planting at the rate of 3 kg a.s./ha.

With Oxamyl 10SL, two magnitude of residue trials and two normal decline trials were conducted. Oxamyl 10SL was applied by drip irrigation to potatoes six times at the rate of 0.7 kg a.s./ha/application for a seasonal application rate of 4.2 kg a.s./ha. The first application occurred on the day of planting. A 14-day spray interval was used between applications, with the last application occurring approximately 70 days after planting, when the crop was at growth stage BBCH 59–69.

In all trials, the residues were <0.01 mg/kg. With the lower application rate of 1.0 kg a.s./ha, residues will remain <0.01 mg/kg.

The residue studies presented were carried out in seven EU countries, Italy, Spain, France, Poland, the United Kingdom, Germany, and Greece, and provide data relevant to conditions in the northern and southern European regions.

All residue studies supportive of the renewal representative use in potatoes (are summarized in the following tables.

Table 13 Residues of oxamyl in potato tubers from supervised trials performed with Oxamyl 10GR

Oxamyl 10GR, 5.0 kg a.s./ha in broadcast; application at planting (BBCH 00); 90-d PHI Renewal representative GAP: CEU Regulatory zone; Oxamyl 10GR, 1.0 kg a.s./ha in furrow; application at planting (BBCH 00); 90-d PHI								
GLP and trial details	**Crop/ Variety**	**Country**	**Application rate (kg a.s./ha)**	**Crop growth stage at last application and at final sampling**	**Spray concentration (kg a.s./hL)**	**DALA[a] (days)**	**Residues found (mg/kg)[b]**	**Recovery data**
DuPont-19526 Trial No. 1 GLP 2006	Potato/ Maris Piper	England, St. Osyth	5.2	BBCH 00, 49	NA	148	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification
DuPont-19526 Trial No. 2 GLP 2006	Potato/ Carlita (early variety)	Spain, Olivares	4.08	BBCH 00, 49	NA	97	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification
DuPont-19526 Trial No. 3 GLP 2006	Potato/ Amila	N. France, Allouagne	5.61	BBCH 00, 49	NA	153	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification
DuPont-19526 Trial No. 4 GLP 2006	Potato/ Annabella	Italy, Corona	5.61	BBCH 00, 49	NA	102	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification

[a] DALA = Days after last application

[b] nd = analyte peak not detected or peak <LOD (<0.0033 mg/kg)

Table 14 Oxamyl 10GR, 5.0 kg a.s./ha in broadcast; application at planting (BBCH 00); 90-d PHI
Renewal representative GAP: CEU Regulatory zone; Oxamyl 10SL, 1.0 kg a.s./ha applied by drip irrigation; application at planting (BBCH 00); 90-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at last application and at final sampling	Spray concentration (kg a.s./hL)	DALA[a] (days)	Residues found (mg/kg)[b]	Recovery data
DuPont-19526 Trial No. 5 GLP 2006	Potato/ Europa	S. France, La Chapelle Villars	5.61	BBCH 00, 49	NA	120	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification
DuPont-19526 Trial No. 6 GLP 2006	Potato/ Mona Lisa	S. France, La Mas Rillier	5.61	BBCH 00, 49	NA	132	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification
DuPont-19526 Trial No.7 GLP 2006	Potato/ Irga	Poland, Rozbity Kamien	5.61	BBCH 00-03, 49	NA	135	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification
DuPont-19526 Trial No. 8 GLP 2006	Potato/ Kenebec	Spain, Lleida	5.61	BBCH 00, 48	NA	92	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification

[a] DALA = Days after last application
[b] nd = analyte peak not detected or peak <LOD (<0.0033 mg/kg)

Table 15 Oxamyl 10GR, 5.0 kg a.s./ha in broadcast; application at planting (BBCH 00); 90-d PHI
Renewal representative GAP: CEU Regulatory zone; Oxamyl 10SL, 1.0 kg a.s./ha applied by drip irrigation; application at planting (BBCH 00); 90-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at last application and at final sampling	Spray concentration (kg a.s./hL)	DALA[a] (days)	Residues found (mg/kg)[b]	Recovery data
DuPont-19526 Trial No. 9 GLP 2006	Potato/ Agria (early variety)	Greece, Nea Magnesia	4.00	BBCH 00, 49	NA	100	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification
DuPont-19526 Trial No. 10 GLP 2006	Potato/ Prinzess	Germany, Motterwitz	5.61	BBCH 01, 49	NA	124	nd	Mean recovery =87% ± 4%, RSD = 5 (n = 4) at 0.005 mg/kg fortification Mean recovery = 92% ± 8%, RSD = 9 (n = 4) at 0.10 mg/kg fortification

[a] DALA = Days after last application
[b] nd = analyte peak not detected or peak <LOD (<0.0033 mg/kg)

Table 16 Residues of oxamyl in potato tubers from supervised trials performed with Oxamyl 5GR
Oxamyl 5GR applied by in-furrow application with incorporation into the soil before planting at the rate of 3 kg a.s./ha.
Renewal representative GAP: CEU Regulatory zone; Oxamyl 10GR, 1.0 kg a.s./ha in furrow; application at planting (BBCH 00); 90-d PHI

GLP and trial details	Crop	Country	Application rate (kg a.s./ha) Application method	Crop growth stage at application and at Sampling	Spray concentration (kg a.s./hL)	DALA[a]	Residues found (mg/kg)[b]	Recovery data
DuPont-5989 Trial No.1 GLP 2001	Potato/ Spunta	Greece, Polimilos, GR-50100, Kozani	3.0 In-furrow	BBCH 00, 49	not relevant for this test	112	ND	Tubers: mean recovery = 75%, RSD = 2 (n = 2) in 0.010 mg/kg fortifications; mean recovery = 81%, RSD = 2 (n = 2) in 0.10 mg/kg fortifications
DuPont-5989 Trial No.2 GLP 2001	Potato/ Primura	Italy, Bagnarola di Budrio, 40050, Bologna	3.19 In-furrow	BBCH 00, 49	not relevant for this test	117	ND	Tubers: mean recovery = 75%, RSD = 2 (n = 2) in 0.010 mg/kg fortifications; mean recovery = 81%, RSD = 2 (n = 2) in 0.10 mg/kg fortifications

[a] DALA = Days after last application
[b] The designation "ND" is used for treated samples for which no oxamyl residue could be detected (below the limit of detection, <0.005 mg/kg).

Table 17 Residues of oxamyl in potato tubers from supervised trials performed with Oxamyl 10SL (applied by drip irrigation)
Renewal representative GAP: CEU Regulatory zone; Oxamyl 10GR, 1.0 kg a.s./ha in furrow; application at planting (BBCH 00); 90-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at last application and at sampling	Spray concentration (kg a.s./hL)	DALA[a] (days)	Residues found (mg/kg)[b]	Recovery data
DuPont-10297, Revision No. 1 Trial No. 1 GLP 2002	Potato/ Estima	United Kingdom, Newport, Shropshire	6 applications at 0.702	1) BBCH 59 2) BBCH 99	0.15- 0.19	73	nd	Tuber: mean recovery = 70.4%, RSD = 2.4 (n = 4 in 0.010–0.10 mg/kg fortification range)
DuPont-10297, Revision No. 1 Trial No. 2 GLP 2002	Potato/ Maris Piper	United Kingdom, Ely, Cambridgeshire	6 applications at 0.702	1) BBCH 65 2) BBCH 97	0.15- 0.18	82	nd	Tuber: mean recovery = 70.4%, RSD = 2.4 (n = 4 in 0.010–0.10 mg/kg fortification range)
DuPont-10297, Revision No. 1 Trial No. 3 GLP 2002	Potato/ Russet Burbank	United Kingdom, Barrow-on-Trent, Derbyshire	6 applications at 0.702	1) BBCH 59 2) BBCH 59, 69, 69, 81, 99	0.15- 0.21	0 14 28 49 83	0.018 0.013 nd nd nd	Tuber: mean recovery = 70.4%, RSD = 2.4 (n = 4 in 0.010–0.10 mg/kg fortification range)
DuPont-10297, Revision No. 1 Trial No. 4 GLP 2002	Potato/ Wilja	United Kingdom, Melbourne, Derbyshire	6 applications at 0.702	1) BBCH 69 2) BBCH 69, 69, 70, 81, 99	0.17- 0.19	0 14 28 49 78	0.060 0.037 0.011 0.008 nd	Tuber: mean recovery = 70.4%, RSD = 2.4 (n = 4 in 0.010–0.10 mg/kg fortification range)

[a] DALA = Days after last application
[b] nd = analyte peak not detected (<0.007 mg/kg)

For the representative us in tomatoes of under protection (green houses), a total of 22 residue trials were conducted on protected tomatoes, including cherry tomatoes, according to the in-season use pattern (the trials are divided in different plots where the different plots received an application of 2.0 kg a.s./ha followed by 1 to 3 applications with a rate of 1 kg a.s./ha).

Oxamyl 10SL may also be applied at 5.5 kg a.s. 30 days before transplant (preplant solarisation), then at transplanting (2.0 kg a.s./ha) followed by three applications at 1.0 kg a.s./ha/application with a 10-day retreatment interval and a 28-day PHI.

In all trials, the residues were <0.01 mg/kg and are comparable to those including the addition of the pre-planting solarisation application according to the renewal representative use for tomatoes under protection.

The residue studies presented were carried out in three EU countries, Italy, Spain, and Greece, and provide data relevant to conditions in the southern European region for protected tomatoes.

Residue studies supportive of the renewal representative use in protected tomatoes are summarized in the table below.

Table 18 Residues of oxamyl in protected tomatoes, including cherry tomatoes, from supervised trials. Renewal representative GAP: Oxamyl 10SL, 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications via drip irrigation

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at last application and at final sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-19519, Revision No. 1 Trial No. 1 GLP 2006	Protected Tomato/ Eldiez	Spain, Los Palacios	2.07 + 1.04 + 1.04	BBCH 12 + 64 + 72, 81	NA	-0 (A3-1h) 21	nd[b] nd	Mean recovery = 76% ± 11%, RSD = 14 (n = 7) at 0.010 mg/kg fortification Mean recovery = 77% ± 10%, RSD = 13 (n = 8) at 0.10 mg/kg fortification
			2.07 + 1.04 + 1.04	BBCH 12 + 62 + 65, 81	NA	28	nd	
			2.07 + 1.04 + 1.04	BBCH 12 + 61 + 65, 81	NA	35 42 49	nd nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 12 + 61 + 64 + 72, 81	NA	-0 (A4-1h) 21	nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 12 + 61 + 62 + 65, 81	NA	28 35 42 49	nd nd nd nd	
DuPont-19519, Revision No. 1 Trial No. 2 GLP 2006	Protected Tomato/ Oskar	Italy, Triginto di Mediglia	2.07 + 1.04 + 1.04	BBCH 14 + 64 + 72, 83/87-89	NA	-0 (A3-1h)	0.008	Mean recovery = 76% ± 11%, RSD = 14 (n = 7) at 0.010 mg/kg fortification Mean recovery = 77% ± 10%, RSD = 13 (n = 8) at 0.10 mg/kg fortification
			2.07 + 1.04 + 1.04	BBCH 14 + 63 + 64, 83/87-89	NA	21 28	nd nd	
			2.07 + 1.04 + 1.04	BBCH 14 + 19-51 + 63-64, 87-89	NA	35 42 49	nd nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 14 + 62 + 64 + 72, 83/87-89	NA	-0 (A4-1h) 21	0.031 nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 14 + 19 + 63 + 64, 89	NA	28 35 42 49	nd nd nd nd	

[a] NA = not applicable
[b] DALA = Days after last application
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 18 Residues of oxamyl in protected tomatoes, including cherry tomatoes, from supervised trials. Renewal representative GAP: Oxamyl 10SL, 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications via drip irrigation

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at last application and at final sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-19519, Revision No. 1 Trial No. 3 GLP 2006	Protected Tomato/ Carso	Italy, Ronco-ferraro	2.07 + 1.04 + 1.04	BBCH 14 + 61 + 63-71, 83	NA	-0 (A3-1h) 21	nd nd	Mean recovery = 76% ± 11%, RSD = 14 (n = 7) at 0.010 mg/kg fortification Mean recovery = 77% ± 10%, RSD = 13 (n = 8) at 0.10 mg/kg fortification
			2.07 + 1.04 + 1.04	BBCH 14 + 52 + 62, 83	NA	28	nd	
			2.07 + 1.04 + 1.04	BBCH 14 + 52 + 61, 86	NA	35 42 49	nd nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 14 + 52 + 61 + 63-71, 83	NA	-0 (A4-1h) 21	nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 14 + 21 + 52 + 62, 87-89	NA	28 35 42 49	nd nd nd nd	
DuPont-19519, Revision No. 1 Trial No. 4 GLP 2006	Protected Tomato/ Caramba	Spain, Lleida	2.07 + 1.04 + 1.04	BBCH 13-14 + 72 + 73, 78-82	NA	-0 (A3-1h) 21	nd nd	Mean recovery = 76% ± 11%, RSD = 14 (n = 7) at 0.010 mg/kg fortification Mean recovery = 77% ± 10%, RSD = 13 (n = 8) at 0.10 mg/kg fortification
			2.07 + 1.04 + 1.04	BBCH 13-14 + 51 + 72-73, 78-82	NA	28	nd	
			2.07 + 1.04 + 1.04	BBCH 13-14 + 26-27 + 22, 82-85	NA	35 42 49	nd nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 13-14 + 29-51 + 72 + 73, 78-82	NA	-0 (A4-1h) 21	nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 13-14 + 19 + 51 + 72-73, 83-85	NA	28 35 42 49	nd nd nd nd	

[a] NA = not applicable
[b] DALA = Days after last application
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 18 Residues of oxamyl in protected tomatoes, including cherry tomatoes, from supervised trials. Renewal representative GAP: Oxamyl 10SL, 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications via drip irrigation

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at last application and at final sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-19519, Revision No. 1 Trial No. 5 GLP 2006	Protected Tomato/ Caramba	Spain, Lleida	2.07 + 1.04 + 1.04	BBCH 13-14 + 71-72 + 75, 83	NA	-0 (A3-1h) 21	nd nd	Mean recovery = 76% ± 11%, RSD = 14 (n = 7) at 0.010 mg/kg fortification Mean recovery = 77% ± 10%, RSD = 13 (n = 8) at 0.10 mg/kg fortification
			2.07 + 1.04 + 1.04	BBCH 13-14 + 61 + 72, 78-83	NA	28	nd	
			2.07 + 1.04 + 1.04	BBCH 13-14 + 51 + 63-64, 78-85	NA	35 42 49	nd nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 13-14 + 29-51 + 72 + 73, 83	NA	-0 (A4-1h) 21 28	nd nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 13-14 + 19 + 51 + 72-73, 78-86	NA	35 42 49	nd nd nd	
DuPont-19519, Revision No. 1 Trial No. 6 GLP 2006	Protected Tomato/ Belladonna	Greece, Profitis	2.00 + 1.00 + 1.00	BBCH 12-13 + 53-61 + 66-72, 89	NA	-0 (A3-1h) 21	nd nd	Mean recovery = 76% ± 11%, RSD = 14 (n = 7) at 0.010 mg/kg fortification Mean recovery = 77% ± 10%, RSD = 13 (n = 8) at 0.10 mg/kg fortification
			2.00 + 1.00 + 1.00	BBCH 12-13 + 51-52+64-71, 89	NA	28	nd	
			2.00 + 1.00 + 1.00	BBCH 12-13 + 16 + 53, 89	NA	35 42 49	nd nd nd	
			2.00 + 1.00 + 1.00 + 1.00	BBCH 12-13 + 51 + 53-61 + 66-72, 89	NA	-0 (A4-1h) 21 28	nd nd nd	
			2.00 + 1.00 + 1.00 + 1.00	BBCH 12-13 + 16 + 51-52 + 64-71, 89	NA	35 42 49	nd nd nd	

[a] NA = not applicable
[b] DALA = Days after last application
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 18Residues of oxamyl in protected tomatoes, including cherry tomatoes, from supervised trials (continued). Renewal representative GAP: Oxamyl 10SL, 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications *via* drip irrigation

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at last application and at final sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-19519, Revision No. 1 Trial No. 7 GLP 2006	Protected Tomato/ Alma	Greece, Nea Magnesia	2.00 + 1.00 + 1.00	BBCH 12-13 + 62-63 + 66-72, 89	NA	-0 (A3-1h) 21	nd nd	Mean recovery = 76% ± 11%, RSD = 14 (n = 7) at 0.010 mg/kg fortification Mean recovery = 77% ± 10%, RSD = 13 (n = 8) at 0.10 mg/kg fortification
			2.00 + 1.00 + 1.00	BBCH 12-13 + 52 + 64-71, 89	NA	28	nd	
			2.00 + 1.00 + 1.00	BBCH 12-13 + 25-26 + 60-62, 89	NA	35 42 49	nd nd nd	
			2.00 + 1.00 + 1.00 + 1.00	BBCH 12-13 + 26-27 + 62-63 + 66-72, 89	NA	-0 (A4-1h) 21 28	nd nd nd	
			2.00 + 1.00 + 1.00 + 1.00	BBCH 12-13 + 25-26 + 52 + 64-71, 89	NA	35 42 49	nd nd nd	
DuPont-19519, Revision No. 1 Trial No. 8 GLP 2006	Protected Tomato/ Panarea	Italy, Vittoria	2.00 + 1.03 + 1.02	BBCH 102 + 64 + 67, 89	NA	-0 (A3-1h) 21	0.010 nd	Mean recovery = 76% ± 11%, RSD = 14 (n = 7) at 0.010 mg/kg fortification Mean recovery = 77% ± 10%, RSD = 13 (n = 8) at 0.10 mg/kg fortification
			2.02 + 1.02 + 1.02	BBCH 102 + 62 + 65, 89	NA	28	nd	
			2.04 + 1.02 + 1.02	BBCH 102 + 61 + 63, 89	NA	35 42 49	nd nd nd	
			2.04 + 1.02 + 1.02 + 1.02	BBCH 102 + 62 + 64 + 67, 89	NA	-0 (A4-1h) 21 28	0.012 nd nd	
			2.04 + 1.01 + 1.02 + 1.02	BBCH 102 + 61 + 62 + 65, 89	NA	35 42 49	nd nd nd	

[a] NA = not applicable
[b] DALA = Days after last application
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 18Residues of oxamyl in protected tomatoes, including cherry tomatoes, from supervised trials (continued). Renewal representative GAP: Oxamyl 10SL, 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications *via* drip irrigation

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-19521 Trial No. 1 GLP 2006	Protected cherry tomatoes/ Lupita	Spain, Los Palacios	2.07 + 1.04 + 1.04	BBCH 12 + 71 + 81, 81, 83	NA	-0 (A3-1h) 21	nd nd	Mean recovery = 76% ± 6%, RSD = 8 (n = 6) at 0.010 mg/kg fortification Mean recovery = 76% ± 6%, RSD = 8 (n = 6) at 0.10 mg/kg fortification
			2.07 + 1.04 + 1.04	BBCH 12 + 66 + 71, 83	NA	28	nd	
			2.07 + 1.04 + 1.04	BBCH 12 + 63 + 66, 83, 83, 83	NA	35 42 49	nd nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 12 + 65 + 71 + 81, 81, 83	NA	-0 (A4-1h) 21 28	0.019 nd nd	
			2.07 + 1.04 + 1.04 + 1.04	BBCH 12 + 63 + 66 + 71, 83,83, 83, 85	NA	35 42 49	nd nd nd	
DuPont-19521 Trial No. 2 GLP 2006	Protected cherry tomatoes/ Carminion de reuter	Italy, Ascoli Picelo	2.02 + 1.00 + 1.01	BBCH 18 + 64 + 81, 80-81 85	NA	-0 (A3-1h) 21	nd nd	Mean recovery = 76% ± 6%, RSD = 8 (n = 6) at 0.010 mg/kg fortification Mean recovery = 76% ± 6%, RSD = 8 (n = 6) at 0.10 mg/kg fortification
			2.00 + 1.00 + 1.01	BBCH 18 + 51 + 77, 85	NA	28	nd	
			2.03 + 1.01 + 1.00	BBCH 18 + 25 + 54, 85, 86-87, 87-88	NA	35 42 48	nd nd nd	
			2.01 + 1.01 + 1.01 + 1.00	BBCH 18 + 29 + 64 + 82, 80-81, 85	NA	-0 (A4-1h) 21 28	nd nd nd	
			2.01 + 1.02 + 1.01 + 1.01	BBCH 18 + 24 + 51 + 77, 85, 86-87, 87-88, 88-89	NA	35 41 49	nd nd nd	

[a] NA = not applicable
[b] DALA = Days after last application
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 18 Residues of oxamyl in protected tomatoes, including cherry tomatoes, from supervised trials. Renewal representative GAP: Oxamyl 10SL, 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications via drip irrigation

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-19521 Trial No. 3 GLP 2006	Protected cherry tomatoes/ Winner	Greece, Profitis	2.00 + 1.00 + 1.00	BBCH 12-13 + 66-72 + 72-74, 72-74, 89	NA	-0 (A3-1h)	nd	Mean recovery = 76% ± 6%, RSD = 8 (n = 6) at 0.010 mg/kg fortification Mean recovery = 76% ± 6%, RSD = 8 (n = 6) at 0.10 mg/kg fortification
						21	nd	
			2.00 + 1.00 + 1.00	BBCH 12-13 + 63-65 + 67-73, 89	NA	29	nd	
			2.00 + 1.00 + 1.00	BBCH 12-13 + 52-54 + 65-71, 89, 89,89	NA	35	nd	
						42	nd	
						49	nd	
			2.00 + 1.00 + 1.00 + 1.00	BBCH 12-13 + 60-63 + 66-72 + 72-74, 72-74, 89	NA	-0 (A4-1h)	nd	
						21	nd	
						29	nd	
			2.00 + 1.00 + 1.00 + 1.00	BBCH 12-13 + 25-27 + 63-65 + 67-73, 89, 89, 89, 89	NA	36	nd	
						43	nd	
						50	nd	

[a] NA = not applicable
[b] DALA = Days after last application
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 18 Residues of oxamyl in protected tomatoes, including cherry tomatoes, from supervised trials. Renewal representative GAP: Oxamyl 10SL, 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications via drip irrigation

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-19521 Trial No. 4 GLP 2006	Protected cherry tomatoes/ Winner	Greece, Nea Magnesia	2.00 + 1.00 + 1.00 2.00 + 1.00 + 1.00 2.00 + 1.00 + 1.00	BBCH 12-13 + 62-64 + 66-73, 72, 89 BBCH 12-13 + 55-57 + 64-72, 89 BBCH 12-13 + 26-27 + 61-64, 89, 89,89	NA NA NA	-0 (A3-1h) 20 28 34 41 49	nd nd nd nd nd nd	Mean recovery = 76% ± 6%, RSD = 8 (n = 6) at 0.010 mg/kg fortification Mean recovery = 76% ± 6%, RSD = 8 (n = 6) at 0.10 mg/kg fortification
			2.00 + 1.00 + 1.00 + 1.00 2.00 + 1.00 + 1.00 + 1.00	BBCH 12-13 + 52-55 + 62-64 + 66-73, 72, 89 BBCH 12-13 + 26-27 + 55-57 + 64-72, 89, 89 89, 89	NA NA	-0 (A4-1h) 20 28 35 42 49	nd nd <u>nd</u> nd nd nd	

[a] NA = not applicable
[b] DALA = Days after last application
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 19 Residues of oxamyl in protected tomato and cherry tomato from supervised trial. EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at Last Application	Spray concentration (g a.s./hL)[a]	DALA[b] (days)	Residues found[c] (mg/kg)	Recovery data
DuPont-31506 Trial No. 1 GLP 2010-2011	Protected Cherry Tomato/ Genio	Italy, Contrada Rinazze di Strada, Sicily	2.12 + 1.06 + 1.06 + 1.06	BBCH 65	NA	20	0.005	Mean recovery = 91% ± 19%, RSD = 21 (n = 4) at 0.010 mg/kg fortification Mean recovery = 80% ± 7%, RSD = 8 (n = 4) at 0.10 mg/kg fortification
			2.12 + 1.06 + 1.06 + 1.06	BBCH 64	NA	30	nd	
			2.11 + 1.06 + 1.06 + 1.06	BBCH 63	NA	43	nd	
			2.12 + 1.06 + 1.06 + 1.06	BBCH 62	NA	58	nd	
DuPont-31506 Trial No. 2 GLP 2010-2011	Protected Cherry Tomato/ Genio	South Spain, Campohermoso, Andalucia	2.13 + 1.01 + 1.01 + 1.01	BBCH 72	NA	21	nd	
			2.13 + 1.07 + 1.01 + 1.01	BBCH 69	NA	30	nd	
			2.13 + 1.07 + 1.07 + 1.01	BBCH 63	NA	45	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 53	NA	60	nd	
DuPont-31506 Trial No. 3 GLP 2010-2011	Protected Cherry Tomato/ Santawest	South Spain, Campohermoso, Andalucia	2.13 + 1.01 + 1.01 + 1.01	BBCH 72	NA	21	0.003	Mean recovery = 91% ± 19%, RSD = 21 (n = 4) at 0.010 mg/kg fortification Mean recovery = 80% ± 7%, RSD = 8 (n = 4) at 0.10 mg/kg fortification
			2.13 + 1.07 + 1.01 + 1.01	BBCH 69	NA	30	nd	
			2.13 + 1.07 + 1.07 + 1.01	BBCH 63	NA	45	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 53	NA	60	nd	
DuPont-31506 Trial No. 4 GLP	Protected Tomato/ Zinac	South Spain, El Ejido, Andalucia	2.13 + 1.07 + 1.01 + 1.01	BBCH 72	NA	21	0.003	
			2.13 + 1.07 + 1.07 + 1.01	BBCH 69	NA	31	nd	

Table 19 Residues of oxamyl in protected tomato and cherry tomato from supervised trial. EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at Last Application	Spray concentration (g a.s./hL)[a]	DALA[b] (days)	Residues found[c] (mg/kg)	Recovery data
2010-2011			2.13 + 1.07 + 1.07 + 1.07	BBCH 65	NA	45	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 53	NA	60	nd	
DuPont-31506 Trial No. 5 GLP 2010-2011	Protected Tomato/ Mayoral	South Spain, Venta del Viso, Andalucia	2.13 + 1.07 + 1.01 + 1.01	BBCH 72	NA	21	nd	Mean recovery = 91% ± 19%, RSD = 21 (n = 4) at 0.010 mg/kg fortification Mean recovery = 80% ± 7%, RSD = 8 (n = 4) at 0.10 mg/kg fortification
			2.13 + 1.07 + 1.07 + 1.01	BBCH 69	NA	30	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 65	NA	45	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 55	NA	60	nd	

[a] NA = not applicable
[b] DALA = Day after last application
[c] nd = analyte peak not detected or peak <LOD (<0.003 mg/kg)

Table 19 - Residues of oxamyl in protected tomato and cherry tomato from supervised trial. EU critical GAP: Oxamyl 10SL, 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications via drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-29313 Trial No. 3 GLP 2009-10	Protected Cherry Tomato/ Catalina	Spain, Albuňol	2.074, 1.037, 1.037, 1.037	BBCH 12 + 52 + 61 + 65 + 85	NA	58	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.074, 1.037, 1.037, 1.037	BBCH 12 + 17 + 51 + 53 + 85	NA	73	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 12 + 13 + 16 + 19 + 85	NA	88	nd	
			2.074, 1.037, 1.037	BBCH 12 + 13 + 16 + 85	NA	98	nd	
			2.074, 1.037	BBCH 12 + 13 + 85	NA	108	nd	
DuPont-29313 Trial No. 4 GLP 2009-10	Protected Tomato/ Zinac	Spain, Las Norias de Daza	2.074, 1.037	BBCH 12 + 72 + 84	NA	57	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.074, 1.037, 1.037	BBCH 12 + 53 + 53-71 + 84	NA	62	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 12 + 19 + 52 + 53/71 + 84	NA	67	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 12 + 16 + 19 + 51 + 84	NA	82	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 12 + 14 + 16 + 19 + 84	NA	92	nd	

a NA = not applicable
b DALA = Days after last application
c The designation "nd" is used for treated samples for which no peak was observed or residue was <LOD (below the limit of detection; <0.007 mg/kg).

Table 209 - Residues of oxamyl in protected tomato and cherry tomato from supervised trial.EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-29313 Trial No. 5 GLP 2009-10	Protected Tomato/ Bernal	Spain, Las Norias de Daza	2.074, 1.037	BBCH 12 + 72 + 82	NA	68	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.074, 1.037, 1.037	BBCH 12 + 53 + 53/71 + 82	NA	73	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 12 + 19 + 51 + 53/71 + 82	NA	78	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 12 + 18 + 19 + 51 + 82	NA	93	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 12 + 14 + 18 + 19 + 82	NA	103	nd	
DuPont-29313 Trial No. 6 GLP 2009-10	Protected Tomato/ Denis	Spain, La Mojonera	2.074, 1.037	BBCH 15 + 52 + 83	NA	55	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.074, 1.037, 1.037	BBCH 15 + 51 + 52 + 83	NA	60	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 15 + 19 + 19 + 51 + 83	NA	65	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 15 + 19 + 19 + 19 + 83	NA	80	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 15 + 17 + 19 + 19 + 83	NA	90	nd	

a NA = not applicable
b DALA = Days after last application
c The designation "nd" is used for treated samples for which no peak was observed or residue was <LOD (below the limit of detection; <0.007 mg/kg).

Table 19 - Residues of oxamyl in protected tomato and cherry tomato from supervised trial. EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-29313 Trial No. 7 GLP 2009-10	Protected Tomato/ Enate	Spain, Puebla de Vicar	2.074, 1.037	BBCH 13 + 72 + 85	NA	54	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.074, 1.037, 1.037	BBCH 13 + 52/71 + 72 + 85	NA	59	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 19 + 32 + 71 + 85	NA	64	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 17 + 18 + 31 + 85	NA	79	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 15 + 17 + 18 + 85	NA	89	nd	
DuPont-29313 Trial No. 8 GLP 2009-10	Protected Tomato/ Octydia	Spain, Ruescas	2.074, 1.037, 1.037	BBCH 13 + 64 + 68 + 83	NA	45	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 51 + 59 + 65 + 83	NA	50	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 16 + 19 + 53 + 83	NA	65	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 14 + 16 + 19 + 83	NA	75	nd	
			2.074	BBCH 13 + 83	NA	105	nd	

a NA = not applicable
b DALA = Days after last application
c The designation "nd" is used for treated samples for which no peak was observed or residue was <LOD (below the limit of detection; <0.007 mg/kg).

Table 19- Residues of oxamyl in protected tomato and cherry tomato from supervised trial. EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-29313 Trial No. 9 GLP 2009-10	Protected Tomato/ Pristila	Spain, Ruescas	2.074, 1.037, 1.037	BBCH 13 + 65 + 68 + 83	NA	45	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 51 + 59 + 66 + 83	NA	50	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 16 + 19 + 53 + 83	NA	65	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 13 + 14 + 16 + 19 + 83	NA	75	nd	
			2.074	BBCH 13 + 83	NA	105	nd	
DuPont-29313 Trial No. 10 GLP 2009-10	Protected Tomato/ Tya	Spain, Ruescas	2.074, 1.037, 1.037	BBCH 14 + 65 + 68 + 84	NA	47	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.074, 1.037, 1.037, 1.037	BBCH 14 + 51 + 59 + 65 + 84	NA	52	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 14 + 17 + 19 + 53 + 84	NA	67	nd	
			2.074, 1.037, 1.037, 1.037	BBCH 14 + 15 + 17 + 19 + 84	NA	77	nd	
			2.074	BBCH 14 + 84	NA	107	nd	

a NA = not applicable
b DALA = Days after last application
c The designation "nd" is used for treated samples for which no peak was observed or residue was <LOD (below the limit of detection; <0.007 mg/kg).

Table 19 - Residues of oxamyl in protected tomato and cherry tomato from supervised trial. EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-29313 Trial No. 11 GLP 2009-10	Protected Cherry Tomato/ Corbus	Greece, Nea Magnisia	2.000, 1.000, 1.000, 1.000	BBCH 16 + 53/61 + 62 + 63 + 81	NA	28	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.000, 1.000, 1.000, 1.000	BBCH 16 + 18/51 + 53/61 + 62 + 81	NA	37	nd	
			2.000, 1.000, 1.000	BBCH 16 + 52/61 + 53/61 + 81	NA	47	nd	
			2.000, 1.000	BBCH 16 + 52/61 + 81	NA	55	nd	
			2.000	BBCH 16 + 81	NA	70	nd	
DuPont-29313 Trial No. 12 GLP 2009-10	Protected Tomato/ Victor	Greece, Nea Magnisia	2.000, 1.000, 1.000, 1.000	BBCH 18 + 53/61 + 62 + 63 + 81	NA	28	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.000, 1.000, 1.000, 1.000	BBCH 18 + 19/51 + 53/61 + 62 + 81	NA	37	nd	
			2.000, 1.000, 1.000	BBCH 18 + 52/61 + 53/61 + 81	NA	47	nd	
			2.000, 1.000	BBCH 18 + 52/61 + 81	NA	55	nd	
			2.000	BBCH 18 + 81	NA	70	nd	

a NA = not applicable
b DALA = Days after last application
c The designation "nd" is used for treated samples for which no peak was observed or residue was <LOD (below the limit of detection; <0.007 mg/kg).

Table 19 -Residues of oxamyl in protected tomato and cherry tomato from supervised trial. EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at application and at sampling	Spray concentration (kg a.s./hL)[a]	DALA[b] (days)	Residues found (mg/kg)[c]	Recovery data
DuPont-29313 Trial No. 13 GLP 2009-10	Protected Cherry Tomato/ Genio	Italy, Contrada Dirillo	2.042, 1.028, 1.029, 1.026	BBCH 13 + 63 + 65 + 66 + 81	NA	31	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.042, 1.031, 1.025, 1.024	BBCH 13 + 62 + 63 + 64 + 81	NA	48	nd	
			2.052, 1.026, 1.025, 1.031	BBCH 13 + 61 + 61 + 62 + 81	NA	62	nd	
			2.052, 1.026, 1.022, 1.031	BBCH 13 + 14 + 18 + 61 + 81	NA	76	nd	
			2.061, 1.027, 1.030, 1.029	BBCH 13 + 14 + 18 + 61 + 81	NA	76	nd	
DuPont-29313 Trial No. 14 GLP 2009-10	Protected Tomato/ Rovente	Italy, Contrada Bosco Rotondo	2.054, 1.031, 1.028, 1.028	BBCH 12 + 61 + 63 + 64 + 81	NA	31	nd	Mean recovery = 85% ± 5%, RSD = 6 (n = 10) at 0.010 mg/kg fortification Mean recovery = 83% ± 4%, RSD = 4 (n = 10) at 0.10 mg/kg fortification Overall Mean recovery= 84% ± 4%, RSD = 5
			2.058, 1.030, 1.029, 1.029	BBCH 12 + 61 + 61 + 62 + 81	NA	46	nd	
			2.052, 1.028, 1.031, 1.028	BBCH 12 + 16 + 19 + 61 + 81	NA	60	nd	
			2.054, 1.026, 1.030, 1.027	BBCH 12 + 14 + 15 + 18 + 81	NA	74	nd	
			2.054, 1.025, 1.030, 1.027	BBCH 12 + 14 + 15 + 18 + 81	NA	74	nd	

a NA = not applicable
b DALA = Days after last application
c The designation "nd" is used for treated samples for which no peak was observed or residue was <LOD (below the limit of detection; <0.007 mg/kg).

Table 19 - Residues of oxamyl in protected tomato and cherry tomato from supervised trials 8continued). EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at Last Application	Spray concentration (g a.s./hL)[a]	DALA[b] (days)	Residues found[c] (mg/kg)	Recovery data
DuPont-31506 Trial No. 1 GLP 2010-2011	Protected Cherry Tomato/ Genio	Italy, Contrada Rinazze di Strada, Sicily	2.12 + 1.06 + 1.06 + 1.06	BBCH 65	NA	20	0.005	Mean recovery = 91% ± 19%, RSD = 21 (n = 4) at 0.010 mg/kg fortification Mean recovery = 80% ± 7%, RSD = 8 (n = 4) at 0.10 mg/kg fortification
			2.12 + 1.06 + 1.06 + 1.06	BBCH 64	NA	30	nd	
			2.11 + 1.06 + 1.06 + 1.06	BBCH 63	NA	43	nd	
			2.12 + 1.06 + 1.06 + 1.06	BBCH 62	NA	58	nd	
DuPont-31506 Trial No. 2 GLP 2010-2011	Protected Cherry Tomato/ Genio	South Spain, Campohermoso, Andalucia	2.13 + 1.01 + 1.01 + 1.01	BBCH 72	NA	21	nd	
			2.13 + 1.07 + 1.01 + 1.01	BBCH 69	NA	30	nd	
			2.13 + 1.07 + 1.07 + 1.01	BBCH 63	NA	45	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 53	NA	60	nd	
DuPont-31506 Trial No. 3 GLP 2010-2011	Protected Cherry Tomato/ Santawest	South Spain, Campohermoso, Andalucia	2.13 + 1.01 + 1.01 + 1.01	BBCH 72	NA	21	0.003	Mean recovery = 91% ± 19%, RSD = 21 (n = 4) at 0.010 mg/kg fortification Mean recovery = 80% ± 7%, RSD = 8 (n = 4) at 0.10 mg/kg fortification
			2.13 + 1.07 + 1.01 + 1.01	BBCH 69	NA	30	nd	
			2.13 + 1.07 + 1.07 + 1.01	BBCH 63	NA	45	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 53	NA	60	nd	
DuPont-31506 Trial No. 4 GLP 2010-2011	Protected Tomato/ Zinac	South Spain, El Ejido, Andalucia	2.13 + 1.07 + 1.01 + 1.01	BBCH 72	NA	21	0.003	
			2.13 + 1.07 + 1.07 + 1.01	BBCH 69	NA	31	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 65	NA	45	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 53	NA	60	nd	
DuPont-31506 Trial No. 5 GLP 2010-2011	Protected Tomato/ Mayoral	South Spain, Venta del Viso, Andalucia	2.13 + 1.07 + 1.01 + 1.01	BBCH 72	NA	21	nd	Mean recovery = 91% ± 19%, RSD = 21 (n = 4) at 0.010 mg/kg fortification Mean recovery = 80% ± 7%, RSD = 8 (n = 4) at 0.10 mg/kg fortification
			2.13 + 1.07 + 1.07 + 1.01	BBCH 69	NA	30	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 65	NA	45	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 55	NA	60	nd	

[a] NA = not applicable
[b] DALA = Day after last application
[c] nd = analyte peak not detected or peak <LOD (<0.003 mg/kg)

Table 19 - Residues of oxamyl in protected tomato and cherry tomato from supervised trials. EU critical GAP: Oxamyl 10SL, 2.0 kg a.s./ha at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; all applications *via* drip irrigation; 28-d PHI

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at Last Application	Spray concentration (g a.s./hL)[a]	DALA[b] (days)	Residues found[c] (mg/kg)	Recovery data
DuPont-31506 Trial No. 6 GLP 2010-2011	Protected Tomato/ Realeza	South Spain, La Mojonera, Andalucia	2.13 + 1.01 + 1.01 + 1.01	BBCH 72	NA	21	0.006	Mean recovery = 91% ± 19%, RSD = 21 (n = 4) at 0.010 mg/kg fortification Mean recovery = 80% ± 7%, RSD = 8 (n = 4) at 0.10 mg/kg fortification
			2.13 + 1.01 + 1.01 + 1.01	BBCH 69	NA	31	0.004	
			2.13 + 1.07 + 1.07 + 1.01	BBCH 64	NA	44	nd	
			2.13 + 1.07 + 1.07 + 1.07	BBCH 54	NA	60	nd	
DuPont-31506 Trial No. 7 GLP 2010-2011	Protected Tomato/ Belladonna	Greece, Almyros, Central Greece	2.12 + 1.00 + 1.00 + 1.00	BBCH 54-55/64	NA	45	nd	Mean recovery = 91% ± 19%, RSD = 21 (n = 4) at 0.010 mg/kg fortification Mean recovery = 80% ± 7%, RSD = 8 (n = 4) at 0.10 mg/kg fortification
			2.12 + 1.00 + 1.00 + 1.00	BBCH 53-54/63	NA	54	nd	
			2.12 + 1.06 + 1.00 + 1.00	BBCH 52-53/61	NA	69	nd	
			2.12 + 1.06 + 1.06	BBCH 52/61	NA	84	nd	

[a] NA = not applicable
[b] DALA = Day after last application
[c] nd = analyte peak not detected or peak <LOD (<0.003 mg/kg)

For the representative use in tobacco, a total of five residue trials were conducted with Oxamyl 10GR or Oxamyl 5GR applied at the GAP rates or higher (in furrow application at 3.5 kg a.s./ha or as broadcast application with 5.5-5.9 kg a.s./ha).

Oxamyl 10GR is applied at planting (BBCH 00) in furrow, at the rate of 3.0 kg a.s./ha, or broadcast at the rate of 5.5 kg a.s./ha.

In all trials, the residues in green tobacco leaves were <0.01 mg/kg. The residue studies presented were carried out in three EU countries, Italy, Spain, and Greece and provide data relevant to conditions in southern Europe to support granular application of oxamyl at transplant of tobacco and foliar application of oxamyl on tobacco.

Residue studies supportive of the renewal representative use in tobacco are summarized in the table below.

Table 210 Residues of oxamyl in tobacco leaves from supervised trials following applications of Oxamyl 10GR or Oxamyl 5GR
Renewal representative GAP: SEU; One 5.5 kg a.s./ha application (broadcast) or one 3.0 kg a.s./ha application (in-furrow) of Oxamyl 10GR at transplant

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at applications and at sampling	Spray conc (kg a.s./hL)[a]	DALA[b]	Residues found[c] (mg/kg)			Recovery data
							Green leaves	Dried leaves	Dried, fermented leaves	
DuPont-14667 Trial No. 1 GLP 2005	Tobacco/ Burley	Bovolone (Verona), Veneto, Italy	5.900- broadcast	BBCH 14–15 BBCH 49	NA	94	nd	nd	nd	Green Leaves: mean recovery = 93%, RSD = 14 (n = 8) in 0.010–0.10 mg/kg fortification range; Dried Leaves: mean recovery = 92%, RSD = 8 (n = 10) in 0.010–0.40 mg/kg fortification range; Dried Fermented Leaves: mean recovery = 92%, RSD = 1 (n = 4) in 0.010–0.10 mg/kg fortification range)
DuPont-14667 Trial No. 2 GLP 2005	Tobacco/ Bright	Bovolone (Verona), Veneto, Italy	5.900- broadcast	BBCH 14–15 BBCH 49	NA	105	nd	nd	nd	Green Leaves: mean recovery = 93%, RSD = 14 (n = 8) in 0.010–0.10 mg/kg fortification range; Dried Leaves: mean recovery = 92%, RSD = 8 (n = 10) in 0.010–0.40 mg/kg fortification range; Dried Fermented Leaves: mean recovery = 92%, RSD = 1 (n = 4) in 0.010–0.10 mg/kg fortification range)

[a] NA = not applicable
[b] DALA = Days after last application b
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 21 - Residues of oxamyl in tobacco leaves from supervised trials following applications of Oxamyl 10GR or Oxamyl 5GR (continued)
Renewal representative GAP: SEU; One 5.5 kg a.s./ha application (broadcast) or one 3.0 kg a.s./ha application (in-furrow) of Oxamyl 10GR at transplant

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at applications and at sampling	Spray conc (kg a.s./hL)[a]	DALA[b]	Residues found[c] (mg/kg)			Recovery data
							Green leaves	Dried leaves	Dried, fermented leaves	
DuPont-14667 Trial No. 3 GLP 2005	Tobacco/ Basmas	Thessaloniki, Central Macedonia, GR-57020, Greece	3.495– in-furrow	BBCH 12–13 BBCH 49	NA	78	nd	0.020	nd	Green Leaves: mean recovery = 93%, RSD = 14 (n = 8) in 0.010–0.10 mg/kg fortification range; Dried Leaves: mean recovery = 92%, RSD = 8 (n = 10) in 0.010–0.40 mg/kg fortification range; Dried Fermented Leaves: mean recovery = 92%, RSD = 1 (n = 4) in 0.010–0.10 mg/kg fortification range)
DuPont-14667 Trial No. 4 GLP 2005	Tobacco/ Katerinis	Pieria, Central Macedonia, GR-60100, Greece	3.495– in-furrow	BBCH 12–13 BBCH 49	NA	78	nd	nd	nd	Green Leaves: mean recovery = 93%, RSD = 14 (n = 8) in 0.010–0.10 mg/kg fortification range; Dried Leaves: mean recovery = 92%, RSD = 8 (n = 10) in 0.010–0.40 mg/kg fortification range; Dried Fermented Leaves: mean recovery = 92%, RSD = 1 (n = 4) in 0.010–0.10 mg/kg fortification range)

[a] NA = not applicable
[b] DALA = Days after last application b
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 21 - Residues of oxamyl in tobacco leaves from supervised trials following applications of Oxamyl 10GR or Oxamyl 5GR

Renewal representative GAP: SEU; One 5.5 kg a.s./ha application (broadcast) or one 3.0 kg a.s./ha application (in-furrow) of Oxamyl 10GR at transplant

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at applications and at sampling	Spray conc (kg a.s./hL)[a]	DAL[ab]	Residues found[c] (mg/kg)			Recovery data
							Green leaves	Dried leaves	Dried, fermented leaves	
DuPont-14667 Trial No. 5 GLP 2005	Tobacco/ Burley	Santa Fe, Granada, Andalucia, Spain	5.500– broadcast	BBCH 13–14 BBCH 92	NA	105	nd	nd	nd	Green Leaves: mean recovery = 93%, RSD = 14 (n = 8) in 0.010–0.10 mg/kg fortification range; Dried Leaves: mean recovery = 92%, RSD = 8 (n = 10) in 0.010–0.40 mg/kg fortification range; Dried Fermented Leaves: mean recovery = 92%, RSD = 1 (n = 4) in 0.010–0.10 mg/kg fortification range)

[a] NA = not applicable
[b] DALA = Days after last application b
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

Table 221- Residues of oxamyl in tobacco leaves from supervised trials following applications of Oxamyl 10GR or Oxamyl 5GR
Renewal representative GAP: SEU; One 5.5 kg a.s./ha application (broadcast) or one 3.0 kg a.s./ha application (in-furrow) of Oxamyl 10GR at transplant

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at applications and at sampling	Spray conc (kg a.s./hL)[a]	DALA[b]	Residues found[c] (mg/kg)			Recovery data
							Green leaves	Dried leaves	Dried, fermented leaves	
DuPont-14667 Trial No. 1 GLP 2005	Tobacco/ Burley	Bovolone (Verona), Veneto, Italy	5.900- broadcast	BBCH 14–15 BBCH 49	NA	94	nd	nd	nd	Green Leaves: mean recovery = 93%, RSD = 14 (n = 8) in 0.010–0.10 mg/kg fortification range; Dried Leaves: mean recovery = 92%, RSD = 8 (n = 10) in 0.010–0.40 mg/kg fortification range; Dried Fermented Leaves: mean recovery = 92%, RSD = 1 (n = 4) in 0.010–0.10 mg/kg fortification range)
DuPont-14667 Trial No. 2 GLP 2005	Tobacco/ Bright	Bovolone (Verona), Veneto, Italy	5.900- broadcast	BBCH 14–15 BBCH 49	NA	105	nd	nd	nd	Green Leaves: mean recovery = 93%, RSD = 14 (n = 8) in 0.010–0.10 mg/kg fortification range; Dried Leaves: mean recovery = 92%, RSD = 8 (n = 10) in 0.010–0.40 mg/kg fortification range; Dried Fermented Leaves: mean recovery = 92%, RSD = 1 (n = 4) in 0.010–0.10 mg/kg fortification range)

[a] NA = not applicable
[b] DALA = Days after last application b
[c] nd = analyte peak not detected or peak <LOD (<0.007 mg/kg)

The renewal representative use of solarisation is for vegetables grown under protection. Oxamyl 10SL is applied a minimum of 30 days prior to transplanting (preplant solarisation), at the rate of 5.5 kg a.s./ha. For tomatoes, this preplant solarisation application is followed at transplanting with a rate of 2.0 kg a.s./ha followed by three applications at 1.0 kg a.s./ha/application with a 10-day retreatment interval and a 28-day PHI.

Four residue bridging trials were conducted to support Oxamyl 10SL for use in solarisation applications. In all trials, the residues in fruiting vegetables (cherry tomatoes or courgettes) harvested following in-season applications at the critical GAP were comparable, regardless of the addition of the preplanting solarisation applications.

Overall consistent residue behaviour was found in EU for application and sampling conducted to support the use of Oxamyl 10SL for solarisation applications.

Residue studies supportive of the renewal representative use on solarisation are summarized in the table below.

Table 232 Residues of oxamyl in protected cherry tomatoes and courgettes.Renewal representative GAP: Oxamyl 10SL, 5.5 kg a.s. 30 days before transplant (preplant solarisation) followed by 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications *via* drip irrigation

GLP and trial details	Crop/ Variety	Country	Application rate (kg a.s./ha)	Crop growth stage at last application and at final sampling	Spray conc. (kg a.s./hL)[a]	DALA[b] (days)	Residues found[c] (mg/kg)	Recovery data
DuPont-35356 Trial No. 1 GLP 2012	Protected Cherry Tomato/ Daterino	Spain, Los Palacios	2.134 + 1.067 + 1.067 + 1.067	BBCH 12 + 63 + 63 + 71, 74 + 81	NA	30 42	nd nd	Mean recovery = 73% (n = 2) at 0.010 mg/kg fortification Mean recovery = 73% (n = 2) at 0.10 mg/kg fortification
			5.869 + 2.134 + 1.067 + 1.067 + 1.067	Preplant+BBCH 12 + 63 + 63 + 71, 74 + 81	NA	30 42	nd nd	
DuPont-35356 Trial No. 2 GLP 2012	Protected Courgette/ Jedida	Spain, Los Palacios	2.134 + 1.067	BBCH 12 + 16, 89	NA	41	0.003	Mean recovery = 72% (n = 2) at 0.010 mg/kg fortification Mean recovery = 74% (n = 2) at 0.10 mg/kg fortification
			5.869 + 2.134 + 1.067	Preplant + BBCH 12 + 16, 89	NA	41	nd	
DuPont-35356 Trial No. 3 GLP 2012	Protected Cherry Tomato/ Panarea	Italy, Contrada Moglie, Acate (Ragusa), Sicily,	2.122 + 1.065 + 1.063 + 1.066	BBCH 13 + 62 + 64 + 71, 81	NA	28	0.008	Mean recovery = 73% (n = 2) at 0.010 mg/kg fortification Mean recovery = 73% (n = 2) at 0.10 mg/kg fortification
			5.856 + 2.128 + 1.065 + 1.064 + 1.065	Preplant+ BBCH 13 + 62 + 64 + 71, 81	NA	28	0.006	

Table 232 Residues of oxamyl in protected cherry tomatoes and courgettes.Renewal representative GAP: Oxamyl 10SL, 5.5 kg a.s. 30 days before transplant (preplant solarisation) followed by 2.0 kg a.s. at transplanting followed by 3 applications at 1.0 kg a.s./ha/application, 10 days apart; 28-d PHI; all applications *via* drip irrigation

DuPont-35356 Trial No. 4 GLP 2012	Protected Courgette/ Ezra F1	Greece, Nea Magnisia, Thessaloniki, Central Macedonia,	2.134 + 1.067	BBCH 11 + 15, 79	NA	45	nd	Mean recovery = 72% (n = 2) at 0.010 mg/kg fortification Mean recovery = 74% (n = 2) at 0.10 mg/kg fortification
			5.869 + 2.134 + 1.067	Preplant+ BBCH 11 + 15, 79	NA	45	nd	

[a] NA = not applicable
[b] DALA = Days after last application
[c] nd = analyte peak not detected or peak <LOD (<0.003 mg/kg)

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

The proposed GAP for oxamyl involves application to only one potential animal feed crop - potatoes. Residues in potato tubers when treated in accordance with the proposed GAP are <0.01 mg/kg. These low feed residues result in livestock dietary burdens <0.004 mg/kg bw/day. The Commission Regulation (EU) No 283/2013 states livestock feeding studies shall not be required where intake is below except in cases where the residue, that is to say the active substance, its metabolites or breakdown products, as defined in the residue definition for risk assessment, tends to accumulate. In the case of oxamyl, livestock feeding studies are not required since anticipated residues in the entire diet received are less than 0.004 mg/kg bw/day.

In addition, Commission Regulation (EU) No 283/2013 states livestock feeding studies shall be provided where metabolism studies indicate that residues at levels of above 0.01 mg/kg may occur in edible animal tissue, milk, eggs, or fish, taking into account the residue levels in potential feeding stuffs, obtained at the 1 × dose rate, calculated on the dry weight basis. In metabolism studies with oxamyl in livestock, no residues of oxamyl were found (<0.01 mg/kg) in human foodstuffs - milk, eggs, or edible tissues. Consequently, feeding studies are not necessary to assess human exposure to oxamyl from animal food sources.

2.6.6 Summary of effects of processing

Commission Regulation (EU) No 283/2013 states that 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 oxamyl residues (≤0.01 mg/kg) were found in commonly processed commodities (potatoes, tomato, tobacco) at the time of harvest or during residue decline studies. Consequently, processing studies are not required.

However, a study investigating the nature of the residue following high-temperature hydrolysis simulating industrial processing and/or household preparation was conducted, submitted, and evaluated as part of the Annex I inclusion of oxamyl in 2004.

In addition, data from a follow-up study are discussed. In one study, the transfer of residues from raw potato tubers to potato tubers following baking, boiling, and microwave preparation has been investigated and is summarised as supplementary data.

2.6.7 Summary of residues in rotational crops

Three confined rotational crop studies were conducted, submitted, and evaluated in the Oxamyl Monograph 2004. The studies were conducted with [1-^{14}C]oxamyl applied to the soil and the soil aged for 30, 120, and/or 363 days. Significant [1-^{14}C-]oxamyl residues remained in the soil at planting in all three studies, allowing for assessment of the potential for accumulation of oxamyl derived residues in rotational crops (beets, cabbage, sorghum, barley, and lettuce). In the confined rotational crop studies, oxamyl, IN-A2213, and IN-D2708 were identified at concentrations >0.01 mg/kg (oxamyl equivalents) in barley, beet, cabbage, and lettuce commodities planted 30 and 120 days after soil treatments of 9 and 120 kg oxamyl/ha. These components have been previously identified in plant metabolism studies and all were present in the soil at planting. The identification of these components and the characterisation of several tentatively identified metabolites (IN-KP532, IN-T2921, IN-L2953, and IN-N0079) in barley planted 30 days after soil treatment at 8 kg oxamyl/ha further support the metabolic profile in the rotated crop. The proposed metabolic pathway of oxamyl in rotated crops is consistent with the pathway seen in plants following oxamyl application at planting or post emergence and verifies the residue definition for food of plant origin as parent oxamyl only.

At four residue trial locations in the northern EU, oxamyl residues were determined in rotational crops planted in a field that had previously contained potatoes treated with Oxamyl 10GR applied at planting at 5.0-5.5 kg a.s./ha. Oxamyl residues in succeeding crops (lettuce, carrot roots and tops, and cereal grain, hay, and straw) planted 80 and 120 days after Oxamyl 10GR application and harvested at maturity were <0.007 mg/kg.

At two residue trial locations in the southern EU, oxamyl residues were determined in rotational crops planted in protected plots that had previously contained melons treated with Oxamyl 10SL applied at 6.0 kg a.s./ha/season.

Oxamyl residues in succeeding crops (lettuce and radish roots and radish tops) planted *ca.* 30, 60, 90 and 120 days after Oxamyl 10SL application and harvested at maturity were <0.007 mg/kg.

2.6.8 Summary of other studies

A unit-to-unit variability study was carried out in one EU country and provides data relevant to protected conditions in the southern European region. Oxamyl residues in 30 individual cucumber fruit treated 5 times at 1.2 kg a.s./ha *via* drip irrigation and collected 3 days after the last application, ranged from not detectable (<0.005 mg/kg) to 0.22 mg/kg. The overall average was 0.060 mg/kg (RSD = 93%), and the median was 0.048 mg/kg. The unit-to-unit variability factor was 3.7, calculated by dividing the maximum individual residue by the overall average residue.

Several studies to assess the magnitude of oxamyl residues in wildlife feed items (ground dwelling arthropods, earthworms, weed seedlings, pollen, guttation drops, nectar) and dust from applications to which wildlife is exposed, providing input information for wildlife exposure assessments are provided.

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

The current ADI, ARfD, and NOAEL for oxamyl are summarised in the table below and considered in the dietary risk assessment as worst-case compared to new proposed ARfD and ADI based on a SF of 10 instead of 100.

Endpoint	Value (mg/kg bw/d)	Study	Safety factor	Reference
Acceptable Daily Intake (ADI)	0.001	Acute neurotoxicity study in rat	100	EFSA Scientific Report 2005
Acute Reference Dose (ARfD)	0.001		100	
NOAEL, inhalation	0.1		Not applicable for the NOAEL	

[a] The only available inhalation study is an acute inhalation toxicity study. Therefore, the short- and intermediate-term inhalation endpoints are based on the acute neurotoxicity study in the rat. Since the chronic dietary endpoint is also based on the acute neurotoxicity study in the rat, this study better predicts effects for inhalation exposure that is greater than one day.

TMDI calculations

The calculation of the TMDI was performed using the maximum residue limit (MRL) for all crops (Reference: Commission Regulation (EU) No 61/2014, 24 January 2014) to estimate the TMDI.

With the current EFSA model, the TMDI of oxamyl are ≤71.9% of the ADI. The highest calculated TMDI was for the French toddler.

NEDI calculations

The TMDI were ≤71.9% of the ADIs for oxamyl. Therefore, no further refinements to the long-term dietary exposure assessment were conducted.

NESTI calculations

The calculation of the NESTI was performed taking into account potatoes and tomatoes, the representative use crops. Since residues in the supervised residue trials were less than the limit of quantification in the edible portions, the LOQs are used to estimate the NESTI. For potato tubers, the highest transfer factor observed for commodities prepared for consumption (0.15 for baked potatoes) was applied to the LOQ. Residue inputs used were:

- tomatoes: 0.01 mg/kg
- potato tubers: 0.01 mg/kg × 0.15 = 0.0015 mg/kg

The highest calculated acute exposure of consumers to oxamyl was 58.1% of the ARfD from tomatoes.

Exposure *via* water

PECgw values for oxamyl metabolites IN-A2213 and IN-D2708 exceeded 0.1 µg/L but were less than 0.75 µg/L. From a risk management point of view, the exposure of consumers to metabolites 'non-relevant' in the hazard assessment at levels less than 0.75 µg/L is considered acceptable (threshold of concern approach), and therefore, for metabolites IN-A2213 and IN-D2708, no further assessment was conducted.

Inhalation Risk Assessment

It is assumed that the greatest exposure to oxamyl will come from cigarettes. A conservative exposure estimate assuming oxamyl residues remain intact and are 100% inhaled during smoking indicates the Margin of Exposure (MOE) is 17500, much higher than the target MOE of 100.

$$\text{MOE} = \frac{\text{NOAEL, inhalation}}{\text{Exposure, tobacco}}$$

$$\text{Exposure} = \frac{\text{\# of cigarettes per day x g tobacco/cigarette x conversion factor x mg oxamyl/kg tobacco}}{\text{average adult bodyweight}}$$

$$\text{MOE} = \frac{0.1}{20 \times 1 \times 0.001 \times 0.02 \div 70} = \frac{0.1}{0.000006} = 17500$$

Where,

- NOAEL, inhalation = 0.1 mg/kg bw/day
- # cigarettes per day = 20[1]
- g tobacco/cigarette = 1
- conversion factor = 0.001 kg/1 g
- highest residues in dried tobacco leaves = 0.02 mg oxamyl/kg
- average adult bodyweight = 70 kg

2.6.10 Proposed MRLs and compliance with existing MRLs

EU MRLs for oxamyl are listed published by Commission Regulation (EU) No 61/2014, 24 January 2014. MRLs are not set on tobacco; however, guideline residue levels for green and dried leaves are proposed. The established/proposed MRLs are well supported by the residues data presented for the representative uses. The established/proposed MRLs are summarised in the following table.

[1] Reference: Average U.S. smoker smokes 15 cigarettes per day. (Pierce, J.P., *et al*. 1989. Tobacco Use in 1986 – Methods and Basic Tabulations from Adult Use of Tobacco Survey. U.S. Dept. of Health and Human Services Publication Number OM90-2004. Office on Smoking and Health, Rockville, Maryland.)

Table 243 Summary of approved oxamyl MRLs - Commodities of plant origin for representative uses

Commodities	CXLs (mg/kg)	EU current MRL (mg/kg)	Proposed EU MRL/GRL (mg/kg)
Potato	None established	0.01[a]	0.01[a]
Tomato	2	0.01[a]	0.01[a]
Tobacco	None established	None established	0.01[a,b]

[a] Indicates lower limit of analytical determination

[b] This GRL falls within the one approved/pending use in place in Italy with a different GAP and formulation that will be supported after Annex I Renewal of oxamyl.

2.6.11 Proposed import tolerances and compliance with existing import tolerances

No import tolerance MRLs for oxamyl are included with this submission.

2.7 Fate and behaviour in the environment

2.7.1 Summary of fate and behaviour in soil

Four aerobic soil degradation studies in nine soils for oxamyl under laboratory conditions, one aerobic degradation study for metabolite IN-D2708 (DMOA) in three soils under laboratory conditions, one aerobic degradation study for metabolite IN-N0079 (DMCF) in three soils under laboratory conditions, and one photodegradation study for oxamyl and its metabolite IN-N0079 (DMCF) in one soil under laboratory conditions were carried out. Since the studies do not contain a kinetic evaluation of the data according to recent FOCUS recommendations (FOCUS, 2006[2], 2011[3]), residue data of these studies were re-evaluated to derive persistence and modelling endpoints for oxamyl and its metabolites IN-A2213, IN-D2708, and IN-N0079 under aerobic soil conditions, and for oxamyl and its photolytic metabolite IN-N0079 under irradiated conditions (photodegradation).

Residue data from soil dissipation studies were re-evaluated to meet the requirements of the current FOCUS (2006, 2011, 2014a[4]) and EFSA (2014)[5] guidelines on degradation kinetics.

Two field dissipation studies for oxamyl were conducted at European trial sites in Ottersum in The Netherlands and Spalding in the UK. In both field dissipation studies, the Oxamyl 10GR (granule, 10% oxamyl) was applied at 4 (NL) and 5.5 kg a.s./ha (UK) onto bare ground, and the granules were further incorporated into the topsoil. Persistence endpoints and modelling endpoints were then calculated for comparison against trigger values and for use in exposure modelling, respectively.

The worst-case persistence DT_{50} and DT_{90} values for oxamyl were determined to be 9.5 and 31.4 days, respectively. The worst-case modelling DT_{50} was 6.9 days.

For IN-A2213, the worst-case persistence DT_{50} and DT_{90} values were 17.5 and 58.0 days. The worst-case modelling DT_{50} was 8.8 days. Formation fractions of 0.83 and 0.77 were estimated from soil Ottersum, NL, for non-normalised data and normalised data, respectively.

[2] FOCUS (2006) Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the Work Group on Degradation Kinetics of FOCUS. EC Document Reference SANCO/10058/2005 version 2.0, June 2006.

[3] FOCUS (2011) Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, version 1.0.

[4] FOCUS (2014a) Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Version 1.1, 18 December, 2014.

[5] EFSA (2014) EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain $DegT_{50}$ values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 12(5):3662.

The worst-case persistence DT_{50} and DT_{90} values for IN-D2708 were 9.1 and 30.1 days, respectively. The worst-case modelling DT_{50} was 4.7 days. The formation fraction from the primary metabolite IN-A2213 was estimated to be 1.

Degradation model of oxamyl in the field

Oxamyl can degrade *via* hydrolysis, microbial degradation, photolysis, and Fe^{II}-ions catalysis. Since oxamyl was incorporated into the soil directly after application, surface related processes like photodegradation and volatilization were considered not significant, and the procedure proposed by EFSA (2014) for the evaluation of tailored $DegT_{50\ matrix}$ field studies was followed. Consequently, all persistence and modelling endpoints were determined based on current guidance of the FOCUS workgroup (FOCUS, 2006, 2011, 2014a) and including those residue data that were measured before 10 mm of cumulative rainfall has occurred.

Based on aerobic conditions in the topsoil, the same degradation pathway as established for kinetic evaluation of the laboratory studies was used.

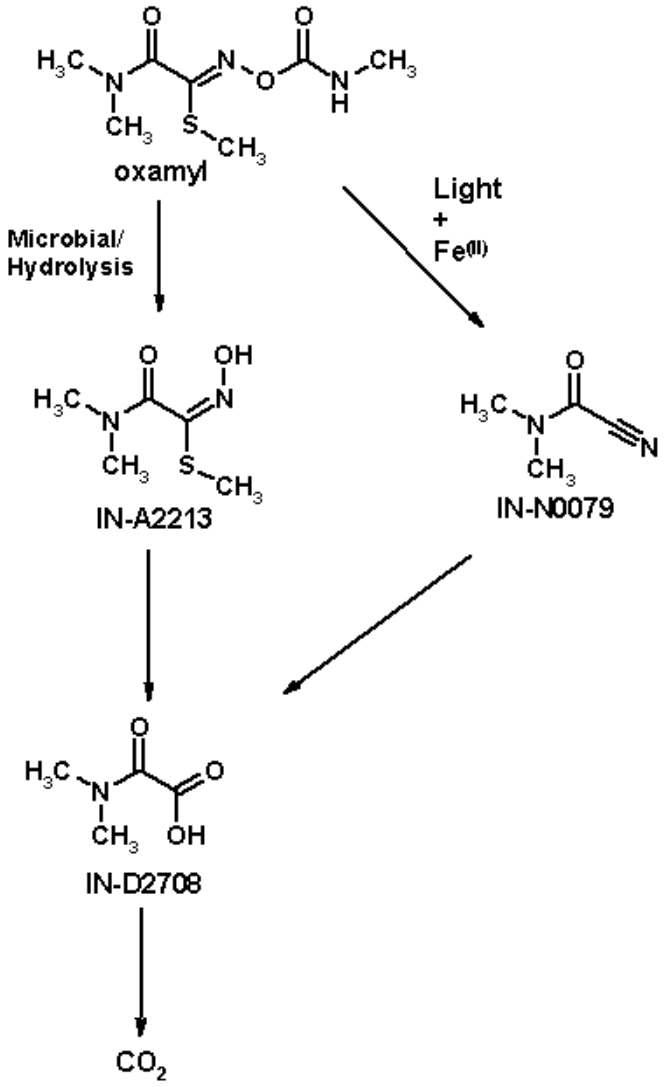
Estimation of the kinetic endpoints

Persistence and modelling endpoints were derived from non-normalised and normalised residue data, respectively, and following the decision trees and stepwise approaches specified by the FOCUS workgroup (2006, 2011, and 2014a). The degradation rates of oxamyl were estimated in parent-only fits using best-fit kinetic models for persistence endpoints and SFO model for modelling endpoints where possible.

As for metabolites (IN-A2213 and IN-D2708), their degradation rates could be well described by the pathway fit (SFO-SFO model) in soil Ottersum, NL; however, endpoints were derived from the decline phase (SFO model) for the soil Spalding, UK. In addition, the formation fraction of IN-D2708 from the primary metabolite IN−A2213 was estimated to be 1 in preliminary evaluations, indicating that IN-A2213 was fully degraded to IN−D2708, and no additional sink was needed to adequately describe the degradation pathway. Consequently, the fraction was fixed to 1 for all pathway fits and excluded from the optimization process.

On the basis of the described soil metabolism studies, the primary route of degradation for oxamyl is *via* microbial decomposition and hydrolysis to form IN-A2213, which is further microbially degraded to IN-D2708 and then extensive mineralization to CO_2 and bound residue. In the presence of light, oxamyl can also undergo a photocatalyzed, iron-mediated conversion to IN-N0079 as an additional minor degradation route. Degradation *via* this alternate, light-mediated, route does also proceed to formation of IN-D2708, which can then undergo microbial mineralization. Therefore, the proposed degradation pathway of oxamyl in soil is as shown below.

Pathway of oxamyl degradation in soil



2.7.2 Summary of fate and behaviour in water and sediment

Chemical routes of oxamyl degradation in water were investigated in hydrolysis and photolysis studies. Hydrolysis was base-catalysed (E1cb elimination reaction). Oxamyl was shown to be hydrolytically stable at acidic pH 4. The rate of degradation was temperature dependent and increased with increasing temperature with DT_{50} values of 21.1, 9.01, and 4.16 days at 20, 25, and 30°C for pH 7, respectively, and 0.200, 0.098, and 0.046 days at 20, 25, and 30°C for pH 9, respectively. The only product observed was IN-A2213, and this was stable to further hydrolysis. Hydrolysis studies for the degradates IN-A2213, IN-D2708, IN-N0079, and IN-T2921 at 20°C were also conducted. IN-A2213, IN-D2708, and IN-T2921 were stable (DT_{50} >30–34 days) at pH 4, pH 7, and pH 9. IN-N0079 was observed to hydrolyse at pH 9 and pH 7, and the DT_{50} values were 3 days and 136 days, respectively. IN-T2921 and IN-D2708 were the observed hydrolysis products from IN-N0079. IN-N0079 was stable to hydrolysis (DT_{50} >30 days) at pH 4.

The photolysis of oxamyl was investigated at a hydrolytically stable pH (pH 5) using an artificial light source with wavelength cut-off of <295 nm to simulate natural sunlight. Oxamyl was degraded by photolysis to a significant extent following exposure to artificial light with a first order DT_{50} of 3.5 days of irradiation corresponding to environmental half-lives estimated as 4.1, 5.8, 6.3, 7.9, or 8.7 mid-summer days in Phoenix, Arizona (USA, 33.3 °N); Edmonton, Alberta (Canada, 53.3 °N); Athens, Greece (EU, 38.0 °N); London, Great Britain (EU, 51.3 °N); and Tokyo (Japan, 35.1 °N), respectively. Photolytic degradation leads primarily to

IN-N0079, which comprised a maximum of 67.6% of the applied amount at study termination. Only minor levels of IN-A2213 were observed (max 1.6%). Since oxamyl does not absorb light above 290 nm, a quantum yield could not be calculated and is thus zero. It is believed that the rapid photolytic degradation observed in the new 2014 aqueous photolysis study is attributed to enhancement of the ferrous iron (Fe^{2+}) reduction of oxamyl to IN-N0079 by the presence of light. This reaction has been well documented both in the public literature and in the saturated zone degradation studies. This reaction is favoured under anoxic (reductive) conditions, and the use of sealed test vessels of minimal headspace would have promoted such reductive conditions. Aqueous photolysis studies for the major degradates IN-A2213, IN-D2708, IN-N0079, and IN-T2921 were not conducted, since their molar absorptivities at 290 nm were experimentally determined to be negligible.

The behaviour of oxamyl in natural aerobic surface waters was investigated in the mineralization in surface water study. Oxamyl undergoes limited mineralization in natural surface water, but is rapidly degraded *via* hydrolysis to form IN-A2213.

The fate of oxamyl was investigated in two natural water/sediment systems. Two differing application techniques were investigated. Firstly, addition of compound to the water phase (reflecting the more likely method of entry into natural water systems) and secondly, vigorous mixing of water and sediment after application of compound. The second method unsurprisingly resulted in a greater initial association of radioactivity with the sediment and much higher initial amounts of IN-N0079. The rapid appearance of IN-N0079 after vigorously mixing the water and anaerobic sediment is likely due to oxamyl reduction by ferrous iron (Fe^{2+}). The relevance of the vigorous mixing approach of dosing is likely to be low in natural conditions, and the effect of mixing aerobic and anaerobic phases is difficult to predict. Therefore, the results obtained from this second application method are not considered further.

When dosed to the surface of the water phase (in accordance with the OECD guideline), oxamyl degraded rapidly in the water phase (<50% remaining on day 1), and significant amounts were never found in the sediment phase. Since both water systems were slightly alkaline, it is likely that a component of this rapid degradation was the result of chemical hydrolysis. IN-A2213, the hydrolysis product, reached a maximum of 25.3–48.8% AR in the water phase on Day 2 and then decreased to non-detectable levels by Day 61. Low levels were found in the sediments (max. 4.4%), and the pattern reflected that observed in the water phase. In one system, high levels of IN-N0079 (maximum 52.9% at Day 2) were observed in the water phase, and the pattern of formation and decline was parallel to that of IN-A2213. As discussed above, the rapid appearance of significant amounts of IN-N0079 was likely due to the Fe^{+2}-oxamyl reduction reaction with Fe^{+2} near or within the anaerobic sediment phase. Following the decline of the IN-A2213 and IN-N0079, levels of IN-D2708 in the water subsequently rose (maximum 64.2–66.8% at Day 30) and then declined during the remainder of the study. Low levels of IN-D2708 (maximum 10.4% to 12.1%) were observed in the sediment, and the pattern of occurrence of this sediment residue coincided with the maximum level of IN-D2708 in the water phase, suggesting a simple gradient diffusion of IN-D2708 from the water phase into the sediment pore water in the static test system. In one system only, levels of IN-T2921 exceeded 10% in the water phase. However, this was only at one time point (Day 14), the maximum level was only 11.4%, and subsequent degradation was rapid (not detected at the next time point, Day 30). Amounts of carbon dioxide evolved reached 27.9 to 60.9% by the end of the study. In anaerobic water/sediment systems, oxamyl degraded similarly as in the aerobic system, with IN-A2213, IN-N0079, and IN-D2708 being the major transformation products. In one sediment system under anaerobic conditions, IN-SBY69 was observed as an additional transition metabolite. This metabolite is formed *via* cysteine conjugate cyclyzation of IN-N0079. It is believed that IN-SBY69 was observed in the anaerobic water/sediment study only because the anaerobic conditions create a reductive environment that favours the Fe^{+2}-oxamyl reduction reaction that produces its precursor, IN-N0079. Thus, this metabolite (IN-SBY69) was only present at major, observable levels because of the drastically increased levels of IN-N0079 formed in this one anaerobic sediment system. In typical water/sediment systems, such high levels of IN-N0079 are not expected to form, and thus only minor, if any, levels of IN-SBY69 can be expected to occur in the environment.

Overall, the water/sediment studies show degradation of oxamyl to IN-A2213 or IN-N0079 and further to IN-T2921 and IN-D2708 in the water phase. No compounds reached consistently significant levels in the sediment. Carbon dioxide was the ultimate degradation product in both test systems. The kinetics presented in this original report are superseded by the updated FOCUS kinetic results.

The persistence DT_{50} values for oxamyl in the whole system were 0.69 to 0.82 day and the DT_{90} values were 2.28 to 8.31 days, but these are also effectively the values in the water phase. Robust whole system DT_{50} values

were also calculated for IN-A2213, and they ranged from 5.67 to 8.24. A summary of the FOCUS kinetic results for this study is presented in the following tables.

Table 254 Summary of water/sediment study persistence endpoints for oxamyl

System	Water/sediment system	Values in days	Kinetic level and type
Red Oak Stream	System	$DegT_{50}$ = 0.82 $DegT_{90}$ = 8.31	P-I; HS Best-fit Model
	Water	DT_{50} = 0.82 DT_{90} = 8.31	P-I; HS Best-fit Model
	Sediment	-	Oxamyl appeared only in small amounts at only 2 data points
Town Park Pond	System	$DegT_{50}$ = 0.69 $DegT_{90}$ = 2.28	P-I; SFO Best-fit Model
	Water	DT_{50} = 0.69 DT_{90} = 2.28	P-I; SFO Best-fit Model
	Sediment	-	Oxamyl did not appear in sediment

Summary of water/sediment study persistence endpoints for IN-A2213

System	Water/sediment system	Values in days	Best fit model	Type of endpoint and comments
Red Oak Stream	System	$DegT_{50}$ = 8.24 $DegT_{90}$ = 27.38	HS-SFO	System degradation endpoint
	Water	DT_{50} = 14.16 DT_{90} = 47.05	SFO	Water decline endpoint
	Sediment	DT_{50} = 11.62 DT_{90} = 38.61	SFO	Sediment decline endpoint
Town Park Pond	System	$DegT_{50}$ = 5.67 $DegT_{90}$ = 18.84	SFO-SFO	System degradation endpoint
	Water	DT_{50} = 6.50 DT_{90} = 21.58	SFO	Water decline endpoint
	Sediment	DT_{50} = 5.15 DT_{90} = 28.10	HS	Sediment decline endpoint

2.7.3 Summary of fate and behaviour in air

Neither oxamyl nor any of its principal degradation products have significant volatility. The vapour pressure of oxamyl is 1.80×10^{-5} Pa at 20°C Pa. There is no guidance currently available for conducting meaningful studies regarding the potential breakdown of oxamyl or its degradation products in air.

Further, the Henry's law constant of oxamyl is less than 3×10^{-2} Pa-m^3/mol, suggesting little potential for volatilisation in the environment. Henry's law constants below this value show that the compound is less volatile than water and can be considered essentially non-volatile.

Given that oxamyl is non-volatile by virtue of its very low vapour pressure and calculated Henry's Law constant, only negligible quantities would be transferred to the troposphere. These negligible quantities would then undergo rapid photochemical oxidative degradation (half-life = 5.68 hours), and therefore, oxamyl does not have the potential for long range transport in air.

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

National groundwater monitoring data from the Environmental Agency in England and Wales has been compiled for oxamyl, considering different sites in England and Wales (from 2005 through 2011). Two position papers analyse the vulnerability of these monitoring sites with respect to the site hydrology, soil pH, and the

environmental properties of oxamyl. The results demonstrate that many of the sampling boreholes can be classified as vulnerability for oxamyl leaching from potato uses. In particular, soil pH at the monitoring sites was analysed since the rapid hydrolytic degradation of oxamyl does not occur in acidic soils. However, the data from the monitoring database clearly illustrate that significant levels of oxamyl were not detected at any of the identified vulnerable sampling sites. Thus, these monitoring data demonstrate that the risk of oxamyl leaching to groundwater following typical use on potatoes in the U.K. regions is low and not pH dependent.

2.7.5 Definition of the residues in the environment requiring further assessment

The environmental metabolites assessed for relevance were IN-A2213, IN-N0079, IN-D2708, IN-T2921, and IN-SBY69. The metabolites IN-A2213, IN-N0079, and IN-D2708 were assessed for relevance in soil, while IN-A2213, IN-N0079, IN-D2708, IN-T2921, and IN-SBY69 were assessed for relevance in surface water. In groundwater, the significance of modelled environmental concentrations of IN-A2213, IN-N0079, and IN-D2708 were considered. With regard to the air compartment, no metabolites needed to be considered for relevance because of lack of volatility. The reasons for choosing metabolites for assessment of relevance are outlined below, for each environmental compartment. Then the metabolites are assessed, on a case by case basis, for relevance in the environmental compartments where there may be present.

Selection of metabolites for assessment of relevance in soil.

On the basis of the described soil metabolism studies, the primary route of degradation for oxamyl is *via* microbial decomposition and hydrolysis to form IN-A2213, which is further microbially degraded to IN-D2708 and then rapid mineralization to CO_2 and bound residue. In the presence of light, oxamyl can also undergo a photocatalysed, iron-mediated conversion to IN-N0079 as an additional minor degradation route. Degradation *via* this alternate, light-mediated route does also proceed to formation of IN-D2708, which can then undergo microbial mineralization.

In general, carbon dioxide was the principal degradation product. It was detected in the primary laboratory aerobic soil metabolism study at levels up to 108.5% of applied radioactivity. IN-A2213 was detected in the laboratory aerobic soil metabolism studies at levels up to 51% of applied radioactivity, and in the laboratory anaerobic soil metabolism study at levels up to 69.5% AR. The metabolite IN-D2708 was also a prominent soil metabolite, being detected in the laboratory aerobic soil metabolism studies, the anaerobic soil study, and the soil photolysis study at maximum levels of 78.0, 23.1, and 45.4% of applied radioactivity respectively. The metabolite IN-N0079 was not observed in any laboratory aerobic or anaerobic soil study, but was a major metabolite in the soil photolysis study (max 10.2% AR).

Selection of metabolites for assessment of relevance in water

The results of the experimental investigations on the fate and behaviour of oxamyl in water indicate that oxamyl is readily hydrolysed to IN-A2213 in neutral and basic waters. Based on its lack of absorbance above 290 nm, oxamyl does not undergo direct photolysis, but the results of the laboratory aqueous photolysis demonstrate that oxamyl can be transformed to IN-N0079 in the presence of dissolved ferrous iron (Fe^{2+}); this catalytic reaction however, is only favourable under reductive conditions. In the water/sediment studies, oxamyl degraded rapidly in the water phase (<50% remaining on day 1), and significant amounts were never found in the sediment phase. The hydrolysis product, IN-A2213, reached a maximum of 25.3–48.8% AR in the water phase on Day 2 and then decreased to non-detectable levels by Day 61. Low levels were found in the sediments (max. 4.4%), and the pattern reflected that observed in the water phase. In one system, high levels of IN-N0079 (maximum 52.9% at Day 2) were observed in the water phase, and the pattern of formation and decline was parallel to that of IN-A2213. As discussed above, the rapid appearance of significant amounts of IN-N0079 was likely due to the Fe^{+2}-oxamyl reduction reaction with Fe^{+2} near or within the anaerobic sediment phase. Following the decline of the IN-A2213 and IN-N0079, levels of IN-D2708 in the water subsequently rose (maximum 64.2-66.8% at Day 30) and then declined during the remainder of the study. Low levels of IN-D2708 (maximum 10.4–12.1%) were observed in the sediment, and the pattern of occurrence of this sediment residue coincided with the maximum level of IN-D2708 in the water phase, suggesting a simple gradient diffusion of IN-D2708 from the water phase into the sediment pore water in the static test system. In one system only, levels of IN-T2921 exceeded 10% in the water phase. However, this was only at one time point (Day 14); the maximum level was only 11.4%, and subsequent degradation was rapid (not detected at the next time point, Day 30). Therefore, IN-T2921 is not considered relevant for surface water risk assessment. Amounts of carbon dioxide evolved reached 27.9–60.9%

by the end of the study. In anaerobic water/sediment systems, oxamyl degraded similarly as in the aerobic system, with IN-A2213, IN-N0079, and IN-D2708 being the major transformation products. In one sediment system under anaerobic conditions, IN-SBY69 was observed as an additional transition metabolite. This metabolite is formed *via* cysteine conjugate cyclization of IN-N0079. It is believed that IN-SBY69 was observed in the anaerobic water/sediment study only because the anaerobic conditions create a reductive environment that favours the Fe^{+2}-oxamyl reduction reaction that produces its precursor, IN-N0079. Thus, this metabolite (IN-SBY69) was only present at major, observable levels because of the drastically increased levels of IN-N0079 formed in this one anaerobic sediment system. In typical water/sediment systems, such high levels of IN-N0079 are not expected to form, and thus only minor, if any, levels of IN-SBY69 can be expected to occur in the environment. Therefore, IN-SBY69 is not considered relevant for risk assessment.

Selection of metabolites for assessment of relevance in air

Given that oxamyl is non-volatile by virtue of its very low vapour pressure and calculated Henry's Law, no metabolites were considered for relevance in air.

2.7.6 Summary of exposure calculations and product assessment

2.8 Effects on non-target species

2.8.1 Summary of effects on birds and other terrestrial vertebrates

Table 265 Summary of avian toxicity endpoints for oxamyl, Oxamyl 10GR and Oxamyl 10SL

Toxicity study (species)	Test substance	LD_{50} or LC_{50}	NOEL or NOEC	Reference
Acute oral (mallard)	Oxamyl	3.16 mg a.s./kg bw	1.0 mg a.s./kg bw	HLO 89-81
Acute oral (northern bobwhite)	Oxamyl	9.5 mg a.s./kg bw	0.8 mg a.s./kg bw	DuPont-2954
Acute oral (northern bobwhite)	Oxamyl 10GR	12.5 mg a.s./kg bw	1.0 mg a.s./kg bw	DuPont-2955[b]
Acute oral (northern bobwhite)	Oxamyl 10SL	11.0 mg a.s./kg bw	1.0 mg a.s./kg bw	DuPont-2956[c]
Short-term dietary (mallard)	Oxamyl	96.6 mg a.s./kg bw (766 mg a.s./kg feed)	<78 mg a.s./kg feed	HLO 48-88
Short-term dietary (northern bobwhite)	Oxamyl	85 mg/kg bw (340 mg a.s./kg feed)	39 mg a.s./kg feed	HLO 47-88
Subchronic and reproductive (mallard)	Oxamyl	Not calculated	1.5 mg a.s./kg bw/day (10 mg a.s./kg feed)	HLO 337-82
Subchronic and reproductive (northern bobwhite)	Oxamyl	Not calculated	4.36 mg a.s./kg bw/day (50 mg a.s./kg feed)	HLO 453-82

Table 276 Summary of mammal toxicity endpoints for oxamyl and Oxamyl 10GR

Toxicity study (species)	Test substance	LD_{50} or LC_{50} (mg a.s. or metabolite/kg bw/day)	Lowest lethal dose (mg oxamyl/kg bw/day)	NOEL or NOEC (mg oxamyl/kg bw/day)	Reference
Acute oral (rat)	oxamyl	3.1 (males) 2.5 (females)	2.5	<1.0	DuPont-26931[a]
Acute oral (rat)	Oxamyl 10GR	4.3 (males) 3.4 (females)	3.5	2.2	DuPont-2703[b]
Acute oral (rat)	IN-A2213	ALD = 11000	11000	90	HLR 300-68[c]
Acute oral (rat)	IN-D2708	LD_{50} = 3540	5000	Not given	HLR 399-72[c]
Acute oral (rat)	IN-L2953	LD_{50} = 6675	4000	<4000	HLR 126-73[c]
Acute oral (rat)	IN-N0079	ALD = 450	450	Not given	HLR 585-74[c]
Subchronic and reproductive (rat)	oxamyl	Not applicable	5.43 (150 mg a.s./kg feed)	1.43 (25 mg a.s./kg feed)	HLR 423-90[c]

a Study summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU
b Study summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10GR, DuPont-40954 EU

b Study summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10SL, DuPont-42130 EU

2.8.2 Summary of effects on aquatic organisms

Aquatic toxicity endpoints

A summary of the aquatic toxicity testing values obtained with oxamyl, its metabolites, Oxamyl 10GR, and Oxamyl 10SL is included below.

Table 28 Oxamyl aquatic toxicity endpoint values

Species	Test/duration	Measurement endpoint	Endpoint value (mg a.s./L)	Reference[a]
Rainbow trout	acute (96 h)	LC_{50}	3.13	DuPont-2907
Bluegill sunfish	acute (96 h)	LC_{50}	6.12	DuPont-2908
Daphnia magna	acute (48 h)	EC_{50}	0.319	DuPont-2553
Pseudokirchneriella subcapitata[b]	data gap			
Lemna gibba	chronic (7-d)	EC_{50}	1.670	DuPont-34272
Chironomus tentans	acute (48 h)	LC_{50}	0.350	DuPont-37400
Chimarra atterima	acute (48 h)	LC_{50}	0.096	DuPont-37402
Centroptilum triangulifer	acute (48 h)	LC_{50}	0.067	DuPont-37401
Hyalella azteca	acute (48 h)	LC_{50}	0.320	DuPont-37397
Ceriodaphnia dubia	acute (48 h)	EC_{50}	0.094	DuPont-37399
Americamysis bahia	acute (48 h)	LC_{50}	0.0465	DuPont-34271
Crassostrea virginica	acute (96 h)	EC_{50}	27.5	DuPont-34273
Fathead minnow	early life stage (28d)	NOEC	0.500 supportive	HLR 877-81
Sheepshead minnow	early life stage (29 d)	NOEC	0.356	DuPont-34270
Daphnia magna	chronic (21 d)	NOEC	0.0268	DuPont-2554
Americamysis bahia	chronic (28 d)	NOEC	0.0189	DuPont-34269

[a] Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU

[b] Formerly known as *Selenastrum capricornutum*.

A summary of the aquatic toxicity testing values obtained with the metabolites of oxamyl is included below.

Table 28 Aquatic toxicity endpoint values for the metabolites of Oxamyl

Metabolite	Species	Test/duration	Measurement endpoint	Endpoint value (mg met/L)	Reference[a]
IN-A2213	Rainbow trout	acute (96 h)	LC_{50}	>132	DuPont-2500
	Daphnia magna	acute (48 h)	EC_{50}	>125	DuPont-2502
	Pseudokirchneriella subcapitata[b]	acute (72 h)	EC_{50}	>122 supportive	DuPont-2505
IN-D2708	Rainbow trout	acute (96 h)	LC_{50}	93.8 supportive	DuPont-2507
	Daphnia magna	acute 48 h)	EC_{50}	>134	DuPont-2510
	Pseudokirchneriella subcapitata[b]				
	Daphnia magna	chronic (21 d)	NOEC	66.1	DuPont-3909
IN-N0079	Rainbow trout	acute (96 h)	LC_{50}	22.4	DuPont-2512
	Daphnia magna	acute (48 h)	EC_{50}	>128	DuPont-2513
	Pseudokirchneriella subcapitata[b]				
IN-T2921	Rainbow trout	acute (96 h)	LC_{50}	>127	DuPont-4439
	Daphnia magna	acute (48 h)	EC_{50}	>123	DuPont-4441
	Pseudokirchneriella subcapitata[b]	acute (72 h)	EC_{50}	>113	DuPont-4442

[a]Studies summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU
[b]Formerly known as *Selenastrum capricornutum*.

Acute toxicity of Oxamyl 10SL to aquatic organisms

Test species	Test duration	Test conc.[a]	Effect endpoint	50% effect conc. (mg f.p./L)	50% effect conc. (mg a.s./L)	Effect parameter	Reference[b]
Rainbow trout	acute (96 h)	M	LC_{50}	27	2.70	Mortality	DuPont-2910
Bluegill sunfish	acute (96 h)	M	LC_{50}	51	5.10	Mortality	DuPont-2911
Daphnia magna	acute (48 h)	M	EC_{50}	3.0	0.30	Immobility	DuPont-2556
Pseudokirchneriella subcapitata	data gap						

[a]M = Measured concentration; N = Nominal concentration.[b]

Acute of Oxamyl 10GR to aquatic organisms

Test species	Test duration	Test conc.[a]	Effect endpoint (mg/L)	50% effect conc. (mg a.s./L)	Effect parameter	Reference[c]
Rainbow trout	acute (96 h)	N	LC_{50}	3.6	Mortality	DuPont-2912
Bluegill sunfish	acute (96 h)	N	LC_{50}	4.7	Mortality	DuPont-2913
Daphnia magna	acute (48 h)	N	EC_{50}	0.33	Immobility	DuPont-2555
Pseudokirchneriella subcapitata	data gap					

[a] M = Measured concentration; N = Nominal concentration (analytically confirmed)
[b] Biomass is lowest value
[c] Study summarised in this document

2.8.2.1 Endocrine disrupting properties

Two studies with vertebrates (amphibians and fish) were conducted with oxamyl active substance at the request of the United States Environmental Protection Agency to assist in development of the U.S. EPA Endocrine Disruption Screening and Testing Program and are summarized below. From the screening Amphibian Metamorphosis Assay (AMA) with the frog *Xenopus laevis* there are no clear evidence the oxamyl may interfere with the normal function of the hypothalamic-pituitary-thyroid (HPT) axis. Apical endpoints are not affected, but the incidence and severity of the recorded follicular cell hypertrophy found in tyroid hystopatology might represent an indicator of hormonal activity as a possible treatment related effect cannot be excluded with certainty. Therefore the possible interference with the normal function of the hypothalamic-pituitary-thyroid (HPT) axis should be further addressed. In this respect, the RMS highlights that, looking at the Human health section of this DAR, the complete data package support the conclusion that oxamyl is not an endocrine disrupter. According to OECD guidance 150 (Table C.3.6), a longer-term amphibian test would be the next step which could be taken in case the indicators of hormonal activity are positive with "Strong evidence for in vivo thyroid activity in amphibians". In the available AMA study, the relevance of the recorded follicular cell hypertrophy is debatable.

The 21d fish short term reproduction assay (OPPTS 890.1350 (2009) resulted in no effect for apical endpoints or indicators related to endocrine disruption. This test (according to OECD 229) is proposed as Level 3 test in the OECD conceptual framework (Guidance document on standardised test guideline for evaluating chemicals for endocrine disruption, N° 150, 2012).

2.8.3 Summary of effects on arthropods

Oxamyl, Oxamyl 10GR, and Oxamyl 10SL toxicity endpoint values on beneficial arthropods are summarised below.

Table 29 Oxamyl, Oxamyl 10GR, and Oxamyl 10SL toxicity endpoint values on beneficial arthropods including other terrestrial invertebrates

Species	Test (test substance)	Measurement endpoint	Endpoint value	Reference[a]
Apis mellifera	48-hr Oral (oxamyl)	LD_{50}	0.38 µg a.s./bee	DuPont-2740
Apis mellifera	48-hr Contact (oxamyl)	LD_{50}	0.47 µg a.s./bee	DuPont-2740
Apis mellifera	48-hr Oral (Oxamyl 10SL)	LD_{50}	0.26 µg a.s./bee	DuPont-2718[b]
Apis mellifera	48-hr Contact (Oxamyl 10SL)	LD_{50}	0.23 µg a.s./bee	DuPont-2718[b]
Apis mellifera	10-d adult oral (oxamyl)	LD_{50} NOED	0.14 µg a.s./bee 0.07µg a.s./bee	DuPont-39665
Apis mellifera	72-hr larvae (oxamyl)	LD_{50} NOED	0.81 µg a.s./ larva/d 0.18µg a.s./ larva/d	DuPont-39678
Bombus terrestris	48-hr Oral (oxamyl)	LD_{50}	0.36 µg a.s./bee	DuPont-39670
Bombus terrestris	48-hr Contact (oxamyl)	LD_{50}	39.3 µg a.s./bee	DuPont-39670
Typhlodromus pyri	Oxamyl 10SL Glass plate dose response (14 d)	7 d LR_{50} 7 d LR_{30} 30% effect on reproduction	1.8 g oxamyl/ha 1.0 g oxamyl/ha >0.8 g a.s/ha Supportive information	DuPont-4037
Extended Laboratory tests				
Aphidius rhopalosiphi			Not reliable	
Typhlodromus pyri			Not reliable	
Additional species				
Aleochara bilineata	Laboratory Tier 2 Oxamyl 10L (0, 1.5, 2, 2.5, 3 mg a.s./kg dry soil) (LUFA 2.1 soil)	7-d Mortality: 28d Reduction in reproduction (versus control):	2.50,3.75,1.25,0.0% 9.0,10.4,21.9,29.3%	
Poecilus cupreus	Laboratory Tier 2 Oxamyl 10L (3.3 and 33 mg a.s./kg dry soil)	14-d Corrected mortality: Reduction in food consumption(versus control):	6.7, 10% -7.4, -6.7%	
Pardosa spp.	Laboratory Tier 2 Oxamyl 10L (2, 4, 6 mg a.s./kg dry soil)	21-d Corrected mortality: Mean feeding rate (flies/spider/day): % reduction in feeding rate (versus control)	8.8%, 35.3%, 35.3% 3.7, 3.4, 3.4, 3.0 (Control), 4.4 (toxic standard) -23.3, -13.3, -13.3,	
Pardosa spp.	Laboratory Tier 2 Oxamyl 10L (7,15,23 mg a.s./kg dry soil)	14-d Corrected mortality: Reduction in mean feeding rate (flies/spider/day):	52, 100,100% 4.3, 30.4, 52.2 %	

Aleochara bilineata	Oxamyl 10GR (3.85 mg oxamyl/kg dry soil) Tier 2 (LUFA 2.1 soil)	7 d mortality: 0 d aged soil 7 d aged soil 14 d aged soil 28 d aged soil Reduction in reproduction: 0 d aged soil 7 d aged soil 14 d aged soil 28 d aged soil LR50/ER50 for reproduction (EC50)	 0% 2.5% 0% 0% 40.4% 31.8% 24.6% 13.4% >3.85 mg a.s./kg dws (55 kg prod./ha)
Poecilus cupreus	Oxamyl 10GR (3.85 mg oxamyl/kg dry soil) Tier 2 (LUFA 2.1 soil)	14-d corrected mortality Reduction in Feeding rate (relative to controls) LR50/ER50 for feeding rate	0% -41.4% >3.85 mg a.s./kg dws (55 kg prod./ha)
Pardosa spp.	Oxamyl 10GR (3.85 mg oxamyl/kg dry soil) Tier 2 (LUFA 2.1 soil)	21 d mortality 21 d Reduction in feeding rate LR50/ER50 for food consumption (EC50)	17% 4.3% >3.85 mg a.s./kg dws (55 kg prod./ha)

2.8.4 Summary of effects on non-target soil meso- and macrofauna

Oxamyl, Oxamyl 10GR, and Oxamyl 10SL toxicity endpoint values for earthworms and soil macro organisms are summarised below.

Table 30 Toxicity endpoint values for non-target soil meso- and macrofauna

Test organism	Test substance	Time scale	Endpoint	Toxicity
Earthworms				
Eisenia fetida	Oxamyl	Acute, 14 d	LC_{50}	112 mg a.s./kg dry wt soil
Eisenia fetida	Oxamyl 10GR	Acute, 14 d	LC_{50}	>100 mg a.s./kg dry wt soil
Eisenia fetida	Oxamyl 10GR	Sub-lethal, 56 d	NOEC	6.4 mg a.s./kg dry wt soil
Eisenia fetida	Oxamyl 10SL	Sub-lethal, 56 d	NOEC	3.2 mg a.s.
Eisenia fetida	IN-A2213	Acute, 14 d	LC_{50}	>1000 mg met/kg dry wt soil
Eisenia fetida	IN-A2213	Sub-lethal, 56 d	NOEC EC_{10}	25 mg met/kg dry wt soil 26.6 mg met/kg dry wt soil
Eisenia fetida	IN-D2708	Acute, 14 d	LC_{50}	>1000 mg met/kg dry wt soil
Eisenia fetida	IN-D2708	Sub-lethal, 56 d	NOEC	100 mg met/kg dry wt soil
Eisenia fetida	IN-N0079	Acute, 14 d	LC_{50}	640 mg met/kg dry wt soil
Eisenia fetida	IN-N0079	Sub-lethal, 56 d	NOEC	50 mg met/kg dry wt soil
Other soil macro-organisms				
Folsomia candida	Oxamyl	Sub-lethal, 28 d	NOEC EC_{10}	0.25 mg a.s/kg dry wt soil 0.435 mg a.s/kg dry wt soil
Folsomia candida	IN-A2213	Sub-lethal, 28 d	NOEC EC_{10}	100 mg met/kg dry wt soil >100 mg met/kg dry wt soil
Folsomia candida	IN-D2708	Sub-lethal, 28 d	NOEC EC_{10}	100 mg met/kg dry wt soil Not calculable
Folsomia candida	IN-N0079	Sub-lethal, 28 d	NOEC EC_{10}	12.5 mg met/kg dry wt soil To be calculated
Hypoaspis aculeifer	Oxamyl	Sub-lethal, 14 d	NOEC EC_{10}	16 mg a.s/kg dry wt soil Not calculable
Hypoaspis aculeifer	IN-A2213	Sub-lethal, 14 d	NOEC EC_{10}	100 mg met/kg dry wt soil Not calculable
Hypoaspis aculeifer	IN-D2708	Sub-lethal, 14 d	NOEC EC_{10}	100 mg met/kg dry wt soil Not calculable
Hypoaspis aculeifer	IN-N0079	Sub-lethal, 14 d	NOEC EC_{10}	25 mg met/kg dry wt soil 38.71 mg met/kg dry wt soil

2.8.5 Summary of effects on soil nitrogen transformation

The summary of soil microflora toxicity endpoints for Oxamyl 10GR, Oxamyl 10SL, and soil metabolites is included below.

Table 291 Effects of Oxamyl 10GR, Oxamyl 10SL, and soil metabolites on non-target soil microorganisms

Test design[a]	Test substance	Endpoint value Nitrate formation rate (mg/kg soil d.w./d)	Reference
28-day R + N	Oxamyl	<25% effect at doses of 12.0 and 60.0	RF-0014.218.286.07
56-day	Oxamyl 10GR	Not valid	
28-day R + N	Oxamyl 10SL	<25% effect at doses of 1.5 and 15 Kg a.s./ha and 23 mg a.s/Kg soil dw	DuPont-4114
56-day R + N	IN-A2213	<25% effect at doses of 4.9 >25% effect at doses of 49	DuPont-DuPont-4131
28-day R + N	IN-D2708	Not valid	DuPont-4133
28-day[c] R + N	IN-N0079	<25% effect at doses of 3.0, 15 >25% effect at doses of 30	DuPont-4135
28-day[c] R + N	IN-T2921	Not reliable	DuPont-4736

[a] N = Nitrogen transformation, R = Respiration.

2.8.6 Summary of effects on terrestrial non-target higher plants

Summaries of the seedling emergence and vegetative vigour studies performed with the spray formulation Oxamyl 24L (as surrogate worst-case of representative formulations) had been submitted and evaluated.

Exposure of non-target plant to Oxamyl 24L is considered a worst-case scenario and elicit greater responses compared to Oxamyl 10SL. Effects on vegetative vigour following a foliar application to seedlings were assessed and are summarised in the table below.

Table 32 Effects of Oxamyl 24SL on thenon target-terrestrial plants

Species	Genus/species	ER_{50} (kg a.s./ha)[a]	Reference
Seedling emergence (soil application)			
Corn	*Zea mays*	>2.24	DuPont-5817 Additional information
Oat	*Avena sativa*	>2.24	
Onion	*Allium cepa*	>2.24	
Sorghum	*Sorghum bicolor*	>2.24	
Cucumber	*Cucumis sativus*	>2.24	
Oilseed Rape	*Brassica napus*	>2.24	
Pea	*Pisum sativum*	>2.24	
Soybean	*Glycine max*	>2.24	
Sugar Beet	*Beta vulgaris*	>2.24	
Tomato	*Lycopersicon esculentum*	>2.24	
Vegetative vigour (foliar application)			
Corn	*Zea mays*	>2.24	DuPont-34275 Supportive information
Oat	*Avena sativa*	>2.24	
Onion	*Allium cepa*	>2.24	
Perennial Ryegrass	*Lolium perenne*	>2.24	
Cucumber	*Cucumis sativus*	>2.24	
Pea	*Pisum sativum*	>2.24	
Oilseed Rape	*Brassica napus*	>2.24	
Soybean	*Glycine max*	>2.24	
Sugar Beet	*Beta vulgaris*	>2.24	
Tomato	*Lycopersicon esculentum*	>2.24	

[a] Oxamyl 24SL nominally contains 24% a.s.

2.8.7 Summary of effects on other terrestrial organisms (flora and fauna)

A study evaluating effects on other terrestrial organisms (flora and fauna) was conducted with test materials IN-A2213 technical metabolite, IN-D2708 technical metabolite, IN-N0079 technical metabolite, and IN-T2921 technical metabolite. Guidelines were not given. A review of this study indicates that there is no current guideline number for an insecticide activity screening study.

In conclusion, the metabolites IN-A2213, IN-D2708, IN-N0079 IN-T2921 did not show insecticidal acitivity on the five insect species (*Peregrinus maidis, Teranicus urticae, Myzus persicae, Spodoptera frugiperla*, and *Diabrotica undecimpuntata*).

2.8.8 Summary of effects on biological methods for sewage treatment

A study on effects of biological methods for sewage treatment was conducted under guideline OECD 209 (1984) with test material pure oxamyl (PAI), which indicates a LC50> 100mg/L. A quantitative risk assessment with the PEC for STP should be submitted.

2.8.9 Summary of product exposure and risk assessment

Bird and mammal risk assessment:

Bird risk assessment

Oxamyl 10GR

For the proposed uses of Oxamyl 10GR, the TER_a and TER_{lt} derived for oxamyl at rates based on the maximum rate of the formulated product have been calculated. Different scenarios have been assessed to evaluate risk of Oxamyl 10GR to birds according to the EFSA guideline (2009), whose conclusions are summarized below.

Avian risk assessment conclusion

Scenario assessed	Conclusion
Birds ingesting granules as a food source	Due to the low nutritional status it is considered unlikely that the granules will be actively sought by birds. Other routes of exposure are considered more important.
Birds ingesting granules as grit	Small birds: For in-furrow application to potato, TERa and TERlt are > trigger values, indicating risks are acceptable in the main field. The Applicant should address the risk also at the row ends. The in-furrow and broadcast applications to tobacco indicate unacceptable risk. A low number of granules present on the soil surface would be sufficient to achieve TERa and TERlt < trigger values, i.e. >10 and >4.3 granules/m^2. It is arguable if current agricultural practice can reach such levels of granule incorporation. The available field studies monitored lethal and sublethal effects after in-furrow application of 2.0 kg a.s./ha and broadcast application of 5.5 kg a.s./ha only up to 48 hours, hence the conclusions of absence of effects might be not fully supported. These studies were evaluated during the previous EU peer review and should be re-evaluated by the RMS upon submission of the studies reports. In conclusion, for use in tobacco in furrow 3 kg a.s./ha and tobacco broadcast 5.5 kg a.s./ha, the chronic risk to birds taking granules as grit remain to be addressed. Large birds: Acceptable risk because granules are smaller than the size that would be taken by large birds (2-6 mm).
Birds ingesting granules as seed	Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. They do not resemble seeds and would not be ingested by birds as a source of food. No risk assessment is required.
Birds ingesting soil-contaminated food	TER_a and TER_{lt} are >trigger values, indicating risks are acceptable.
Birds consuming food contaminated with a.s. residues – emergent weed seedlings	Not relevant to the risk assessment
Birds consuming food contaminated with a.s. residues – contaminated earthworms	TERacute are > trigger value for potato scenario indicating risks are acceptable. For the tobacco scenarios TER < trigger indicating potential risk. Higher tier field studies (evaluated during the previous EU peer review) documented the lack of acute effects within 48 hours after in-furrow application of 2.0 kg a.s./ha and broadcast application of 5.5 kg a.s./ha, supporting a conclusion of safe use at each application rate. This conclusion has to be confirmed upon submission and re-evaluation by the RMS. The results might have a margin of uncertainty due to the short observation time.

Birds consuming food contaminated with a.s. residues – soil residue bioconcentration in earthworms	Exposure calculated with measured worm BAF. TERlt are >trigger value for potato scenario (risk acceptable). TERlt based on initial PECsoil are < trigger for the in-furrow and broadcast tobacco scenarios (risks not acceptable). Refinement needed for these scenarios. .
Birds consuming water contaminated with a.s. residues	Exposure refined with FOCUS Step 3 PEC_{sw}. TER_a and TER_{lt} are >trigger values, indicating risks are acceptable.

Oxamyl 10SL

Oxamyl 10SL will be used within enclosed spaces (glasshouses). In closed glasshouse, birds are considered to be not exposed to residues of the formulated product, the active substance oxamyl, or its metabolites. The conclusion of no risk is acceptable only if application of the product is made in closed glasshouse.

Mammal risk assessment

Oxamyl 10GR

For the proposed uses of Oxamyl 10GR, the TERa and TERlt derived for oxamyl at rates based on the maximum rate of the formulated product have been calculated. Different scenarios have been assessed to evaluate risk of Oxamyl 10GR to mammals according to the EFSA guideline (2009), whose conclusions are summarized below.

Mammal risk assessment conclusions for mammals exposed to Oxamyl 10GR

Scenario assessed	Conclusion
Mammals ingesting granules as a food source	Due to the low nutritional status it is considered unlikely that the granules will be actively sought by mammals. Other routes are considered more important.
Mammals ingesting granules as seed	Not relevant for mammals
Mammals ingesting granules when eating soil-contaminated food	TER_a and TER_{lt} are >trigger values, indicating risks are acceptable.
Mammals consuming food contaminated with a.s. residues – emergent weed seedlings	Not relevant to the risk assessment
Mammals consuming food contaminated with a.s. residues – contaminated earthworms	The acute risk assessment for the general focal species “shrew” has not been presented and should be submitted.
Mammals consuming food contaminated with a.s. residues – soil residue bioconcentration in earthworms	For the potato and tobacco broadcast scenarios TERlt are >trigger value, indicating risks are acceptable. For tobacco in-furrow scenario a refinement should be submitted.
Mammals consuming water contaminated with a.s. residues	TER_a and TER_{lt} are >trigger values, indicating risks are acceptable.

Oxamyl 10SL

Oxamyl 10SL will be used within enclosed spaces (glasshouses). In closed glasshouse, birds are considered to be not exposed to residues of the formulated product, the active substance oxamyl, or its metabolites. The conclusion of no risk is acceptable only if application of the product is made in closed glasshouse. Risk assessment for aquatic organisms.

Risk assessment for aquatic organisms

Oxamyl 10GR

For the proposed uses of Oxamyl 10GR, the TER_a and TER_{lt} derived for oxamyl at rates based on the maximum rate of the formulated product have been calculated and reported in detail in the LOEP. Hereunder the conclusions for all the aquatic taxa are reported.

Fish: for all the uses proposed the acute and chronic risk to fish are acceptable when PECsw values calculated with FOCUS Step 3a-c modelling are used.

Invertebrates: based on the *Daphnia magna* EC50 = 319 µg a.s./L, it is concluded that the uses of Oxamyl 10GR in Potatoes 1 x 1000 g a.s./ha and Tobacco, 1 x 3000 g a.s./ha are safe upon acute exposure without the implementation of mitigation measures, while use in Tobacco broadcast at 1 x 5500 g a.s./ha requires the application of a 20m NSZ in order to achieve an acceptable acute risk. The acute risk to *Daphnia magna* is considered to cover also the risk to the other (most sensitive) invertebrate species for which data are available. The chronic risk *Daphnia magna* is acceptable for use in Tobacco, 1 x 3000 g a.s./ha g a.s./ha. For use in Potatoes 1 x 1000 g a.s./ha, a NSZ of 10 m should be implemented. For use in Tobacco broadcast 1 x 5500 g a.s./ha, a NSZ of 25 m is needed to achieve an acceptable chronic risk.

Algae: For oxamyl, oxamyl GR and metabolites IN-D2708 and IN-N0079, a data gap is concluded, hence the risk assessment cannot be carried out. For the water metabolites IN-A2213 and IN-T2921, the risk is acceptable.

Macrophytes (Lemna): for all the uses proposed, the risk to Macrophytes is acceptable.

Oxamyl 10SL

For the proposed uses of Oxamyl 10SL (Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha, and Solarisation 1 x 5500 g a.s./ha), the TER_a and TER_{lt} derived for oxamyl at rates based on the maximum rate of the formulated product have been calculated and reported in detail in the LOEP. Hereunder the conclusions for all the aquatic taxa are reported.

Fish: for all the uses proposed the acute risk to fish is acceptable when PECsw values calculated with FOCUS Step 2-3a modelling are used, while for chronic toxicity the TERs are above the trigger using PECsw at FOCUS Step 3a.

Invertebrates: Acceptable acute and chronic risk to *Daphnia magna* are calculated upon use of PECsw at Step a-d. At these exposures, also acute risk to the most sensitive crustacean species *Americamysis bahia* is concluded low.

Algae: The risk that Oxamyl 10SL poses to algae species cannot be assessed because reliable data are missing. For the metabolites IN-A2213 and IN-T2921 the risk is acceptable. For the metabolites IN-D2708 and IN-N0079 reliable data are not available, hence the risk cannot be assessed (see Table 34).

Macrophytes (Lemna): The calculated Step-3a PECsw values resulted in acceptable TER for Lemna. **Risk assessment for effects on non-target arthropods**

Oxamyl 10GR

Oxamyl 10GR is a nematicide for use in potatoes and tobacco as a single application in-furrow of 1000 g a.s./ha at planting and 3000 g a.s./ha at planting (BBCH 00), respectively, and in tobacco as evenly incorporated into soil depth of at least 10 cm after broadcast application at a rate of 5500 g a.s./ha at pre-planting (BBCH 00).. No flowering plants are to be expected during application within the treated field since granules are directly applied into bare soil *via* in-furrow and broadcast application at, respectively, pre-planting and transplanting of the crops.

Risk to honey bees:

For the exposure scenario “dust drift in field margin”, the risk is acceptable. For plants in soil-treated field, an unacceptable risk for oral acute and chronic exposure of adults and for the oral chronic exposure of larvae is concluded. With the purpose of refinement of risk in soil-treated field, the Applicant submitted a semi-field study with honey bees exposed to Phacelia tanacetifolia treated with Oxamyl 10GR (DuPont-39667) carried out according to OECD guidance document No. 75 (2007). The study is judged not reliable. In addition, semi-field studies are considered of limited use against the protection goals identified in EFSA (2013), due to the limited size of colonies (overwintering information not recorded) and short duration (two brood cycles not covered).

Risk to bumble bees:

For the exposure scenario "dust drift in field margin", the risk is acceptable. For the scenario "plants in soil-treated field", unacceptable risk upon acute exposure to bumblebees is concluded.

For the refinement of risk in soil-treated field with in-furrow application, the Applicant submitted a semi-field study with bumblebees (DuPont-39666). The biological results of this study were judged not valid. In addition, semi-field studies are considered of limited use against the protection goals identified in EFSA (2013), due to the limited size of colonies (overwintering information not recorded) and short duration (two brood cycles not covered). Anyhow data on residues from this study could be used for the risk refinement. For the refinement of risk upon broadcast application, the proposed extrapolation of the results of the field test with honey bees to bumblebees, based on a similar acute sensitivity to oxamyl, is not straightforward because of the higher food consumption of bumble bees. The low risk to bumble bees is not demonstrated.

In conclusion:

Although it is acknowledged that the EFSA Bee Guidance Document (2013) is not yet in force, it was agreed at the Pesticides Peer Review Expert Meeting 133 (September, 2015) that it should be used at least for the first tier scheme and the general principles for the higher tier. For all the proposed uses, the Applicant should submit a revised risk assessment according to the EFSA Bee Guidance Document (2013) (for the first tier), taking into account the comments made by the RMS.

As for non-target arthropods, reliable toxicity endpoints are not available for the two standard species *A. rhopalosiphi* and *T. pyri,* hence a unacceptable risk is assumed. The extended laboratory studies conducted with the soil-dwelling arthropods *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa spp*., have been usedto refine the in-field risk assessment of non-target arthropods, taking into account that in-field exposure to foliage-dwelling arthropods is considered unlikely during the application of the product. According to the proposed use pattern, soil-dwelling arthropods are mainly exposed to Oxamyl 10GR below ground, which is already considered in the exposure regime of the extended laboratory studies with *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp. All soil arthropod species showed acceptable risk by ER_{50} (EC_{50}) at >55 kg Oxamyl 10GR/ha (38.5 mg Oxamyl 10GR/kg dry weight soil). Predicted environmental concentrations were generated to simulate applications of oxamyl to potatoes or tobacco in the EU. The predicted soil concentrations (PEC_s) of oxamyl were determined based upon the recommendations of the FOCUS group. A summary of the predicted environmental concentrations in soil for oxamyl in comparison with the relevant EC_{50} for non-target arthropod species is provided in the table below.

Tier 2 in-field risk assessment for non-target arthropods for the use of Oxamyl 10GR in potato and tobacco

Use pattern	Application method	Soil depth (cm)	Maximum PEC_s (mg a.s./kg soil)	EC_{50} (mg a.s./kg soil)	Acceptable risk?
Potato at 1 × 1000 g a.s./ha	in-furrow	10	0.667	>3.85	Yes
Tobacco at 1 × 3000 g a.s./ha	in-furrow	5	4.000	>3.85	No
Tobacco at 1 × 5500 g a.s./ha	broadcast	10	3.667	>3.85	Yes

At Tier 2, the in-field risk assessment to soil-dwelling arthropods for use on potato at 1 x 1000 g a.s./ha (in-furrow) and on tobacco at 1 x 5500 g a.s./ha (broadcast) is acceptable. For use in Tobacco in furrow at 1 x 3000 g a.s./ha, considering that the ER_{50} (EC_{50}) is actually a "higher than" value (>3.85 mg a.s./kg) and it is very closed to the PEC (4.0 mg a.s./kg), and that the DTsoil of 5.3 days, it can be concluded that in case of adverse effects, ground-dwelling arthropods populations would recover by recolonization within one year.

In order to draw definitive conclusion, the Applicant should clarify if the calculated PEC soil values are the concentrations within the furrow or represent the mean concentrations in the treated field.

The results of the tier 2 off-field risk assessment are presented in the following table.

Tier 2 off-field risk assessment for non-target arthropods for the use of Oxamyl 10GR in potato and tobacco

Use pattern	Drift factor	Veg. distr. factor	Correction factor	Off-field PERg Oxamyl 10GR/ha)	ER_{50} (g Oxamyl 10GR/ha)	Acceptable risk?
Tobacco at 1 × 55 kg Oxamyl 10GR/ha, broadcast (+soil incorporation)	0.0149	10	5	40.98	>55000	Yes

Considering a risk assessment using tier 2 extended laboratory data of *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp., Oxamyl 10GR poses no unacceptable off-field risk to soil-dwelling non-target arthropods. The risk to foliage dwelling organisms present off-field remains to be addressed.

Oxamyl 10SL

Solarisation: There will be no exposure of **honey bees** or **bumble bees** to oxamyl residues after soil solarisation in closed glasshouses. It can be concluded that solarisation is a safe use.

Although oxamyl is possibly very toxic to standard sensitive species in the laboratory, exposure to foliage dwelling **arthropods** is expected to negligible because Oxamyl 10SL is applied to the bare glasshouse soils by direct incorporation into soil and concurrent coverage by plastic foil.

After soil incorporation of Oxamyl 10SL followed by solarisation for 30 days, the soil may be considered sterile in terms of ground dwelling arthropods. To define a structural protection goal, the Guidance Document on Terrestrial Ecotoxicology (2002) states that "generally it has to be demonstrated that there is a potential for recolonisation/recovery at least within one year but preferably in a shorter period depending on the biology (seasonal) pattern of the species. The assessment may be based on field studies or other evidence (*e.g.*, results of aged-residues studies, environmental fate information)."

In order to demonstrate the potential for recovery, three ground-dwelling species (*Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp.) were exposed to soil residues of oxamyl after application of Oxamyl 10SL on LUFA 2.1 soil. Feeding rates of carabid beetles and spiders were not significantly affected after exposure to formulation at PEC_{soil} equivalent to 3.85 mg a.s./kg dry soil (5.5 kg a.s./ha, 10-cm soil depth). Reproduction of staphilinid beetles was not significantly affected (<30% effect) after exposure to formulation at 3.85 mg a.s./kg dry soil (10-cm soil depth) after soil was allowed to age for 14 days.

Taking into account the worst case soil DT_{50} = 11.1 days, and the maximum PEC_{soil} value for solarisation ($PEC_{soil, max,}$ = is 7.333 mg a.s./kg dry soil for the standard soil depth of 5 cm), it would take less than 2 weeks for the soil concentration to decline below concentrations evaluated in the extended laboratory studies on *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp. This demonstrates that there is a potential for recovery/re-colonisation for soil dwelling arthropods, beginning 2 weeks after the solarisation process is over.

Therefore, Oxamyl 10SL should not be harmful to ground-dwelling arthropods after usage in solarisation.

Drip Irrigation to Tomatoes:

Due to glasshouse application, direct or indirect exposure of **honey bees** to Oxamyl 10SL will be negligible provided that glasshouse are closed. However, exposure to **bumblebees** could occur. A Tier 1, the risk

assessment for bumblebees was conducted using residues of oxamyl active ingredient in pollinator food items from two studies conducted with oxamyl 10GR after in-furrow soil applications to Phacelia (3.0 kg a.s./ha) and potatoes (1.0 kg a.s./ha). The assumption that the residues in nectar and pollen determined after in-furrow application to *Phacelia* are relevant to tomatoes after drip irrigation (max single application rate of 2 kg a.s./ha) is not sufficiently discussed and supported (possible higher root uptake?). In the TER calculation presented by the Applicant, the exposure does not take into account of the pollen intake,

In a glasshouse study, tomatoes were irrigated six times with Oxamyl 10SL at a rate equivalent to 1.0 kg oxamyl/ha and an application interval of 14 days. Directly following the sixth drip irrigation, bumblebees (commercial bumblebee hives of *Bombus terrestris*) were allowed to pollinate the tomato crop for 4 weeks in six separate oxamyl-treated and six separate untreated glasshouse plots. In the glasshouse study, bumble bees were forced to forage exclusively on the only food source available, the tomato crop that had been treated six times with Oxamyl 10SL *via* drip irrigation. In this situation, selective foraging by pollinators (*i.e.*, migration, avoidance, infrequent foraging through diversifying food sources) is excluded, and the potential for exposure to oxamyl is maximized. Anyhow, each single bumble bee colony was fed with sugar solution ad libitum because tomato flowers produce no nectar. This is recognized as a limit intrinsic in the tests with Bombus.No notable effects on mortality of bumble bee adults and larvae, crop pollination, hive weight, and sugar consumption were observed. Also, at a final brood assessment, no effects compared to the control were noted. It was concluded that oxamyl, when applied six times at 1.0 kg oxamyl/ha with a 14-day application interval *via* drip irrigation had no significant effects on bumble bee adults and larvae, crop pollination, hive weight, and sugar consumption or on brood development.

In the glasshouse study, the product Oxamyl 10SL was applied six times at 1 Kg a.s./ha at 14 day intervals, while the proposed GAP is a maximum of 4 application at different rates (2 +1+1+1 Kg a.s./ha). A reasoned statement should be made by the Applicant that the test design represents a worst case compared to the GAP.

In conclusion for use in tomato, the risk assessment to bumble bees remains to be addressed.

For the assessment of risk to non-target arthropods under glasshouse conditions, extended laboratory studies were submitted for *Typhlodromus pyri*, *Aphidius rhopalosiphi,* and *Orius laevigatus,* but they were judged not reliable by the RMS. For the study with *Typhlodromus pyri* and *Aphidius rhopalosiphi* the reason of the non-acceptability was the lack of a reference toxicant group. Applications of 6 × 1.0 kg a.s./ha were made to sweet pepper plants in glasshouse treated by simulated drip irrigation. Three days after the first and sixth application, leaves were cut off and arthropods were added to these leaves. No effects were found on mortality or reproduction for any of the two species after three days from application. The studies can only be used as additional information (weight of evidence) of low risk to foliage dwelling arthropods for the indoor uses.

For application as soil injection, or soil incorporation, tests with soil arthropods are more relevant than tests with foliar dwelling arthropods. Tests on three soil dwelling arthropods are available. For *Aleochara bilineata*, *Pardosa* spp, and *Poecilus cupreus*, lethal and sublethal effects were <50% at application rates above the maximum predicted PEC of 2.839 mg a.s./kg soil. *A. bilineata* has a sensitive in-soil life stage, which was also tested in the study. Thus this study is the most representative.

Furthermore, IPM is possible in glasshouse uses. For IPM, effects should be below 25% at relevant test rates. For both *A. bilineata* and *Pardosa* spp., significant effects >25% were found at 3.0 and 4.0 kg a.s./ha. Therefore, the following mitigation should be considered:

- *Please note that this agent may be harmful to natural enemies. Consult your supplier of natural enemies on the use of this agent in combination with the use of natural enemies.*

Therefore, Oxamyl 10SL should not be harmful to ground-dwelling arthropods under normal agricultural practice.

Risk assessment for soil macro organisms

The TER values were determined for oxamyl, Oxamyl 10GR, and oxamyl metabolites based on the ratio of the LC_{50} or NOEC values to the maximum initial PEC_s.

Oxamyl 10GR

The calculated PEC_S and TER_a values for oxamyl and its metabolites, and oxamyl as contained in Oxamyl 10GR following use in potato and tobacco are shown in the table below.

Acute TERs for earthworms exposed to maximum potential predicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in potato and tobacco

Test substance component	Duration of test (days)	LC_{50} (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_a
Potato at 1 × 1000 g a.s./ha				
Oxamyl	14	112	0.667	168
Oxamyl 10GR	14	>100	0.667	>150
IN-A2213	14	>1000	0.256	>3906
IN-D2708	14	>1000	0.280	>3571
IN-N0079	14	640	0.030	21333
Tobacco at 1 × 3000 g a.s./ha				
Oxamyl	14	112	0.667	28
Oxamyl 10GR	14	>100	0.667	>25
IN-A2213	14	>1000	1.538	650
IN-D2708	14	>1000	1.681	595
IN-N0079	14	640	0.183	3497
Tobacco at 1 × 5500 g a.s./ha				
Oxamyl	14	112	0.667	31
Oxamyl 10GR	14	>100	0.667	>27
IN-A2213	14	>1000	1.410	709
IN-D2708	14	>1000	1.541	649
IN-N0079	14	640	0.167	3832

The TER_a values exceed the relevant Regulation (EC) 546/2011 trigger value of 10 for earthworms. Therefore, it can be concluded that acute risk to earthworms for oxamyl from the use of Oxamyl 10GR in potato and tobacco will be low.

The calculated PEC_s and TER_{lt} values for Oxamyl 10GR use in potato and tobacco are shown in the table below. Refined PECs calculations were conducted for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios.

Chronic TERs for earthworms exposed to maximum potential predicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in soil in potato and tobacco

Test substance component	Duration of test (days)	NOEC (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_{lt}
Potato at 1 × 1000 g a.s./ha				
Oxamyl 10GR	56	6.4	0.667	9.6
IN-A2213	56	25	0.256	104
IN-D2708	56	100	0.280	357
IN-N0079	56	50	0.030	1667
Tobacco at 1 × 3000 g a.s./ha				
Oxamyl 10GR	56	6.4	1.199 (refined)	5.3
IN-A2213	56	25	1.538	17
IN-D2708	56	100	1.681	59
IN-N0079	56	50	0.183	273
Tobacco at 1 × 5500 g a.s./ha				
Oxamyl 10GR	56	6.4	2.202 (refined)	**2.9**
IN-A2213	56	25	3.667	7
IN-D2708	56	100	1.541	65
IN-N0079	56	50	0.167	299

Based on refined $PEC_{s,}$ chronic risk is acceptable for the proposed in-furrow use in potatoes and tobacco, while **the risk upon broadcast application to tobacco at 1 x 5500 g a.s./ha remains to be addressed.**

The calculated PEC_s and TER_{lt} values for soil non-target macro organisms other than earthworms exposed to oxamyl for Oxamyl 10GR use in potato and tobacco are shown in the table below. The risk assessment is based on refined PECs calculated for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios.

Refined chronic TERs for non-target soil meso- and macrofauna exposed to maximum potential predicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in soil in potato and tobacco

Test substance component	Species	Duration of test (days)	NOEC (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_{lt}
Potato at 1 × 1000 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	0.469	**0.53**
Oxamyl	*Hypoaspis aculeifer*	14	16	0.469	34
IN-A2213	*Folsomia candida*	28	100	0.256	391
	Hypoaspis aculeifer	14	100	0.256	391
IN-D2708	*Folsomia candida*	28	100	0.280	357
	Hypoaspis aculeifer	14	100	0.280	357
IN-N0079	*Folsomia candida*	28	12.5	0.030	417
	Hypoaspis aculeifer	14	25	0.030	833
Tobacco at 1 × 3000 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	1.199	**0.21**
Oxamyl	*Hypoaspis aculeifer*	14	16	1.199	13
IN-A2213	*Folsomia candida*	28	100	1.538	65
	Hypoaspis aculeifer	14	100	1.538	65
IN-D2708	*Folsomia candida*	28	100	1.681	59
	Hypoaspis aculeifer	14	100	1.681	59
IN-N0079	*Folsomia candida*	28	12.5	0.183	68
	Hypoaspis aculeifer	14	25	0.183	137
Tobacco at 1 × 5500 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	2.202	**0.11**
Oxamyl	*Hypoaspis aculeifer*	14	16	2.202	7.3
IN-A2213	*Folsomia candida*	28	100	1.410	71
	Hypoaspis aculeifer	14	100	1.410	71
IN-D2708	*Folsomia candida*	28	100	1.541	65
	Hypoaspis aculeifer	14	100	1.541	65

IN-N0079	*Folsomia candida*	28	12.5	0.167	75
	Hypoaspis aculeifer	14	25	0.167	150

Values in bold are below the relevant trigger of 5

The risk to soil meso- and macrofauna is acceptable for the oxamyl metabolites. For *Collembola* TER values are below the relevant trigger, indicating a potential risk. A population modelling study was performed to evaluate potential effects of oxamyl on *Collembola* following applications to potato and tobacco. For this purpose the SpringSim (SPRINGtails SIMulation) 2.1 model has been used to simulate population dynamics of *Folsomia candida* over the course of 15 years. Since the reliability of the results is doubtful (see comments in Vol 3 a.s. B9), the chronic risk to collembolan from the active substance remains to be addressed.

Oxamyl 10SL

For most protected crops (glasshouse/plastic house) grown in EU where the substrate is a soil, the 'soil' is merely considered as a substrate to grow crops. That is, it should not be viewed as an ecologically relevant soil. Most glasshouses in SEU either chemically fumigate the soil/substrate or solarize the soil/substrate to reduce crop losses from nematodes and pathogens. Solarisation involves leaving the protected area (soil) at high temperature for a prolonged period with the intention of reducing crop injury from soil-borne pests. Hence, risk assessments for soil macroorganisms is not warranted in these protected environments.

For permanent structures, a risk assessment is only necessary for persistent substances ($DegT_{90}$>1 year from Uniform principles [Regulation EU no 546/2011])." Oxamyl and the soil metabolites, IN-A2213, IN-D2708, and IN-N0079 are not persistent substances, thus no risk assessment for soil organisms is necessary. In absence of a risk assessment, at MS level it should be specified that the product can be applied only in "permanent" glasshouses.

Risk assessment for soil micro organisms

Oxamyl 10GR

The submitted study conducted with Oxamyl 10GR was judged not valid. No conclusion can be drawn about the risk of Oxamyl 10GR risk to soil microflora function.

Laboratory testing was conducted to evaluate the effects of oxamyl metabolites, IN-A2213, and IN-N0079 on non-target soil micro-organisms. Soil was treated with 49 mg IN-A2213/kg soil (which is 13-times the maximum PEC_S), and 30 mg IN-N0079/kg soil (which is 160-times the maximum PEC_s), respectively, and effects on nitrogen transformation and carbon mineralisation were evaluated. The risk of metabolites IN-A2213 and IN-N0079 to soil microflora function is acceptable, but no conclusion can be drawn for IN-D2708 because the test is not valid (see dRAR a.s. Vol. 3B9).

Data gap for effect to micro-organisms function for Oxamyl 10GR and IN-D2708.

Oxamyl 10SL

For most protected crops (glasshouse/plastic house) grown in EU where the substrate is a soil, the 'soil' is merely considered as a substrate to grow crops. That is, it should not be viewed as an ecologically relevant soil. Most glasshouses in SEU either chemically fumigate the soil/substrate or solarise the soil/substrate to reduce crop losses from nematodes and pathogens. Solarisation involves leaving the protected area (soil) at high temperature for a prolonged period with the intention of reducing crop injury from soil-borne pests. Hence, risk assessments for soil micro-organisms are not warranted in these protected environments.

The EFSA Guidance Document on Emissions of Active Substances from Protected Crops (EFSA Journal 2014;12 [3]:3615) states, "For all structures that can be considered non-permanent, risk assessment for the soil compartment should be performed using the approaches for open field. For permanent structures a risk assessment is only necessary for persistent substances ($DegT_{90}$>1 year from Uniform principles [Regulation EU no 546/2011])." Oxamyl and the soil metabolites, IN-A2213, IN-D2708, and IN-N0079 are not persistent substances, thus no risk assessment for soil organisms has been submitted by the Applicant. The conclusion can

only apply to permanent structures, and this should specified in the GAP and in product authorization l>abel. For use in any other protected structures, a risk assessment should be presented.

Risk assessment for terrestrial non-target plants

Oxamyl 10GR

Effects on non-target plants are of concern in the off-field environment. For granular application in general, plants may be exposed to dust drift.

Non-target plant testing conducted with the oxamyl spray formulation Oxamyl 24L to evaluate potential effects of oxamyl following pre-emergent (soil) and post-emergent (foliar) exposure resulted for all tested species with an EC_{50} >2240 g a.s/ha. Upon re-evaluation of the study according current guidelines, the seedling emergence test is not fully valid and the results can be used as additional information and the full validity of the vegetative vigour study could not established, hence the results are to be considered as supportive information. Both studies show effects much lower that 50% at 2240 g a.s./ha (the maximum concentration tested). For illustrative purposes, a risk assessment was presented for broadcast application of 5 kg product/ha. A maximum of 1.49% of the application rate was assumed to reach off-crop areas at 1 m from the edge of the crop (worst-case scenario), giving a PECdrift =81.95 g a.s./ha.

The conservative assumptions in the risk assessment, and the TER (>27) exceedance of the trigger 5 for can represent weight of evidence of a likely low risk to plants growing adjacent to the application site.

Oxamyl 10SL:

Testing of Oxamyl 24SL at a rate of 2.24 kg a.s./ha, although not fully valid according to the present guidelines, showed no impact on growth or emergence of 10 sensitive non-target plant species (Oxamyl dRAR a.s. Vol 3B). Studies on the effects on non-target plants are not currently required where exposure is not likely (such as in the case of active substances used in glasshouses where exposure is precluded) according to Commission Regulation (EU) No 284/2013; however, available data have been summarised and submitted. No guidance is available to estimate risks to non-target plants in glasshouses. It can be concluded that the proposed uses in glasshouses pose low risk to non-target plants.

2.9 Classification and labelling

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures for oxamyl 42%TK

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives	Not classified		Not classified	The substance does not possess explosive properties. The mixture does not meet CLP criteria, Annex I, paragraph 2.1.2.
2.2.	Flammable gases	Not applicable		Not classified	The substance is not a gas. The mixture does not meet CLP definition, Annex I, paragraph 2.2.1
2.3.	Flammable aerosols	Not applicable		Not classified	The substance is not an aerosol. The substance does not meet CLP definition, Annex I, paragraph 2.3.1
2.4.	Oxidising gases	Not applicable		Not classified	The substance is not a gas. The substance does not meet CLP definition, Annex I, paragraph 2.4.1.
2.5.	Gases under pressure	Not applicable		Not classified	The substance is not a gas. The substance does not meet CLP definition, Annex I, paragraph 2.4.1.
2.6.	Flammable liquids	Flammable		Flammable	57.4 °C Category 3
2.7.	Flammable solids	Not applicable		Not classified	The substance is not a solid. The substance does not meet CLP definition, Annex I, paragraph 2.7.1
2.8.	Self-reactive substances and mixtures	Not classified		Not classified	The substance does not possess explosive properties and does not meet CLP definition, Annex I, paragraph 2.8.1.1

2.9.	Pyrophoric liquids	Not classified		Not classified	The substance does not ignite in contact with air and does not meet CLP definition, Annex I, paragraph 2.9.1.
2.10.	Pyrophoric solids	Not applicable		Not classified	The mixture does not ignite in contact with air and does not meet CLP definition, Annex I, paragraph 2.9.10.
2.11.	Self-heating substances and mixtures	Not classified		Not classified	Test substance has an auto-ignition temperature of 303 °C.
2.12.	Substances and mixtures which in contact with water emit flammable gases	Not classified		Not classified	The mixture does not react in contact with water and does not meet CLP definition, Annex I, paragraph 2.12.1.
2.13.	Oxidising liquids	Not classified		Not classified	The substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen
2.14.	Oxidising solids	Not applicable		Not classified	The mixture is not a solid. The mixture does not meet CLP definition, Annex I point 2.13.1.
2.15.	Organic peroxides	Not classified		Not classified	The mixture is not a peroxide. The mixture does not meet CLP definition, Annex I point 2.14.1
2.16.	Substance and mixtures corrosive to metals	Not classified		Not classified	
3.1.	Acute toxicity - oral	8.7 mg/kg Category 2		8.7 mg/kg Category 2	HLR 109-88
	Acute toxicity - dermal	>5000 mg/kg Category 4		>5000 mg/kg Category 4	DuPont-8718OECD 402 The mixture does not meet CLP criteria Annex I, Part 3, paragraph 3.1.3. based on the result of testing. However the classification category 4 is kept on the basis of its presence in Annex VI of the Regulation.
	Acute toxicity - inhalation	0.11 mg/L Category 2		0.11 mg/L Category 2	HLR 199-88

3.2.	Skin corrosion / irritation	Not a skin irritant Not classified		Not a skin irritant Not classified	DuPont-7082 OECD 404 The mixture does not meet CLP criteria Annex I, Part 3, paragraph 3.2.3.
3.3.	Serious eye damage / eye irritation	Irritating to eyes Category 2		Irritating to eyes Category 2	HLR 710-87 HLR 710-87 rev. 1 DuPont-7059
3.4.	Respiratory sensitisation	Cannot classify		Not classified	It does not exist specific test for respiratory sensitization and there is no human or animal experience recorded that can be used to asses classification for this criteria.
3.4.	Skin sensitisation	Not classified		Not classified	HR 179-88
3.5.	Germ cell mutagenicity	Not classified		Not classified	Data available only on oxamyl pure.
3.6.	Carcinogenicity	Not classified		Not classified	Data available only on oxamyl pure.
3.7.	Reproductive toxicity	Not classified		Not classified	Data available only on oxamyl pure.
3.8.	Specific target organ toxicity –single exposure	Cannot classify		Not classified	Data available only on oxamyl pure.
3.9.	Specific target organ toxicity – repeated exposure	Cannot classify		Not classified	Data available only on oxamyl pure.
3.10.	Aspiration hazard	Not classified		Not classified	The components of oxamyl tech 42 do not contain hydrocarbons in a total concentration equal to or greater than 10%.
4.1.	Hazardous to the aquatic environment	Classified **Aquatic Chronic 2**		Classified	
5.1.	Hazardous to the ozone layer	Not classified		Not classified	

[1)] Including specific concentration limits (SCLs) and M-factors. [2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Proposed notes assigned to an entry:

Notes in accordance with CLP Regulation, Annex VI, Section 1.1.3

The active substance oxamyl is classified in Annex VI of Regulation (EC) No. 1272/2008; therefore, this harmonised classification applies, and DuPont proposes only classification for the remaining, non-harmonised hazards.

Classification and labeling is referring to 42%TK oxamyl, which is shipped and handled at manufacturing site. Pure active oxamyl (PAI) is never isolated.

Classification

Category	**Hazard class**
Flammable liquids, Category 3	H226: Flammable liquid and vapour.
Acute toxicity, Category 2	H300: Fatal if swallowed.
Acute toxicity, Category 2	H330: Fatal if inhaled.
Acute toxicity, Category 4	H312: Harmful in contact with skin.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Chronic aquatic toxicity, Category 2	H411: Toxic to aquatic life with long lasting effects.

Label elements

Signal word: Warning

Hazard statements:

H226 Flammable liquid and vapour

H300 Fatal if swallowed

H330 Fatal if inhaled

H312 Harmful in contact with skin

H319 Causes serious eye irritation

H411 Toxic to aquatic life with long lasting effects.

Special labelling of certain substances and mixtures

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

Proposed classification and labelling for Oxamyl 10GR

Classification

Category	**Hazard class**
Acute toxicity, Category 2	H300: Fatal if swallowed.
Acute toxicity, Category 3	H331: Toxic if inhaled.
Chronic aquatic toxicity, Category 3	H412: Harmful to aquatic life with long lasting effects.

Label elements

Skull and

crossbones

Signal word: Danger

Hazard Statements

H300 – Fatal if swallowed.

H331 – Toxic if inhaled.

H412 – Harmful to aquatic life with long lasting effects.

Toxic – R23/25: Toxic by inhalation and if swallowed.

Dangerous for the environment

Special labelling of certain substances and mixtures

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

Proposed classification and labelling for Oxamyl 10SL

Classification

Category	**Hazard class**
Acute toxicity, Category 2	H300: Fatal if swallowed.
Acute toxicity, Category 3	H331: Toxic if inhaled.
Chronic aquatic toxicity, Category 3	H412: Harmful to aquatic life with long lasting effects.

Label elements

Skull and

crossbones

Signal word: Danger

Hazard Statements

H300 – Fatal if swallowed.

H331 – Toxic if inhaled.

H412 – Harmful to aquatic life with long lasting effects.

Dangerous for the environment

Special labelling of certain substances and mixtures

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

2.10 Relevance of metabolites in groundwater

2.10.1 STEP 1: Exclusion of degradation products of no concern

The identified metabolites of oxamyl in soil (IN-A2213, IN-D2708, and IN-N0079) do not meet the criteria for exclusion as degradation products of no concern.

2.10.2 STEP 2: Quantification of potential groundwater contamination

Simulations to predict PEC_{gw} for oxamyl and its soil metabolites IN-A2213, IN-D2708, and IN-N0079 were performed for oxamyl application in the open field (Oxamyl 10GR formulation) and in greenhouses (Oxamyl 10SL formulation). The report is summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 (DuPont-40953 EU and DuPont-42129 EU, respectively).

The application framework for oxamyl in the open field included in-furrow application to potatoes at 1 × 1000 g a.s./ha, in-furrow application to tobacco at 1 × 3000 g a.s./ha, and broadcast application to tobacco at 1 × 5500 g a.s./ha with incorporation. The application framework in greenhouses included applications *via* drip irrigation to tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha and solarisation use at 1 × 5500 g a.s./ha.

The PEC_{gw} calculations for oxamyl and degradation products were based on the geometric mean $DegT_{50}$ values determined from the laboratory degradation studies. For IN-N0079, a conservative value of 1 day was chosen. Geometric mean organic carbon normalised sorption coefficients were taken forward. The simulations were performed for two separate pathways. Pathway A represented main degradation pathway of oxamyl in aerobic soils resulting in formation of IN-A2213 and IN-D2708. Pathway B represented a minor degradation pathway resulting in formation of IN-N0079 and IN-D2708. Values as calculated in pathway A are presented, as maximum of both pathways (PEARL and PELMO). The most recent groundwater simulation models were used:

FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3. The simulations were performed following FOCUS groundwater guidelines (FOCUS, 2000[6] and 2009[7]; European Commission, 2014[8]).

Potential annual average concentrations of the active substance (PEC_{gw}) and its relevant degradation products in soil pore water at a depth of one meter were calculated.

For open field uses, maximum 80th percentile for applications of oxamyl to potatoes and tobacco are discussed. For oxamyl annual application to potatoes maximum 80th percentile PEC_{gw} for IN-A2213was estimated to be above 0.1 but below 0.75 µg/L and for IN-D2708 and IN-N0079 below 0.1 µg/L. These results are conservative because potatoes are not planted on the same field every year. Refined simulations were therefore performed for oxamyl applications to potatoes once every three years. Maximum 80th percentile PEC_{gw} for IN-A2213 was estimated to be below 0.1 µg/L.

Following oxamyl applications to tobacco, maximum 80th percentile PEC_{gw} for the metabolites IN-A2213, IN-D2708, and IN-N0079 were below 0.1 µg/L.

For greenhouse uses, calculations were performed following a tiered approach. At Tier 1, greenhouse uses (tomatoes and solarisation) were evaluated using an open-field approach. That means the simulations did not take into account that conditions in greenhouses differ to those outdoors (EFSA, 2014[9]). At Tier 2, refined modelling was performed for the three worst-case scenarios of the greenhouse uses. As a conservative estimate, temperatures in greenhouses were assumed to be 2°C above those outdoors.

Following application of oxamyl to tomatoes, Tier 1 maximum 80th percentile PEC_{gw} for IN-A2213 and IN-D2708 were estimated to be above 0.1 but below 0.75 µg/L and below 0.1 µg/L for IN-N0079. At Tier 2, maximum 80th percentile PEC_{gw} for IN-D2708 was also below 0.1 µg/L. Only in one Tier 2 scenario simulated with FOCUS PELMO 5.5.3 PEC_{gw} for IN-A2213 exceeded 0.1 µg/L.

Maximum 80th percentile PEC_{gw} for IN-A2213 and IN-D2708 for solarisation use were estimated to exceed 0.1 µg/L but calculated to be below 1 µg/L at Tier 1. Tier 1 maximum 80th percentile PEC_{gw} for IN-N0079 was consistently below 0.1 µg/L. At Tier 2, PEC_{gw} estimates for IN-A2213 were below the threshold of 0.1 µg/L and for IN-D2708 below 0.75 µg/L. It is important to mention that Tier 2 estimates can be considerate conservative, as in reality not only temperatures but also water input in greenhouses are different to those outdoors.

A summary of maximum 80th percentile PEC_{gw} is presented in Table to Table (open field uses) and Table to Table 38 (greenhouse uses). A summary of results is shown in Table 39 (open field uses) and Table 30 (greenhouse uses).

Table 33 Maximum 80th percentile PEC_{gw} concentration for oxamyl and its soil metabolites following applications to potatoes at 1 × 1000 g a.s./ha (annual applications)

FOCUS Model	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708	IN-N0079
PEARL 4.4.4	0.105	0.077	0.080	0.012
PELMO 5.5.3	0.250	0.226[a]	0.066	0.012

[a] Simulation with FOCUS PELMO 5.5.3 considering oxamyl application to potatoes every three years resulted in reduced 80th percentile PEC_{gw} for oxamyl and its metabolites. Maximum 80th percentile PEC_{gw} for IN-A2213 was reduced to 0.067 µg/L.

[6] FOCUS (2000): FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 rev.2, 202 pp.

[7] FOCUS (2009): Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 1, 604 pp.

[8] European Commission (EC) (2014): "Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU" Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp.

[9] EFSA (2014): EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3): 3615. [43 pp.] doi:10.2903/j.efsa.2014.3615.

Table 34 Maximum 80th percentile PEC_{gw} concentration for oxamyl and its soil metabolites following applications to potatoes at 1 × 1000 g a.s./ha (annual applications)

FOCUS Model	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708	IN-N0079
PEARL 4.4.4	0.105	0.077	0.080	0.012
PELMO 5.5.3	0.250	0.226[a]	0.066	0.012

Simulation with FOCUS PELMO 5.5.3 considering oxamyl application to potatoes every three years resulted in reduced 80th percentile PECgw for oxamyl and its metabolites. Maximum 80th percentile PECgw for IN-A2213 was reduced to 0.067 µg/L.

Table 35 Maximum 80th percentile PEC_{gw} concentration for oxamyl and its soil metabolites following applications to tobacco at 1 × 3000 g a.s./ha

FOCUS Model	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708	IN-N0079
PEARL 4.4.4	0.003	0.002	0.005	<0.001
PELMO 5.5.3	0.011	0.009	0.013	<0.001

Table 36 Maximum 80th percentile PEC_{gw} concentration for oxamyl and its soil metabolites following applications to tobacco at 1 × 5500 g a.s./ha

FOCUS Model	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708	IN-N0079
PEARL 4.4.4	0.009	0.004	0.024	0.003
PELMO 5.5.3	0.027	0.018	0.059	0.001

Table 37 Maximum 80th percentile PEC_{gw} concentration for oxamyl and its soil metabolites following applications to tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha

FOCUS Model	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708	IN-N0079
Tier 1				
PEARL 4.4.4	0.103	0.047	0.285	0.004
PELMO 5.5.3	0.373	0.371	0.136	0.020
Tier 2				
PEARL 4.4.4	0.024	0.014	0.035	0.001
PELMO 5.5.3	0.232	0.244	0.039	0.012

Table 38 Maximum 80th percentile PEC_{gw} concentration for oxamyl and its soil metabolites following solarisation use at 1 × 5500 g a.s./ha, application on 1 July

FOCUS Model	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708	IN-N0079
Tier 1				
PEARL 4.4.4	0.123	0.054	0.317	0.005
PELMO 5.5.3	0.089	0.058	0.190	0.004
Tier 2				
PEARL 4.4.4	0.029	0.013	0.045	0.001
PELMO 5.5.3	0.029	0.018	0.027	0.001

Table 39 Maximum 80th percentile PEC_{gw} concentration for oxamyl and its soil metabolites following solarisation use at 1 × 5500 g a.s./ha, application on 1 August

FOCUS Model	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708	IN-N0079
Tier 1				
PEARL 4.4.4	0.284	0.142	0.979	0.011
PELMO 5.5.3	0.261	0.163	0.804	0.011
Tier 2				
PEARL 4.4.4	0.077	0.043	0.218	0.003
PELMO 5.5.3	0.077	0.058	0.198	0.003

Table 300 Summary of overall maximum PEC_{gw} values for oxamyl metabolites (open field uses)

Metabolite	Maximum 80th percentile PEC_{gw} (µg/L)
IN-A2213	0.226/0.067[a]
IN-D2708	0.080
IN-N0079	0.012

[a] For applications every three years.

Table 311 Summary of overall maximum PEC_{gw} values for oxamyl metabolites (greenhouse uses)

Metabolite	Maximum 80th percentile PEC_{gw} (µg/L) Tier 1/Tier 2
IN-A2213	0.371/0.244
IN-D2708	0.979/0.218
IN-N0079	0.020/0.012

For open field uses, only concentrations of metabolite IN-A2213 were predicted to exceed 0.1 µg/L. If oxamyl applications to potatoes occur every third year, all open field uses result in no exceedances of the 0.1 µg/L threshold by any of the metabolites.

For greenhouse uses, predicted concentrations of IN-A2213 and IN-D2708 in soil water at 1 m soil depth were estimated to exceed 0.1 µg/L. It was considered appropriate to assess the toxicological relevance of these metabolites.

2.10.3 STEP 3: Hazard assessment – identification of relevant metabolites

2.10.3.1 STEP 3, Stage 1: screening for biological activity

It is generally recognized that carbamate insecticides lose their biological activity upon cleavage of the carbamate moiety. Therefore, the metabolites of oxamyl identified above are not expected to be toxicologically active by this mechanism, since the carbamate ester moiety has been either hydrolysed or metabolically degraded in each case. This conclusion is supported by the lack of insecticidal activity that has been observed with IN-A2213 and IN-D2708 (Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU). Therefore, these metabolites have passed Stage 1 of the assessment.

2.10.3.2 STEP 3, Stage 2: screening for genotoxicity

Based on the proposed metabolic pathway presented below, it can be inferred from the genotoxicity studies conducted with the parent compound oxamyl, that the metabolites IN-A2213 and IN-D2708 do not possess the potential to be mutagenic or clastogenic. This is because with metabolic activation *in vitro* and *in vivo*, these metabolites would have been present, and no positive responses were observed in any of the genotoxicity studies with parent, oxamyl. Furthermore, it has been confirmed *in vitro* and *in vivo* that IN-A2213 is the major metabolite formed, and the metabolic pathway is similar when oxamyl or IN-A2213 were compared and the same conjugates appeared in the urine regardless of which compound was administered to rats (Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU). Therefore, it can be concluded that IN-A2213 and IN-D2708 do not possess genotoxic potential and have passed Stage 2 of the assessment.

2.10.3.3 2.11.3.3 STEP 3, Stage 3: screening for toxicity

According to the draft guidance on investigating the relevance of metabolites (CTB, 1999[10]), metabolites can be considered non-relevant if they have been found in significant quantities in relevant body compartments of mammalian laboratory animals used in relevant toxicity studies on the active substance. This approach remains consistent with recent guidance provided by the EU Commission (SANCO/221/2000-25 February 2003). As discussed above, it is evident that the principal metabolites of oxamyl either occur or are proposed as intermediates in rodent metabolism studies and their non-relevance is, therefore, concluded.

In addition, a limited number of toxicity studies have been conducted with IN-A2213 and IN-D2708, which indicate that the acute oral toxicity is much lower than the parent as expected based on the rapid hydrolysis to the major metabolite IN-A2213. The approximate lethal dose of IN-A2213 was determined to be 11000 mg/kg bw/day, several orders of magnitude less toxic than the parent. Also, in a 10-day subacute oral gavage study at 1000 mg/kg bw/day, no mortalities occurred and only mild, reversible histopathological changes in the lymphoid tissue and liver were observed, indicating that the repeated-dose oral and cumulative potential of this major metabolite are low. IN-D2708 was also evaluated for acute oral toxicity and the LD_{50} was determined to be 3540 mg/kg bw, again several orders of magnitude less toxic than the parent. Moreover, based on the proposed metabolic pathway presented below, it can be inferred from the extensive data set of studies conducted with the parent compound oxamyl that the metabolites IN-A2213 and IN-D2708 do not possess the potential to be carcinogenic, mutagenic, reproductive toxicants, nor would they be expected to damage target organs or exhibit toxicity to organ systems as concluded by EFSA (EFSA Scientific Report (2005) 26, 1–78, Conclusion on the peer review of oxamyl).

Therefore, these metabolites are of no concern and can be considered to be non-relevant in the context of the criteria outlined in the guidance document. Therefore, IN-A2213 and IN-2708 pass Stage 3 of the assessment.

[10] CTB, 1999. Guidelines for Authorisation of Pesticides, version 0.1. College voor de Toelating van Bestrijdingsmiddelen, Wageningen, The Netherlands. (in Dutch)

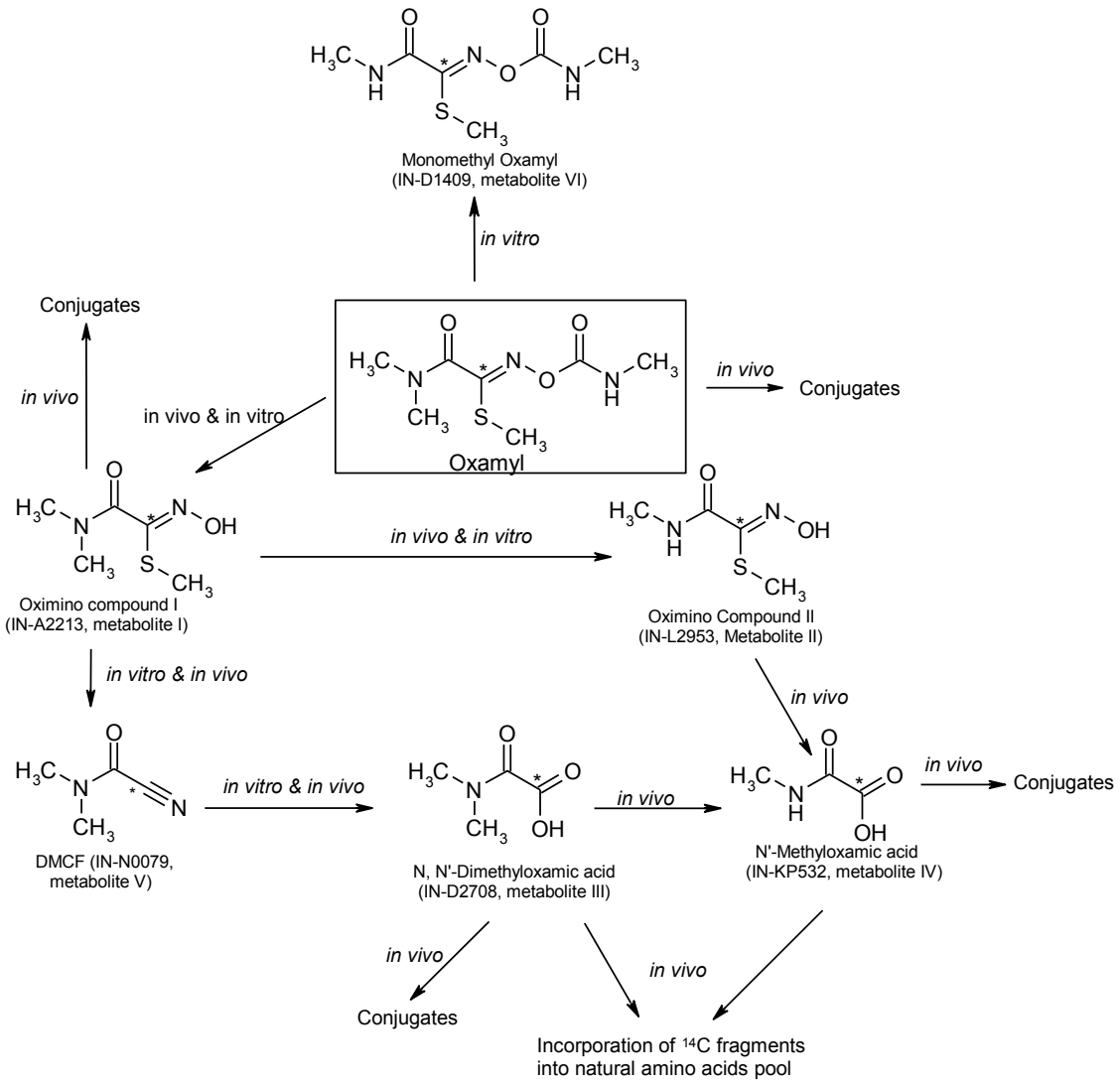


Figure 2 Proposed metabolic pathway of oxamyl and its metabolites in vitro and in vivo

2.10.4 STEP 4: Exposure assessment – threshold of concern approach

The European Commission guidance indicates that metabolites that pass Step 3 and are below a threshold concentration of 0.75 µg/L in drinking water (or 0.02 µg/kg bw/day), need no further assessments. Since the PEC_{gw} values for the oxamyl metabolites IN-A2213 and IN-D2708 are below the 0.75 µg/L threshold, they have met this threshold-of-concern criterion and need no further assessment.

2.10.5 STEP 5: Refined risk assessment

No further assessment of IN-A2213 or IN-D2708 is required or presented as they have passed Steps 1–4 and can be considered as toxicologically non-relevant.

2.10.6 Overall conclusion

The metabolites of oxamyl, IN-A2213 and IN-D2708, have passed all the assessments required for groundwater metabolites and can be considered as toxicologically non-relevant. Therefore, it can be concluded that these metabolites do not pose a concern or hazard to human health.

2.11 Consideration of isomeric composition in the risk assessment

2.11.1 Identity and physical chemical properties

Oxamyl is not a chiral molecule and thus the technical material used in regulatory testing is not a racemic mixture or a resolved isomer of a chiral molecule. All relevant physical-chemical studies were performed on purified test material, >96% oxamyl, and thus the results of all testing reflect the properties of oxamyl itself and were not influenced by the presence of additional stereoisomers.

2.11.2 Methods of analysis

Oxamyl is not a chiral molecule; therefore, no method was developed for the determination of the geometric isomer of oxamyl.

2.11.3 Mammalian toxicity

Oxamyl is not a chiral molecule; therefore, the technical material used in animal metabolism and toxicity studies was not a racemic mixture or a resolved isomer of a chiral molecule. Therefore, no investigations were needed into preferential metabolism or toxicity of a given stereoisomer over another.

2.11.4 Operator, Worker, Bystander and Resident exposure

Oxamyl is not a chiral molecule; therefore, the technical material in the formulated products is not a racemic mixture or a resolved isomer of a chiral molecule. Therefore, no investigations were needed into preferential exposure to a given stereoisomer over another.

2.11.5 Residues and Consumer risk assessment

Oxamyl is not a chiral molecule; therefore, the technical material used in plant and animal metabolism and residue studies was not a racemic mixture or a resolved isomer of a chiral molecule. Therefore, no investigations were needed into preferential metabolism of a given stereoisomer over another.

2.11.6 Environmental fate

Oxamyl is not a chiral molecule and thus the technical material used in environmental fate testing is not a racemic mixture or a resolved isomer of a chiral molecule. Therefore, no investigations were needed into preferential degradation of a given isomer over another. A geometric isomer of oxamyl (IN-F3708) was not observed to form in any environmental fate studies.

2.11.7 Ecotoxciology

Oxamyl is not a chiral molecule and thus the technical material used in ecotoxicology studies was not a racemic mixture or a resolved isomer of a chiral molecule. Therefore, no investigations were needed into preferential metabolism of a given stereoisomer over another.

2.12 Residue definitions

2.12.1 Definition of residues for exposure/risk assessment

Food of plant origin: Oxamyl

Food of animal origin: Oxamyl

Soil: Oxamyl, IN-A2213, IN-N0079, and IN-D2708

Groundwater: Oxamyl, N-A2213, IN-N0079, and IN D2708

Surface water: Oxamyl**,** IN-A2213, IN-N0079, IN-D2708, IN-T2921, and IN-SBY69

Sediment: Oxamyl, IN-A2213, IN-N0079, and IN-D2708

Air: Oxamyl

2.12.2 Definition of residues for monitoring

Food of plant origin: Oxamyl

Food of animal origin: Oxamyl

Soil: Oxamyl

Groundwater: Oxamyl

Surface water: Oxamyl

Sediment: Oxamyl

Air: Oxamyl

3.1.1 PROPOSAL ON ACCEPTABILITY AGAINST THE DECISION-MAKING CRITERIA – ARTICLE 4 AND ANNEX II OF REGULATION (EC) No 1107/2009

3.1.1.1 Article 4				
		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	X		*Oxamyl* *Oxamyl 10 SL* *Oxamyl 10 GR* *Potato, Tabacco, Tomatoes.*
3.1.1.2 Submission of further information				
		Yes	No	
i)	It is considered that a complete dossier has been submitted	X		
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.	---		----
3.1.1.3 Restrictions on approval				
		Yes	No	
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.		X	

3.1.1.4 Criteria for the approval of an active substance				
Dossier				
		Yes	No	
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	X		
	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals; (e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.	X		
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.	X		
Efficacy				
		Yes	No	

	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	X		
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.	X		
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.	X		
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.	X		
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted	X		
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities	X		

	of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.			
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.	X		
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		
Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		*SF to derive AOEL proposed is 10x instead of 100*
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as**		X	

	mutagen category 1A or 1B.			
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**		X	
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.	X		
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or 1B.**		X	
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic	X		

	proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties**		X	
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2 and** in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**		X	
iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.	X		
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				

		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		X	
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		X	
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	
Ecotoxicology				
		Yes	No	
	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.	X		
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine disrupting properties that may cause adverse effects on non-target		X	

	organisms.			
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.	X		
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: — will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.	X		
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X		
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and	X		

	authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.			

3.1.2 PROPOSAL – CANDIDATE FOR SUBSTITUTION

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution	X		

3.1.3 PROPOSAL – LOW RISK ACTIVE SUBSTANCE

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** In particular it is considered that the substance **should NOT be classified or proposed for classification** in accordance with Regulation (EC) No 1272/2008 as at least one of the following: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**: — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.		X	

3.1.4 LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.1 Identity of the active substance or formulation				
None				
3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
None				
3.1.4.3 Data on uses and efficacy				
None				
3.1.4.4 Data on handling, storage, transport, packaging and labelling				
None				
3.1.4.5 Methods of analysis				

None				
3.1.4.6 Toxicology and metabolism				
None				
3.1.4.7 Residue data				
None				
3.1.4.8 Environmental fate and behaviour				
None				
3.1.4.9 Ecotoxicology				
None				

3.1.5 ISSUES THAT COULD NOT BE FINALISED

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	**Relevance in relation to representative use(s)**
none	*none*

3.1.6 CRITICAL AREAS OF CONCERN

An issue is listed as a critical area of concern:

(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or

(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	**Relevance in relation to representative use(s)**
none	*none*

3.1.7 OVERVIEW TABLE OF THE CONCERNS IDENTIFIED FOR EACH REPRESENTATIVE USE CONSIDERED

Representative use		Potato	Tomato	Tobacco
Operator risk	Risk identified			
	Assessment not finalised	X	X	X
Worker risk	Risk identified			
	Assessment not finalised	X	X	X
Bystander risk	Risk identified			
	Assessment not finalised	**X**	**X**	**X**
Consumer risk	Risk identified			
	Assessment not finalised	X	X	X
Risk to wild non target terrestrial vertebrates	Risk identified			
	Assessment not finalised	X	X	X
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified			
	Assessment not finalised	X	X	X
Risk to aquatic organisms	Risk identified			
	Assessment not finalised	X	X	X
Groundwater exposure active substance	Legal parametric value breached			
	Assessment not finalised	X	X	X
Groundwater exposure metabolites	Legal parametric value breached			
	Parametric value of 10µg/L[(a)] breached		X	
	Assessment not finalised	X	X	X
Comments/Remarks		--	--	--

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8 AREA(S) WHERE EXPERT CONSULTATION IS CONSIDERED NECESSARY

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	**Justification**
Not established jet	

3.1.9 CRITICAL ISSUES ON WHICH THE Co-RMS DID NOT AGREE WITH THE ASSESSMENT BY THE RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	**Opinion of Co-RMS**	**Opinion of RMS**
LoEP – section 2 –Mammalian Toxicology – Acute toxicity	FR: Could you please, also inform the hazard statements (H-phrases) in the boxes dedicated to classification proposals. Differences between current harmonized classification and the proposed one (Oral: cat.2 vs cat.1, Dermal: cat.4 vs NC) should be more discussed and the need of CLH report to amend the harmonized classification should be considered.	RMS: the argumentation should be discuss.
RAR volume 3(CA) B6 - annex B.6.2.7 Phototoxicity	FR: Co-RMS if of the opinion that the conclusion of the test should be "probable phototoxicity" in section 2 of LoEP since two replicates out of three give a PIF between 2 and 5 in the Markell (2015) study (part B.6.2.7/01). The conclusions of the phototoxicity study in the RAR should be adapted as well (B.6.2.7). Furthermore, the range of wavelengths used in the study was 330-400 while oxamyl maximal absorption is in UVB range (290 nm). It could be therefore suspected that phototoxicity would be more severe under UVB wavelengths. It should be noted that total radioactivity in tissues and carcass represents about 5-6% of the administered dose 168 hours after single oral dosing in rats dosed with 1 mg oxamyl/kg/day, of which more than 50% is contained in skin and carcass (radioactivity in eye tissues was not specifically measured).These figures rise to 22% of the administered dose after repeated oral dosing in a rats dosed with 50-150 ppm oxamyl of which 61-78% is contained in skin and carcass. Therefore, this concern should be raised to the risk managers in the conclusion of the peer review. No guideline is available in the specific case of a "probable phototoxicity"	RMS disagrees, since the OECD TG says: Based on the validation study (8), a test substance with a PIF < 2 or an MPE < 0.1 predicts: "no phototoxicity". A PIF >2 and< 5 or an MPE > 0.1 and< 0.15 predicts: "probable phototoxicity" and a PIF > 5 or an MPE > 0.15 predicts: "phototoxicity" . Therefore, since the MPE was well below the cut off limit of 0.1 the compounds can be regarded as non phototoxic. The evaluation of the PIF is an additional point for evalutaions: in 1 run is consistent, in the other 2 is uncertain. The overall conclusion should be non phototoxic, and according to IT there is no need to change.

	active substance.	
LoEP – section 2 –Mammalian Toxicology – Neurotoxicity	FR: Please mention the critical effects observed in all the neurotoxicity studies reported in RAR volume 3(CA) annex B6. Please, also report the information resulting from the published papers mentioned in part B6.7.1 of the RAR volume 3(CA) annex B6 (mechanistic studies on the inhibition of cholinesterase activity following oxamyl oral exposure).	RMS: disagreed. It is not worthwhile to include in the LoEP all the results, but only those which are considered the most relevant studies (with the lowest reference value) as for any other end-points. For details the text can be consulted.
Vol. 3, B.7.10, Estimation of the potential and actual exposure through diet and other sources LoEP, p. 30	FR: consumer risk assessment should be performed only with the proposed representative uses. Input values used for the calculations should be presented in a table. Please amend accordingly.	RMS: disagree with FR. It should be better to have an exposure evaluation with the contribution of all crops with fixed MRLs in addition to the use proposed in the renewal request.

3.2 PROPOSED DECISION

[redacted]

3.3 RATIONAL FOR THE CONDITIONS AND RESTRCITIONS TO BE ASSOCIATED WITH THE APPORVAL OR AUTHORISATION(S), AS APPROPRIATE

3.3.1 PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISKS IDENTIFIED

Proposed condition/risk mitigation measure	Relevance in relation to representative use(s)
[redacted]	[redacted]

APPENDICES

GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

REFERENCE LIST

LEVEL 3

3 Proposed decision with respect to the application

3.1 Background to the proposed decision

3.1.1 Proposal on acceptability against the approval criteria – Article 4 and Annex II of Regulation (EC) No 1107/2009

3.1.2 Proposal - Candidate for substitution

3.1.3 Proposal – Low risk active substance

3.1.4 List of studies to be generated, still ongoing or available but not evaluated

3.1.5 Issues that could not be finalised

3.1.6 Critical areas of concern

3.1.7 Overview table of the concerns identified for each representative use considered

3.1.8 Area(s) where expert consultation is considered necessary

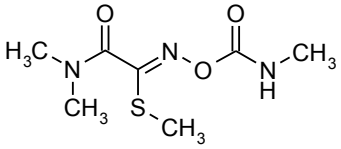
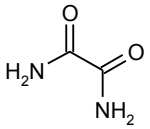
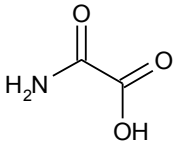
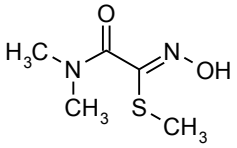
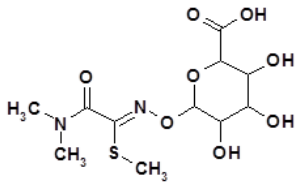
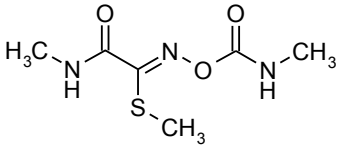
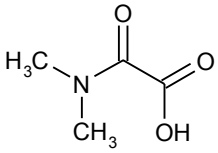
3.1.9 Critical issues on which the Co-RMS did not agree with the assessment by the RMS

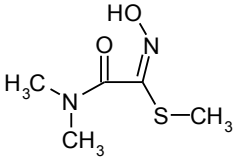
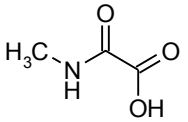
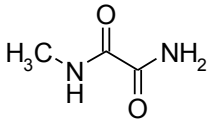
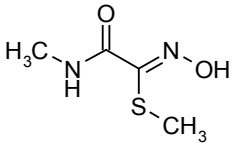
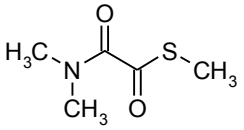
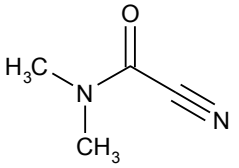
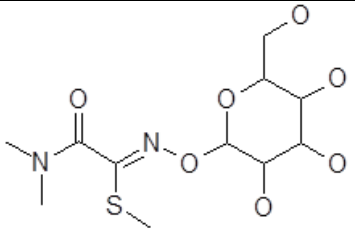
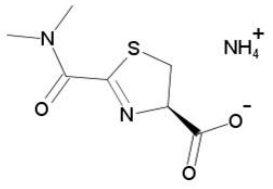
3.2 Proposed decision

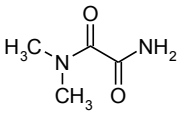
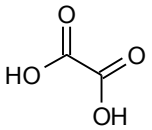
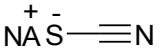
3.3 Rational for the conditions and restrictions to be associated with any approval or authorisation(s), as appropriate

3.3.1 Particular conditions proposed to be take into account to manage the risks identified

APPENDIX 1:
METABOLITES FORMED FROM OXAMYL AND THEIR OCCURRENCE

Code Number (Synonyms)	Description	Compound found in:	Structure
DPX-D1410	**CAS name:** Methyl 2-(dimethylamino)-*N*-[[(methylamino)carbonyl]oxy]-2-oxoethanimidothioate **Common name:** Oxamyl **CAS number**: 23135-22-0 **Molecular weight:** 219.26 g/mole	Parent, active substance	 $C_7H_{13}N_3O_3S$
IN-00699	**CAS name:** Ethanediamide **Common name:** Oxamide **CAS number**: 471-46-5 **Molecular weight:** 88.07 g/mole	Goat	 $C_2H_4N_2O_2$
IN-18474	**CAS name:** Aminooxoacetic acid **Common name:** Oxamic acid **CAS number**: 471-47-6 **Molecular weight:** 89.05 g/mole	Poultry	 $C_2H_3NO_3$
IN-A2213	**CAS name:** Methyl 2-(dimethylamino)-*N*-hydroxy-2-oxoethanimidothioate **Common name:** Oxamyl-oxime **CAS number**: 66344-33-0 (*Z*-isomer) **Molecular weight:** 162.21 g/mole	Plants, rumen fluid, rat, topsoil, saturated zone subsoil, water/sediment, water (hydrolysis)	 $C_5H_{10}N_2O_2S$
A2213 glucuronide	**CAS name:** Not applicable **Common name:** Not applicable **CAS number**: Not applicable **Molecular weight:** 338.34 g/mole	Rat	 $C_{11}H_{18}N_2O_8S$
IN-D1409	**CAS name:** Methyl 2-(methylamino)-*N*-[[(methylamino)carbonyl]oxy]-2-oxoethanimidothioate **Common name:** *N*-demethyl-oxamyl **CAS number**: 50917-40-3 **Molecular weight:** 205.24 g/mole	Rumen fluid, rat liver microsomes	 $C_6H_{11}N_3O_3S$
IN-D2708	**CAS name:** (Dimethylamino)oxoacetic acid **Common name:** DMOA **CAS number**: 32833-96-8 **Molecular weight:** 117.105 g/mole	Plants, rumen fluid, rat liver microsomes, topsoil, saturated zone subsoil, water/sediment	 $C_4H_7NO_3$

Code Number (Synonyms)	Description	Compound found in:	Structure
IN-F3905	**CAS name:** Methyl (*E*) 2-(dimethylamino)-*N*-hydroxy-2-oxoethanimidothioate **Common name:** A2213 isomer **CAS number**: 66344-32-9 (E-isomer) **Molecular weight:** 162.21 g/mole	Plants, poultry, topsoil	 $C_5H_{10}N_2O_2S$
IN-KP532	**CAS name:** (Methylamino)oxoacetic acid **CAS number**: 29262-58-6 **Molecular weight:** 103.08 g/mole	Plants, goat rumen fluid, rat	 $C_3H_5NO_3$
IN-KV998	**CAS name:** *N*-Methylethanediamide **CAS number**: 22509-04-2 **Molecular weight:** 102.09 g/mole	Plants, goat	 $C_3H_6N_2O_2$
IN-L2953	**CAS name:** Methyl *N*-hydroxy-2-(methylamino)-2-oxoethanimidothioate **CAS number**: 66157-67-3 **Molecular weight:** 148.18 g/mole	Plants, rumen fluid, rat liver microsomes, rat	 $C_4H_8N_2O_2S$
IN-M2583	**CAS name:** *S*-Methyl (dimethylamino)oxoethanethioate **CAS number**: Not available **Molecular weight:** 147.20 g/mole	Saturated zone subsoil	 $C_5H_9NO_2S$
IN-N0079	**CAS name:** Dimethylcarbonocyanidic amide **Common name:** DMCF **CAS number**: 16703-51-8 **Molecular weight:** 98.10 g/mole	Plants, rumen fluid, rat, rat liver microsomes, saturated zone subsoil, water/sediment	 $C_4H_6N_2O$
IN-QKT34	**CAS name:** 2-[(Hexopyranosyloxy)imino]-*N, N*-dimethyl-2-(methylthio)acetamide **Common name:** IN-A2213 (oxamyl oxime) glucoside **CAS number**: 66856-02-8 **Molecular weight:** 324 g/mole	Plants	 $C_{11}H_{20}N_2O_7S$
IN-SBY69	**CAS name:** Ammonium (4R)-2-[(dimethylamino)carbonyl)-4,5-dihydro-4-thiazolecarboxylate (1:1) **Common name:** Not applicable **CAS number**: Not applicable **Molecular weight:** 219.26 g/mole	Anaerobic water/sediment	 $C_7H_{13}N_3O_3S$

Code Number (Synonyms)	Description	Compound found in:	Structure
IN-T2921	**CAS name:** *N,N*-Dimethylethanediamide **Common name:** DMEA (also DMO) **CAS number**: 600-39-5 **Molecular weight:** 116.12 g/mole	Rumen fluid, plants, saturated zone subsoil, water/sediment	 $C_4H_8N_2O_2$
N/A	**CAS name:** Ethanedioic acid **Common name:** Oxalic Acid **CAS number**: 144-62-7 **Molecular weight:** 90.04 g/mole	Goat, poultry	 $C_2H_2O_4$
N/A	**CAS name:** Sodium thiocyanate **Common name:** Thiocyanate ion (shown as sodium salt) **CAS number**: 540-72-7 **Molecular weight:** 97.18 g/mole	Goat, poultry	 NaSCN