European Commission

Second Programme for the Renewal of the Inclusion of Active Substances in Annex I of Council Directive 91/414/EEC

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1141/2010

Oxamyl
List of Endpoints

Rapporteur Member State: Italy
Co-Rapporteur Member State: France
December 2017

VERSION HISTORY

Date	Data points containing amendments or additions	Document identifier or version number
May 2016	First RAR of Italy	
December 2017	Revised RAR after comment CoRMS (France)	

LISTING OF ENDPOINTS FOR *OXAMYL, OXAMYL 10GR,* AND *OXAMYL 10SL*

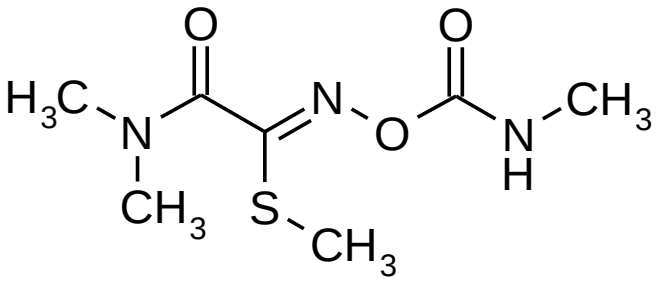
Section 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Oxamyl
Function (*e.g.* fungicide)	Nematicide

Rapporteur Member State	Italy
Co-rapporteur Member State	France

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	N,N-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio) acetamide
Chemical name (CA)	Methyl 2-(dimethylamino)-N-[[(methylamino) carbonyl]oxy]-2-oxoethanimidothioate
CIPAC No	342
CAS No	23135-22-0
EC No (EINECS or ELINCS)	245-445-3
FAO Specification (including year of publication)	Oxamyl is not isolated as a technical material (TC), its manufacture involves dilution of the product from synthesis with a solvent, to nominal concentrations of 42% % (w/w) oxamyl in the TK. 42% TK containing 407 g/kg FAO specification 342 (April 2008)
Minimum purity of the active substance as manufactured	926 g/kg (TC) (to be confirmed by latest 5 batch data) Oxamyl is manufactured as technical concentrate (TK). The minimum and maximum content of the active substance in the TK 42% is 411 and 454 g/kg respectively, based on the minimum purity of the TC (or 399 and 441 g/kg respectively, based on pure active substance).
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None of the impurities are considered relevant
Molecular formula	$C_7H_{13}O_3N_3S$
Molecular mass	219.3 g/mol
Structural formula	

Physical-chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	Heated block method: 98.5-100°C (99.9% purity, DuPont-13350) Differential scanning calorimetry method: 99.2°C (98.0% purity, DuPont-14983)
Boiling point (state purity)	No boiling point was observed for oxamyl, as it was observed to decompose at 165°C (98.0% purity, DuPont-14983)
Temperature of decomposition (state purity)	>165°C (98.0% purity, DuPont-14983)
Appearance (state purity)	
Oxamyl 42TK (active substance as manufactured)	Translucent liquid of light green color (Munsell 10Y 9/2) (420 g a.s./kg, RF-0014.001.256.06)
Oxamyl PAI (Pure Active Ingredient)	White, crystalline solid which corresponds to the Munsell colour N 9.5 (100.0% purity, DuPont-2129)
Vapour pressure (state temperature, state purity)	1.80×10^{-5} Pa at 20°C (98.0% purity, DuPont-26259)
Henry's law constant (state temperature)	pH 5: 2.7×10^{-8} Pa m^3/mol (98.0% purity, DuPont-38270)
Solubility in water (state temperature, state purity and pH)	148.1 g/L at 20 ± 0.5°C (pH 5) (98.3% purity, DuPont-13351)
Solubility in organic solvents (state temperature, state purity)	In acetone >250 g/kg at 20°C In dichloromethane >250 g/kg at 20°C In ethyl acetate 4.13×10^4 mg/L at 20°C In n-heptane 10.5 mg/L at 20°C In methanol >250 g/kg at 20°C In o-xylene 3.14×10^3 mg/L at 20°C (100.0% purity, DuPont-4513)
Surface tension (state concentration and temperature, state purity)	73.1 ± 0.3 dynes/cm at 20.4 ± 0.1°C (100.0% purity, DuPont-4318)
Partition coefficient (state temperature, pH and purity)	log P_{OW} = -0.43 at 23°C (double distilled water) (99.1% purity, DuPont-39338)
Dissociation constant (state purity)	Oxamyl does not dissociate between pH 2.4 to pH 11.6 at 20 ± 0.5°C (98.0% purity, DuPont-26918)
UV/VIS absorption (max.) incl. ε (state purity, pH)	ε at 290 nm: 61.6 L/mol/cm at pH 2 80.1 L/mol/cm at pH 7 1150 L/mol/cm at pH 10 (100.0% purity, DuPont-2163)
Flammability (state purity)	
Oxamyl 42TK (active substance as manufactured)	The flash point was 57.4°C (135.26°F). (420 g a.s./kg, DuPont-3655) The auto-ignition temperature was determined to be 303°C (± 5°C). (420 g a.s./kg, 550/77-D2141)
Oxamyl PAI (Pure Active Ingredient)	No self-ignition (auto-flammability) (98.0% purity, DuPont-14828)
Explosive properties (state purity)	Not explosive (420 g a.s./kg, 550/77-D2141)
Oxidising properties (state purity)	Not an oxidizer (99.1% purity, DuPont-40352)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (oxamyl)

(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

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

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

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

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

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**	**L product/ a 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

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment:

No additional uses in addition to uses above, for which MRL application has been made.

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

General:
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).

Oxamyl 10GR:
On potato, Oxamyl 10GR is intended to be applied once at planting (BBCH 00). The maximum intended application rate is 1.0 kg a.s./ha.
On tobacco, Oxamyl 10GR is intended to be applied once at transplanting (BBCH 00) with a maximum application rate of 3.0 kg a.s./ha. Also, on tobacco, one application at pre-planting stage (BBCH 00) of the product evenly soil incorporated to a depth of 5–10 cm at maximum application rate of 5.5 kg a.s./ha.

Oxamyl 10SL:
On tomato, Oxamyl 10SL is applied *via* drip irrigation and recommended to be used up to 2 kg a.s./ha immediately after transplant; followed by up to 3 applications of 1 kg a.s./ha each starting with BBCH 11 (10–14 days after transplant application), up to 42 days after transplanting at planting (BBCH 00).

Considering the solarisation use, Oxamyl 10SL is applied *via* drip irrigation with transparent plastic foil covering soil and before transplant on bare soil (approximately between June and September) at maximum application rate of 5.5 kg a.s./ha. The recommended Plant Back Interval is 30days, and the application to bare soil covered with plastic foil to control soil nematodes before transplant.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

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

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

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

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.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 at Stage 1)

	IN-A2213	IN-D2708
Activity against target organism	no	no

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.

Methods of Analysis

Analytical methods for oxamyl (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	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 is conducted by reversed-phase liquid chromatography (HPLC) or ultra-high pressure liquid chromatography (UPLC), with quantitation by ultraviolet absorbance at 240 nm.
Impurities in technical a.s. (analytical technique)	The method involves dissolution by ultrasonicatiion of oxamyl in a sample diluent of pH 3.0 water adjusted with H_3PO_4. Analysis is conducted by reverse-phase liquid chromatography (HPLC) or ultra-high pressure liquid chromatography (UPLC) with quantitation by ultraviolet absorbance at 205 nm.
Plant protection product (analytical technique)	Oxamyl 10GR/Oxamyl 10SL method involves dissolution by ultrasonication in a solution of 5% methanol and 95% water adjusted to pH 3.0 with H_3PO_4. Analysis by reversed-phase liquid chromatography (HPLC) or ultra-high pressure liquid chromatography (UPLC), with quantitation by ultraviolet absorbance at 240 nm.

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin	Oxamyl parent
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.
Soil	Oxamyl parent
Water surface	Oxamyl parent
drinking/ground	Oxamyl parent
Air	Oxamyl parent
Body fluids and tissues	Oxamyl parent

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Matrices: Dry, watery, oily, acidic and difficult to analyse crops Separation/Quantitation: QuECHERS MRM and HPLC/MS/MS LOQ: 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Matrices: Meat (bovine), fat (bovine), liver (bovine), milk, eggs Separation/Quantitation: QuECHERS MRM HPLC/MS/MS LOQ: 0.01 mg/kg
Soil (analytical technique and LOQ)	Separation/Quantitation: HPLC-MS/MS LOQ: 0.001 mg/kg
Water (analytical technique and LOQ)	Separation/Quantitation: HPLC-MS/MS LOQ: 0.0001 mg/L
Air (analytical technique and LOQ)	Separation/Quantitation: HPLC-MS/MS LOQ: 0.05 $\mu g/m^3$
Body fluids and tissues (analytical technique and LOQ)	Separation/Quantitation: HPLC-MS/MS LOQ: 0.05 mg/L

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Oxamyl Technical 42% TK (Pure Active Ingredient [PAI] is never isolated nor shipped and thus is not relevant for CLP classification). PAI already has a harmonized classification according to regulation 1278/2008.
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	Pictogram: GHS02, GHS06, GHS09 Signal Word: Warning Flam. Liq. 3 Acute Tox. 2 (oral) Acute Tox. 4 (dermal)[a] Acute Tox. 2 (inhal) Eye Irrit. 2 Aquatic Chronic 2 Hazard statements: H226: Flammable liquid and vapour. H300: Fatal if swallowed. H312: Harmful in contact with skin[a] H330: Fatal if inhaled. H319: Causes serious eye irritation. H411: Toxic to aquatic life with long lasting effects. Precautionary statements: P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking. P261 Avoid breathing vapours. P270 Do not eat, drink or smoke when using this product. P273 Avoid release to the environment. P280 Wear eye protection/ face protection. P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor/ physician. P320 Specific treatment is urgent (see supplemental instructions on the administration of antidotes on this label). P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents/container to an approved incineration plant. Supplementary advice (according to Directive 2003/82/EC amending Directive 91/414/EEC). SP1 Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). SPo 2 Wash all protective clothing after use

[a] 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.

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

Substance	**Oxamyl 10GR** Pictogram: GHS06 Signal Word: Warning Classification: Acute toxicity, Category 2 Acute toxicity, Category 3 Chronic aquatic toxicity, Category 3 Hazard Statements H300 Fatal if swallowed H331 Toxic if inhaled H412 Harmful to aquatic life with long lasting effects. Precautionary statements Prevention: P261 Avoid breathing dust. P264 Wash hands and face thoroughly after handling. Response: P301 + P310 IF SWALLOWED: Immediately call a POISON Center or doctor/physician. P304 + P340 + P310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON Center or doctor/physician. P321 Specific treatment (see first aid measures on this label). P330 Rinse mouth. Storage P403 + P233 Store in a well-ventilated place. Keep container tightly closed. Disposal P501 Dispose of contents/container to an approved incineration plant. Supplementary advice (according to Regulation (EC) No. 547/2011amending Regulation (EC) No. 1107/2009). SP1 Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

Substance	**Oxamyl 10SL** Pictogram: GHS06 Signal Word: Warning Classificaiton Acute toxicity, Category 2 Acute toxicity, Category 3 Chronic aquatic toxicity, Category Hazard Statements H300 Fatal if swallowed H331 Toxic if inhaled H412 Harmful to aquatic life with long lasting effects. Precautionary statements Prevention: P261 Avoid breathing dust. P264 Wash hands and face thoroughly after handling. Response: P301 + P310 IF SWALLOWED: Immediately call a POISON Center or doctor/physician. P304 + P340 + P310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON Center or doctor/physician. P321 Specific treatment (see first aid measures on this label). P330 Rinse mouth. Storage P403 + P233 Store in a well-ventilated place. Keep container tightly closed. Disposal P501 Dispose of contents/container to an approved incineration plant. Supplementary advice (according to Regulation (EC) No. 547/2011amending Regulation (EC) No. 1107/2009). SP1 Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	None

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Section 2: Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	>90% after single doses of [^{14}C]oxamyl (1 mg/kg bw) to rats (based on urine excretion and residues in tissues and carcass)
Toxicokinetics	Not available
Distribution	Widely distributed Highest concentration in whole blood (0.1 µg eq/g), in heart, liver, kidney, lungs, spleen, and the gastro-intestinal tract (0.04 to 0.09 µg eq/g). Concentrations in all other tissues were approximately 0.01 to 0.03 µg eq/g. No significant gender differences
Potential for bioaccumulation	No evidence for bioaccumulation. Tissue residues were low (0.003 to 0.09 mg/kg).
Rate and extent of excretion	After single doses of [1-^{14}C]oxamyl (1 mg/kg bw) to rats, the majority of the dose (>90%) was eliminated in the urine within 168 hours of dosing. Faeces and expired air were minor elimination routes
Metabolism in animals	Extensive (very minor amount of the parent present in the urine. The major route of oxamyl biotransformation was hydrolysis to IN-A2213, then conjugation. Indeed, the major urinary metabolite in oxamyl and IN-A2213-dosed rats was the IN-A2213 glucuronide. Major reactions: Hydrolysis of 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.
In vitro metabolism	For oxamyl, metabolic differences among species have been assessed limited to rats and mice. In the *in vitro* experiment, incubation of oxamyl with mouse liver microsomes gave IN-N0079, IN-D2708, IN-KP532, IN-A2213, and IN-D1409, similarly to the results obtained with rats liver microsomes. No comparative metabolism studies with human cells is available
Toxicologically relevant compounds (animals and plants)	Parent oxamyl; the main metabolites, IN-A2213 and IN-D2708, as well as IN-N0079 and IN-L2953 (oxamyl metabolites found in plants), are generated *in vivo* and are considered to be adequately tested in studies involving parent oxamyl based on the available data. Supplemental information indicate a much lower toxicity for the major metabolites. **Data are missing for IN-T2921, which was never detected in metabolism studies with rodents.**
Toxicologically relevant compounds (environment)	Parent oxamyl; the main metabolites, IN-A2213 and IN D2708, as well as IN-N0079 and IN-L2953 (oxamyl metabolites found in soil, water, and/or sediment) are generated in vivo and are considered to be adequately tested in studies involving parent oxamyl based on the available data. Supplemental information indicate a much lower toxicity for the major metabolites.

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	LD_{50} 2.5 mg/kg bw (female rat)	Cat. 2 H300
Rat LD_{50} dermal	LD_{50} 5027 mg/kg bw (male rat) LD_{50} >5000 mg/kg bw (female rat)	NC
Rat LC_{50} inhalation	LC_{50} 56 mg/m^3 (equivalent to 0.056 mg/L, rat, nose only)	Cat. 2 H330
Skin irritation	Non-irritant (rabbit)	NC
Eye irritation	Non-irritant (rabbit)	NC
Skin sensitisation	Not a sensitiser (guinea pig, 42% TK; modified Buehler test: high purity a.s. was lethal when administered in the M&K test)	**NC**
Phototoxicity	Not phototoxic	**NA**

Short term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ/critical effect	Rat: ↓ body weight gain, urine blood, ↓ absolute organ weight Dog: ↓ plasma and brain cholinesterase activity among males and clinical signs among females Rabbit: ↓ plasma, erythrocyte and brain cholinesterase activity	NC
Relevant oral NOAEL	Rat: 3.9 mg/kg/bw/days (males) 4.3 mg/kg bw/day (females) Dog: 1.46 mg/kg bw/day (based on tremors and cholinesterase inhibition) (LOAEL) 0.93 mg/kg bw/day (*i.e.*, 35 ppm) (based on clinical signs) rounded to **1 mg/kg bw/day** (NOAEL)	NC
Relevant dermal NOAEL	Rabbit, 21 day: 50 mg/kg bw/day (based on decreases in plasma and erythrocyte cholinesterase activity)	NC
Relevant inhalation NOAEL	No data - not required	NA

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

In vitro studies	Gene mutation assays: • Reverse mutation (*Salmonella typhimurium* *Escherichia coli):* negative Chromosome aberration assay: • Mammalian cell gene mutation (Chinese hamster ovary cells): negative DNA damage and repair assay: • *In vitro* cytogenetics (Human peripheral blood lymphocytes): negative	NC
In vivo studies	*In vivo* cytogenetics assay *In vivo* micronucleus (mouse): negative	NC
Photomutagenicity	Not required	NA
Potential for genotoxicity	No genotoxic potential	NC

Long term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Decreased plasma cholinesterase activity (rat)	
Relevant long-term NOAEL	2-year, rat: 50 ppm or 1.97/kg bw per day (male); non neoplastic effects 18 months mouse: 25 ppm or 4.2 mg/kg bw/day (males) non neoplastic effects	NC
Carcinogenicity (target organ, tumour type)	No evidence of carcinogenic potential (rat and mouse)	NC
Relevant NOAEL for carcinogenicity	Not relevant	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target/critical effect	Reduced pup survival and reduced litter size at the parentally toxic dose of 150 ppm (rat) Reduced parental body weight/body weight gain, food consumption & efficiency Reduced pup body weight No effects on reproduction	NC
Relevant parental NOAEL	Rat: 25 ppm (1.43 mg/kg bw/day)	NC
Relevant reproductive NOAEL	Rat: 150 ppm, 12.2 mg/kg bw/day	NC
Relevant offspring NOAEL	Rat pup: 25 ppm	NC

Developmental toxicity

Developmental target/critical effect	Rat: Decreased maternal and foetal body weight (rat)	NC
Relevant maternal NOAEL	Rat: 0.5 mg/kg bw/day Rabbit :1 mg/kg bw/day	NC
Relevant developmental NOAEL	Rat: 0.2 mg/kg bw/day Rabbit: 2 mg/kg bw/day	NC

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	0.1 mg/kg bw/day NOAEL (rat gavage)	NC
Repeated neurotoxicity	1.69 mg/kg bw/day NOAEL (equivalent to 30 ppm; rat 90-day dietary)	NC
Additional studies (*e.g.* delayed neurotoxicity, developmental neurotoxicity)	Acute inhalation neurotoxicity Rat: NOAEL <0.0049 mg/L	NC

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	*See studies below*
Endocrine disrupting properties	No potential for endocrine activity
	Pubertal development and thyroid function in intact juvenile/peripubertal male rats (oral administration) Concentration range: 0.25 and 0.5 mg/kg/day Result: No potential to disrupt hypothalamic-pituitary-thyroid axis.
	Pubertal development and thyroid function in intact juvenile/peripubertal female rats (oral administration) Concentration range: 0.25 and 0.5 mg/kg/day Result: No potential to disrupt the hypothalamic-pituitary-thyroid axis.

In vitro aromatase inhibition (human recombinant microsomes) Concentration range: 1.0×10^{-10} M to 1.0×10^{-3} M Result: No inhibition of aromatase
Estrogen receptor transcriptional assay (human cell line [HeLa-9903]) Concentration range: $1 \times 10^{-6.8}$ M to $1 \times 10^{-3.3}$ M Result: Not considered an agonist of human oestrogen receptor alpha (hERα) in HeLa-9903
In vitro estrogen receptor binding assay using rat uterine cytosol (ER-RUC) Concentration range: 1.0×10^{-10} to 1.0×10^{-3} M Result: Non-inhibiton in the oestrogen receptor binding assay
3-day Uterotrophic assay Concentration range: 0, 01, 0.25, or 0.5 mg/kg/day Result: No induction of oestrogenic effects when administered up to 0.5 mg/kg/day for 3 consecutive days.
10-Day Hershberger bioassay (Young adult castrated Crl:CD(SD) rats) Concentration range: 0, 01, 0.25, or 0.5 mg/kg/day Result: No induction of androgenic or antiandrogenic activity in the Hershberger Bioassay when administered up to 0.5 mg/kg/day for 10 consecutive days
In vitro Steroidogenesis assay, human cell line, H295R Concentration range: 100, 10, 1, 0.1, 0.01, 0.001, and 0.0001 μM Result: No induction or inhibition of steroid biosynthesis.
In vitro androgen receptor binding assay (Rat prostate cytosol) Concentration range: 1.0×10^{-10} to 1.0×10^{-3} M No competitive binding to the androgen receptor when tested up to a maximum concentration of 1.0×10^{-3} M. Result: No inhibition of the androgen receptor binding. DuPont-32153

Studies performed on metabolites or impurities	All detected as in vivo metabolites in rodents. The studies provide supplemental information
Metabolite IN-A2213	Acute oral (male rats), Acute lethal dose = 11000 mg/kg bw
Metabolite IN-A2213	10-Dose subacute oral (male rats) No NOAEL Mortality, histopathological changes: 2200 mg/kg bw/day histopathological changes clinical signs and body weight loss: 1000mg/kg bw/day
Metabolite IN-L2953	Oral LD_{50} study (male rats) LD_{50} = 6675 mg/kg bw (6370–6990 mg/kg bw)
Metabolite IN-N0079	Acute oral study (male rats) Acute lethal dose = 450 mg/kg bw
Metabolite IN-N0079	10-Dose subacute oral study) (male rats) No NOAEL ↓ 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
Metabolite IN-N0079	90-day oral study (rat) NOEL parental = 50 ppm (4.0 (male) and 4.2 (female) mg/kg bw/day) based on reduced body weight and altered clinical chemistry parameters in both sexes NOEL fertility = 450 ppm (34.3 (male) and 35.7 (female) mg/kg bw/day) NOEL developmental = 150 ppm (11.4 (male) and 12.6 (female) mg/kg bw/day) based on decreased body weight in F1 pups during lactation
Metabolite IN-N0079	Ames study (*S.typhimurium*) Not mutagenic
Metabolite IN-D2708	Oral LD_{50} study (male rats) LD_{50} = 3540 mg/kg

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

No incidents or accidents during the manufacturing process. No data relating to exposure of the general public to oxamyl or epidemiological studies.

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.01	Acute neurotoxicity study (rat)	10
Acute Reference Dose (ARfD)	0.01	Acute neurotoxicity study (rat)	10
Acceptable Operator Exposure Level (AOEL)	0.01	Acute neurotoxicity study (rat)	10
Acute Acceptable Operator Exposure Level (AAOEL)	None proposed[4]	-	-

[3] If available include also reference values for metabolites

[4] There is currently no EU guidance for establishing this endpoint and no established use in current risk assessment methodology.

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Oxamyl 10GR	Triple pack approach on the formulation (*in vivo* rat study with a correction based on *in vitro* results; in vitro data only on the undiluted product): **0.08%** is proposed for the **undiluted product.** **0.72%** is proposed for the **in use field dilution (pro-rata calculation).**
Oxamyl 10SL	Triple pack approach on the formulation (*in vivo* rat study with a correction based on *in vitro* results) Data only on the undiluted product). For the current use this product is applied *via* a drip irrigation system. Once the concentrated product is loaded it is introduced directly to the soil by drip irrigation. Therefore only the undiluted formulations has the opportunity to be absorbed through the skin of the operators, during mixing and loading.

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Oxamyl 10GR	
Operators	Use: Tobacco (pre-plant soil incorporated to a depth of 10 cm) Application method: tractor mounted equipment <u>Based on a field study, with PPE</u> Application rate: 1 kg/ha Use: During planting potatoes Highest individual operator exposure: Dermal route: 0.143 mg/person/day Inhalation route: 0.0132 mg/person/day Dermal absorption: 0.04 % Body weight: 60 kg ([0.143 mg/person/day × 0.0004] + 0.0132 mg/person/day)/60 kg/person = 0.00022 mg/kg/day 2.2% of the systemic AOEL of 0.01 mg/kg bw/day. <u>Worst case estimate based on proposed critical GAP</u> Application rate: 5.5 kg a.s./ha estimated by extrapolating field study results (5.5 × 2.2% of AOEL) 12% of AOEL
Workers	Oxamyl 10GR is applied directly to soil, and worker exposure by contact with crop foliage is negligible. Exposure estimates on potential dermal exposure based on soil residues: EUROPOEM II Residue transfer to skin: 100%. Body weight: 60 kg Dermal absorption: 0.04% Systemic dose equivalent: <1% of AOEL 0.01 mg/kg/day.
Bystanders and residents	Not relevant as exposure to potential bystanders/residents is negligible

Oxamyl 10SL	
Operators	Use: 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) Application rate: 5.5 kg a.s./ha Application method: Drip irrigation Area treated: 1 ha Exposure estimates (model): 4 % of AOEL *UK POEM* Without PPE*:* 0.00037 (mg/kg bw/day) *German model* Without PPE: 0.00042 mg/kg bw/day)
Workers	Oxamyl 10SL is applied directly to soil, and worker exposure by contact with crop foliage is negligible. Exposure estimates on potential dermal exposure based on soil residues*:* EUROPOEM II Residue transfer to skin: 100%. Body weight: 60 kg Dermal absorption: 0.2% Systemic dose equivalent: <1% of AOEL 0.01 mg/kg/day
Bystanders and residents	Not relevant as exposure to potential bystanders/residents is negligible

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance:	Oxamyl 42% TK
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][5]:	H300: Fatal if swallowed. H312: Harmful in contact with skin[a] H330: Fatal if inhaled.
Peer review proposal [6] for harmonised classification according to Regulation (EC) No 1272/2008:	H300: Fatal if swallowed. H312: Harmful in contact with skin[a] H330: Fatal if inhaled.

[a] 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.

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[6] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Section 3: Residues

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**		**DAT** (days)
	Fruit crops	Apple	0.1 kg a.s./hL (painting of fruit)		47
		Orange	0.1 kg a.s./hL (painting of fruit)		42
		Tomato	0.1 kg a.s./hL; surface treatment		7, 11, 14, 21
		Tomato	4 x foliar applications; 4 x soil applications		7, 14
	Root crops	Potato	1 x 8.0 kg a.s./ha; soil treatment		127
		Potato	1 x 3.36 kg a.s./ha; soil treatment or 5 x 0.56-1.12 kg a.s./ha; foliar		- -
	Leafy crops	Tobacco	1 x 10 mg/plant; foliar		7, 15
		Tobacco	1 x 6.7 kg a.s./ha; soil treatment		harvest
	Cereals/grass crops	Not relevant/Not conducted			
	Pulses/Oilseeds	Peanut	1 x 2.24 kg a.s./ha; foliar		28; harvest
		Peanut	2 x 2.24 kg a.s./ha; foliar		harvest
		Peanut	1 x 1.68 kg a.s./ha; pre-planting (in furrow) + 2 x 1.12 kg/ha foliar		40, 70
	Miscellaneous	Bean and cotton seedlings	15 and 20 µL of a 10% aqueous solution; stem injection		1,3, 7, 15 (bean)
Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**	
	Root/tuber crops	beets	30, 120, 363	Oxamyl, IN-A2213, and IN-D2708 were >0.01 mg/kg (oxamyl equivalents) in barley, beet, cabbage, and lettuce commodities planted 30 and 120 days after soil treatments of 9 and 20 kg a.s./ha. Metabolites (IN-KP532, IN-T2921, IN-L2953, and IN-N0079) were tentatively identified in barley planted 30 days after soil treatment at 8 kg a.s./ha.	
	Leafy crops	cabbage, lettuce	30, 120 30, 120, 363		
	Cereal (small grain)	barley	30, 120, 363		
	Other	sorghum	30, 120		
Rotational crop and primary crop metabolism similar?	The proposed metabolic pathway of oxamyl in rotated crops is consistent with the pathway seen in plants following oxamyl application at planting or postemergence.				

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	**Oxamyl (%)**	**IN-A2213 (%)**		
	20 min, 90°C, pH 4	100	0		
	60 min, 100°C, pH 5	57.80	41.42		
	20 min, 120°C, pH 6	0	100		
Residue pattern in processed commodities similar to residue pattern in raw commodities?	With increasing temperatures, oxamyl was found to be increasingly labile with a rapid degradation to IN-A2213 (oxamyl oxime)				

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Oxamyl
Plant residue definition for risk assessment (RD-RA)	Oxamyl
Conversion factor (monitoring to risk assessment)	1

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) Animals covered	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
	Laying hen	2.4 mg/kg bw/d	3	>1000
	Goat/Cow	1.6 mg/kg bw/d	5	>1000
	Pig	-	-	-
	Fish	-	-	-

Time needed to reach a plateau concentration in milk and eggs (days)	At normal feed level (1N), no residues are expected in any milk or egg samples
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Oxamyl
Animal residue definition for risk assessment (RD-RA)	Oxamyl
Conversion factor (monitoring to risk assessment)	1
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) (FAO, 2009)	No

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) OECD Guideline 502	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 20 kg oxamyl/ha. These components have been previously identified in plant metabolism studies, and all were present in the soil at planting.
Field rotational crop study OECD Guideline 504	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.

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

OECD Guideline 506

Plant products (Category)	**Commodity**	**T (°C)**	**Stability (Month)**					
High water content	Leaf lettuce	-18	97 (0)	84 (3)	88 (6)	88 (12)	84 (18)	91 (24)
	Tomato fruit	-18	90 (0)	83 (3)	87 (6)	81 (12)	71 (18)	77 (24)
High oil content	Not applicable	-	-	-	-	-	-	-
High protein content	Not applicable	-	-	-	-	-	-	-
High starch content	Potato tuber	-18	83 (0)	77 (3)	78 (6)	79 (12)	80 (18)	70 (24)
	Sugarbeet root	-18	74 (0)	82 (3)	84 (6)	72 (12)	69 (18)	75 (24)
High acid content	Orange fruit	-20	90 (0)	97 (3)	105 (6)	89 (9)	101 (12)	
	Orange peel	-18	95 (0)		91 (6)	93 (12)	88 (18)	81 (24)
Dry commodity	Tobacco leaves, dried Not applicable	-20	90 (0)	75 (1)	69 (3)	87 (6)		
Oxamyl is stable in watery and starchy crop matrices plus orange peel stored frozen at -18 ± 5°C for at least 24 months, in acidic crop matrices stored frozen at -20 ± 5°C for at least 12 months, and in dry crop matrices stored frozen at -20 ± 5°C for at least 6 months. Degradation of residues during storage of samples is not expected.								

Animal	Animal commodity	T (°C)	Stability (Month/Year)					
	Muscle		Not applicable. No feeding study.					
	Liver		Not applicable. No feeding study.					
	Kidney		Not applicable. No feeding study.					
	Milk		Not applicable. No feeding study.					
	Egg		Not applicable. No feeding study.					
Livestock feeding studies are not necessary to assess human exposure to oxamyl from animal food sources; therefore, stability of oxamyl residues in animal matrices was not required.								

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Representative uses						
Potato	NEU	4 × <0.005, 4 × <0.01		0.01	0.01	0.0075
Potato	SEU	8 × <0.005		0.01	0.005	0.005
Tomato	Indoor	24 × <0.01		0.01	0.01	0.01
Tobacco	SEU	5 × <0.01	**Proposed 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.	0.01**	0.01	0.01
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	Region	Residue data (mg/kg)	Recommendations/comments			
Not required. Trials are carried out with the formulations proposed for Annex I Renewal representative uses.						
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	Region	Residue data (mg/kg)	Recommendations/comments			
Pollen	SEU	<0.001 - 0.532, transplanting of tobacco and treatment with granules in furrow at a rate of 3 kg a.s./ha	DuPont recommends waiving the setting of MRL since there are no guidelines harmonised at the EU or international level that could valuably be followed to generate such data and permit a meaningful interpretation.			

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.

(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.

(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).

(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$)

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Potato tubers	0.01	No detectable residues	0.01	No detectable residues

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d)	Beef cattle	0.0012	Ram/Ewe	0.0016	Breeding	0.0010	Broiler	0.0005	Carp	
	Dairy cattle	0.0015	Lamb	0.0011	Finishing	0.0008	Layer	0.0005	Trout	
(mg/kg DM for fish)							Turkey	0.0007	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		No	
Feeding study submitted	Not required or submitted based on the low dietary burdens.									

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	**Number of tests**[(a)]	**Processing Factor** (PF)		**Conversion Factor** (CF_P) **for RA**[(b)]
		Individual values	Median PF	
Representative uses				
Potato/baked	3	<0.1 (<0.05), 0.08, 0.15	0.08	
Potato/boiled	3	3 x <0.01	<0.1	
Potato/microwaved	3	3 x <0.01	<0.1	

(a): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

(b): When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

ADI	0.001 mg/kg bw per day
TMDI according to EFSA PRIMo (Reference: EFSA; Review of the existing maximum residue levels (MRLs) for oxamyl according to Article 12 of Regulation (EC) No 396/2005.)	Highest TMDI: 6.8 % ADI (UK, infant)
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: Not conducted since TMDI <ADI
Factors included in the calculations	
ARfD	0.001 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI: 15.4% ARfD (potato)
Factors included in IESTI and NESTI	none

Consumer risk assessment limited to the representative uses

TMDI (% ADI), according to EFSA PRIMo	Highest TMDI: 0.3 % ADI potato (UK, infant)
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: Not conducted since TMDI <ADI
Factors included in the calculations	
IESTI (% ARfD, according to EFSA PRIMo)	Highest IESTI: 15.4 % ARfD (Potato)
Factors included in IESTI and NESTI	

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code[(a)]	**Commodity/Group**	**MRL/Import tolerance**[(b)] (mg/kg) **and Comments**	
Plant commodities			
Representative uses			
0211000	Potato	0.01*	Current EU MRL
0231010	Tomato	0.01*	Current EU MRL
	Tobacco	0.01*	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.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

Section 4: Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	7.0 – 108.5 % after 15 – 179 d, [^{14}C-oxamyl]-label (n^7= 10 incubations; 9 soils tested – 7 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C)
Non-extractable residues after 100 days	11.4 – 26.4 % after 15 – 179 d, [^{14}C-oxamyl]-label (n= 10 incubations; 9 soils tested – 7 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	***IN-A2213 :*** maximum 5 – 51.0 % after 2 – 60 d, [^{14}C-oxamyl]-label (n= 10 incubations; 9 soils tested – 7 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C) ***IN-D2708 :*** maximum 20.3 – 78 % after 7 – 90 d, [^{14}C-oxamyl]-label (n= 10 incubations; 9 soils tested – 7 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C)

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	12 – 21 % after 71 d, [^{14}C-oxamyl]-label (n= 2 soils tested – 11 days aerobic incubation followed by 60 days anaerobic incubation at 25 °C)
Non-extractable residues after 100 days	18.4 – 25 % after 71 d, [^{14}C-oxamyl]-label (n= 2 soils tested – 11 days aerobic incubation followed by 60 days anaerobic incubation at 25 °C)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	***IN-D2708 (DMOA) :*** 20 – 23.1 % at 45 and 32 d, [^{14}C-oxamyl]-label (n= 2 soils tested – 11 days aerobic incubation followed by 60 days anaerobic incubation at 25 °C) ***IN-A2213 (Oxime) :*** 13 – 69.5 % at 11 and 20 d, [^{14}C-oxamyl]-label (n= 2 soils tested – 11 days aerobic incubation followed by 60 days anaerobic incubation at 25 °C)

[7] n corresponds to the number of soils.

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	***IN-D2708 :*** maximum *45.4 % after 15 d,* [^{14}C-oxamyl]-label (n=1 irradiated samples) ***IN-N0079 :*** maximum *10.2 % after 5 d,* [^{14}C-oxamyl]-label (n=1 irradiated samples) ***IN-A2213 :*** maximum *4.5 % after 3 d,* [^{14}C-oxamyl]-label (n=1 irradiated samples)
Mineralisation at study end	17.5 % after 15d, [^{14}C-oxamyl]-label (n=1 irradiated samples)
Non-extractable residues at study end	4.1 % after 15d, [^{14}C-oxamyl]-label (n=1 irradiated samples)

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Oxamyl	Dark aerobic conditions					
Soil type	pH[a)]	t.°C/% MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Commerce)	7.0	20°C/33.3	2.8/9.3	1.8[c)]	7.8	SFO
Silt loam (Commerce)	7.0	10°C/33.3	15.8/52.3	3.8[c)]	4.4	SFO
Silt loam (Gross-Umstadt)	7.8	20°C/50	3.7/13.9	3.3	6.2	SFO
Sandy loam clay (Madera)	7.7	25°C/15.4	11.1/36.8	11.4	5.5	SFO
Loam (Nijmegen)	7.0	20°C/33.3	7.8/25.8	5.0	6.6	SFO
Silt loam (Goch)	6.0	20°C/pF 2	0.6/2.0	0.6	0.7	SFO
Sandy loam (LRA-D)	5.6	20°C/pF 2	9.7/79.5	19.4	3.3	FOMC $DegT_{90}$/3.32
Speyer 582 Loamy sand (Speyer)	6.4	20°C/pF 2	7.2/24.0	7.2	5.2	SFO
Silty clay loam (Tama)	7	20°C/pF 2	7.8/48.5	14.3	3.3	FOMC $DegT_{90}$/3.32
Geometric mean (if not pH dependent)				5.3		
pH dependence				No		

a) Measured in water

b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7

c) Geometric mean was calculated for Commerce soil prior to calculation of the overall geometric mean

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

IN-A2213	Dark aerobic conditions precursor from which the maximum f.f. was derived was oxamyl						
Soil type	pH[a)]	t.°C/% MWHC	DT_{50}/DT_{90} (d)	f. f	DT_{50} (d) 20°C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Commerce)	7.0	20°C/33.3	5.8/19.1	0.98	3.6[c)]	6.3	SFO-SFO
Silt loam (Commerce)	7.0	10°C/33.3	22.1/73.3	0.74	5.4[c)]	7.5	SFO-SFO
Silt loam (Gross-Umstadt)	7.8	20°C/50	1.7/5.7	0.98	1.3	11.8	SFO-SFO
Loam (Nijmegen)	7.0	20°C/33.3	1.7/5.5	1.0	1.1	23.2	SFO-SFO
Loamy sand (Speyer)	6.4	20°C/pF 2	1.4/4.5	0.75	1.4	16.3	SFO-SFO
Silty clay loam (Tama)	7	20°C/pF 2	1.8/5.9	0.86	1.8	17.0	FOMC-SFO
Geometric mean (if not pH dependent)					1.7		
Maximum				1.0			
pH dependence					No		

a) Measured in water

b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7

c) Geometric mean was calculated for Commerce soil prior to calculation of the overall geometric mean

d) From modelling fits

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

IN-D2708	Dark aerobic conditions precursor from which the f.f. was derived was IN-A2213						
Soil type	pH[a)]	t.°C/% MWHC	DT_{50}/DT_{90} (d)	f. f. [d)]	DT_{50} (d) 20°C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Commerce)	7.0	20°C/33.3	3.5/11.8	-	2.2[c)]	18.1	SFO-SFO
Silt loam (Gross-Umstadt)	7.8	20°C/50	3.2/10.8	-	2.6[c)]	17.9	SFO-SFO
Loam (Nijmegen)	7.0	20°C/33.3	8.8/29.4	0.73	5.7	9.0	SFO-SFO
Silt loam (Commerce)	7.0	20°C/33.3	7.6/25.3	-	4.8[c)]	17.7	SFO
Silt loam (Gross-Umstadt)	7.8	20°C/50	9.5/31.6	-	8.5[c)]	15.1	SFO
Silty clay loam (Drummer)	4.8	20°C/49.4	12.7/42.2	-	10.6	14.7	SFO
Silty clay loam (Tama)	7	20°C/pF 2	6.8/22.4	1.0	6.8	15.7	FOMC-SFO
Geometric mean (if not pH dependent)					5.7		
maximum				1.0			
pH dependence					No		

a) Measured in water

b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7

c) Geometric mean was calculated for Commerce and Gross-Umstadt soils prior to calculation of the overall geometric mean

d) From modelling fits

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

IN-N0079	Dark aerobic conditions metabolite dosed directly into soil						
Soil type	pH[a)]	t.°C/% MWHC	DT_{50}/DT_{90} (min)	f. f.[c)]	DT_{50} (min) 20°C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Commerce)	7.0	23°C/40-50%	49.5/164.4	-	41.2	6.3	SFO
Silt loam (Gross-Umstadt)	7.8	23°C/40-50%	4.0/13.2	-	4.4	0.8	SFO
Silty clay loam (Drummer)	4.8	23°C/40-50%	23.0/76.5	-	23.0	3.4	SFO
Maximum worst case					1 day		
Arithmetic mean				-			
pH dependence					Not possible to determine		

a) Measured in water

b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7

c) From modelling fits

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Oxamyl		Aerobic conditions							
Soil type	Location	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	St. (χ^2)	Method of calculation
Ottersum (bare soil; incorporated)	Netherlands	6.6 (0-15 cm)	0 - 90	9.5	31.4	7.2	5.0	5.7	SFO
Spalding (bare soil; incorporated)	United Kingdom	7.27 (0 – 15 cm)	0 - 90	0.7	30.6	8.9	6.9	8.2	DFOP slow phase
Greenhouse (bare soil and planted with cucumbers, chemigation)	Spain	7.79 (0 – 10 cm)	0 - 90	3.3	10 -12	$r^2 = 0.98$	-	-	SFO
Greenhouse (bare soil and planted with cucumbers, chemigation)	Italy	7.4 (0 – 10 cm)	0 - 90	5.3	18	$r^2 = 0.97$	-	-	SFO
Geometric mean (if not pH dependent)							6.0[c)]		
pH dependence				Not possible to determine					

a) Measured in calcium chloride solution

b) FOCUS evaluation. Values are normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7, values are $DegT_{50matrix}$

c) Based on the field trials from the Netherlands and the UK. Dissipation in greenhouses in Spain and Italy was not kinetically evaluated based on the recent FOCUS kinetics guidance.

IN-A2213	Aerobic conditions precursor from which the f.f. was derived was oxamyl									
Soil type	Location	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	St. (χ2)	f. f. k_f/k_{dp}	Method of calculation
Ottersum (bare soil; incorporated)	Netherlands	6.6 (0-15 cm)	0 - 90	1.4	4.6	16.8	0.8	16.9	0.77	SFO-SFO
Spalding (bare soil; incorporated)	United Kingdom	7.27 (0 – 15 cm)	0 - 90	17.5	58.0	14.4	8.8	13.0	-	SFO decline fit
Greenhouse (bare soil and planted with cucumbers, chemigation)	Spain	7.79 (0 – 10 cm)	0 - 90	2.1	-	-	-	-	-	SFO
Greenhouse (bare soil and planted with cucumbers, chemigation)	Italy	7.4 (0 – 10 cm)	0 - 90	5.7	-	-	-	-	-	SFO
Geometric mean (if not pH dependent)							4.8[c)]			
Single value									0.77	
pH dependence						Not possible to determine				

a) Measured in calcium chloride solution

b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7 values are $DegT_{50matrix}$

c) Based on the field trials from the Netherlands and the UK. Dissipation in greenhouses in Spain and Italy was not kinetically evaluated based on the recent FOCUS kinetics guidance.

IN-D2708	Aerobic conditions precursor from which the f.f. was derived was IN-A2213									
Soil type	Location	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	St. (χ2)	f. f.	Method of calculation
Ottersum (bare soil; incorporated)	Netherlands	6.6 (0-15 cm)	0 - 90	5.0	16.6	13.3	2.9	11.5	1.0 (fixed)	SFO-SFO
Spalding (bare soil; incorporated)	United Kingdom	7.27 (0 – 15 cm)	0 - 90	9.1	30.1	14.7	4.7	14.4	-	SFO decline fit
Greenhouse (bare soil and planted with cucumbers, chemigation)	Spain	7.79 (0 – 10 cm)	0 - 90	0.52	-	-	-	-	-	SFO
Greenhouse (bare soil and planted with cucumbers, chemigation)	Italy	7.4 (0 – 10 cm)	0 - 90	3.2	-	-	-	-	-	SFO
Geometric mean (if not pH dependent)							4.8[c)]			
Single value									1.0	
pH dependence						Not possible to determine				

a) Measured in calcium chloride solution

b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7 values are $DegT_{50matrix}$

c) Based on the field trials from the Netherlands and the UK. Dissipation in greenhouses in Spain and Italy was not kinetically evaluated based on the recent FOCUS kinetics guidance.

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Modelling is based on laboratory endpoints. Combined laboratory and field kinetic endpoints were therefore not required for the modelling assessment.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	Oxamyl is not expected to be accumulated based on its short half-life in the aerobic laboratory and field dissipation studies. Plateau concentration of 4.000 mg/kg reached after 1 year (worst case result calculated for tobacco use at 1 × 3 kg a.s./ha based on the spreadsheet).

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark anaerobic conditions					
Soil type	pH[a)]	t.°C/% MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20°C[b)]	St. (χ^2)	Method of calculation
Madera	7.7	25°C/50-50%	6/na	na	r^2 = 0.945	Linear regression
Geometric mean (if not pH dependent)						

a) Measured in water

b) Normalised using a Q_{10} of 2.58

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Parent	Soil photolysis					
Soil type	pH[a)]	t.°C/% MWHC	DT_{50}/DT_{90} (d) calculated at 40°N	St. (χ^2)	DT_{50} (d) 20°C pF2/10kPa	Method of calculation
Tama	6.7	21°C/75% FC	4.6/15.2	4.5	3.8	SFO

IN-N0079							
Soil type	pH[a)]	t.°C/% MWHC	DT_{50}/DT_{90} (d) calculated at 40°N	f. f. k_f /k_{dp}	DT_{50} (d) 20°C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Tama	6.7	21°C/75% FC	2/6.5	0.35	1.6	18.0	SFO-SFO

a) Measured in water

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Silt loam (Commerce)	0.2	7.0	0.09	39	0.09	37	1.08
Silt clay loam (Drummer)	2.6	4.8	0.44	17	0.41	16	0.99
Silt loam (Gross Umstadt)	1.2	7.8	0.11	9	0.06	5	0.66
Silt loam (Mattapex)	2.5	6.9	0.19	8	0.18	7	0.95
Loam (Nijmegen)	1.4	7.0	0.14	10	0.12	9	0.78
Sandy loam (Nijmegen)	1.7	6.6	0.075	4.3	0.071	4.1	0.95
Silt clay loam (Tama)	1.9	6.3	0.456	24	0.442	23	0.98
Light clay (Drummer)	3.3	6.2	0.681	21	0.598	18	0.91
Loam (Sassafras)	1.5	5.5	0.173	11	0.164	11	0.95
Loam (Gross-Umstadt)	1.2	7.0	0.138	12	0.128	11	0.93
Sandy loam (Nambsheim)	1.7	7.7	0.147	8.7	0.141	8.4	0.96
Geometric mean (if not pH dependent)					0.17	11.12	
Arithmetic mean (if not pH dependent)							0.92
pH dependence			No				

a) Measured in water

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

IN-A2213							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Silt loam (Mattapex)	2.5	6.9	0.107	4.31	0.119	4.8	0.89
Loam (Nijmegen)	1.4	7.0	0.067	4.78	0.052	3.7	1.06
Loam (Commerce)	0.5	5.8	0.051	10.91	0.048	10.3	1.24
Silt loam (Gross Umstadt)	1.1	7.5	0.108	9.80	0.113	10.2	0.87
Silt loam (Drummer)	3.7	5.8	0.200	5.48	0.203	5.6	1.07
Geometric mean (if not pH dependent)					0.09	6.37	
Arithmetic mean (if not pH dependent)							1.03
pH dependence			No				

a) Measured in water

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

IN-D2708							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Silt loam (Mattapex)	2.5	6.9	0.09	3.56	0.17	7.0	0.592
Loam (Nijmegen)	1.4	7.0	0.03	1.94	0.08	5.5	0.727
Loam (Commerce)	0.5	5.8	0.05	9.73	0.05	11.1	0.728
Silt loam (Gross Umstadt)	1.1	7.5	0.07	6.79	0.15	13.9	0.532
Silt loam (Drummer)	3.7	5.8	0.31	8.57	0.39	10.7	0.762
Geometric mean (if not pH dependent)					0.13	9.13	
Arithmetic mean (if not pH dependent)							0.67
pH dependence			No				

a) Measured in water

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

IN-N0079							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Silt loam (Mattapex)	2.5	6.9	0.04	1.53	na	na	na
Loam (Nijmegen)	1.4	7.0	0.03	2.20	na	na	na
Loam (Commerce)	0.5	5.8	0.12	25.41	na	na	na
Silt loam (Gross Umstadt)	1.1	7.5	0.06	5.16	na	na	na
Silt loam (Drummer)	3.7	5.8	0.31	8.41	na	na	na
Geometric mean (if not pH dependent)			0.08	5.18			
Default							0.9
pH dependence			No				

a) Measured in water

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	It was not necessary to conduct such a study since reliable absorption coefficient values have been obtained.

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	It was not necessary to conduct such a study since reliable absorption coefficient values have been obtained.

Lysimeter/field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2/7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2/9.1.2.3)

Lysimeter/field leaching studies	Neither lysimeter nor field leaching studies were conducted for oxamyl. Data from the adsorption/desorption studies, the aerobic soil degradation studies, and field dissipation studies can be used to adequately define the leaching potential of oxamyl and its metabolites in soil.

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1

Hydrolytic degradation of the active substance and metabolites >10 %	pH 4: stable at 20°C
	pH 7: DT_{50} = 21.1 d at 20°C (1st order, r^2=0.9965) IN-A2213: max. 62.7 % AR at day 29.67
	pH 9: DT_{50} = 0.2 d at 20°C (1st order, r^2=0.9926) IN-A2213: max. 66.6 % AR at day 0.34

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2/ 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %	Artificial radiation: DT_{50}: 3.5 d at 20°C and pH 5 (1^{st} order, r^2=0.9963) IN-N0079: 67.6 % AR at day 10 (n = 2) Natural light: not performed
Quantum yield of direct phototransformation in water at Σ >290 nm	Not calculated as oxamyl does not have any significant absorbance at wavelengths >290 nm

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	no

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier	pH water phase	pH sed	t.°C[a)]	DT_{50}/DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50}/DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to		At study temp	Normalised to x°C		
Fresh water Chula Pond	7.2	na	20	na	na	-	6.68/22.2	6.68	6.04	SFO

a) Temperature of incubation= std temperature of 20°C

IN-A2213	Max in total system 85.5 %AR after 46 days									
System identifier	pH water phase	pH sed	t.°C[a)]	DT_{50}/DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50}/DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x°C[c)]		At study temp	Normalised to x°C[c]		
Fresh water Chula Pond	7.2	na	20	na	na	-	Not evaluated	Not evaluated	-	-

a) Temperature of incubation= std temperature of 20°C

Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation (end of the study)	Non-extractable residues. max *x* % after *n* d (suspended sediment test)	Non-extractable residues. max *x* % after *n* d (end of the study) (suspended sediment test)
Fresh water Chula Pond	7.2	na	5.2% after 60 d.	na– no extractions performed	na–no extractions performed

Water/sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Modelling endpoints. Distribution (Max. sed 1.2 %AR after 61 d in Red Oak Stream)									
Water/sediment system	pH water phase	pH sed	t.°C	DT_{50} whole sys.	St. (χ^2)	DT_{50} water	St. (χ^2)	DT_{50} sed	St. (χ^2)	Method of calculation
Red Oak Stream	7.3	6.7	20	2.5	5.9	1.03	12.0	na	-	HS DT_{90}/3.32, SFO
Town Park Pond	7.5	6.1	20	0.69	8.4	0.69	8.4	na	-	SFO, SFO
Worst case DT_{50} at 20°C				2.5		1.03		na		

IN-A2213	Modelling endpoints. Distribution (max in water 48.8 %AR after 2 d, max in sed 4.4 %AR after 2 d; both in Red Oak Stream), leading to max in total system of 53.2 %AR after 2 days. Kinetic formation fraction in total system: from oxamyl of 0.83 (Red Oak Stream) and 0.35 (Town Park Pond); arithmetic mean is 0.59									
Water/sediment system	pH water phase	pH sed	t.°C	DT_{50} whole sys.	St. (χ^2)	DT_{50} water	St. (χ^2)	DT_{50} sed	St. (χ^2)	Method of calculation
Red Oak Stream	7.3	6.7	20	13.95	5.90	14.16	6.07	11.62	7.94	all SFO, decline fits
Town Park Pond	7.5	6.1	20	6.65	8.51	6.50	9.51	7.29	5.00	all SFO, decline fits
Geometric mean DT_{50} at 20°C				9.6		9.59		9.20		

IN-D2708	Modelling endpoints. Distribution (max in water 66.8 %AR after 30 d, max in sed 12.1 %AR after 61 d; Red Oak Stream/Town Park Pond, respectively). Max in total system of 77.2 %AR after 30 days (Red Oak Stream). Kinetic formation fraction in total system: from IN-A2213 of 1.00 in both systems and from IN-T2921 of 1.00 in both systems									
Water/sediment system	pH water phase	pH sed	t.°C	DT_{50} whole sys.	St. (χ^2)	DT_{50} water	St. (χ^2)	DT_{50} sed	St. (χ^2)	Method of calculation
Red Oak Stream	7.3	6.7	20	na	na	na	-	na	-	SFO-SFO
Town Park Pond	7.5	6.1	20	185.73	11.95	na	-	na	-	SFO-SFO
Single value DT_{50} at 20°C				185.73						

IN-N0079	Modelling endpoints. Distribution (max in water 52.9 %AR after 2 d, max in sed 3.7 %AR after 7 d; both in Town Park Pond). Max in total system of 54.2 %AR after 2 days (Town Park Pond). Kinetic formation fraction in total system: from oxamyl of 0.17 (Red Oak Stream) and 0.65 (Town Park Pond); arithmetic mean is 0.41									
Water/sediment system	pH water phase	pH sed	t.°C	DT_{50} whole sys.	St. (χ^2)	DT_{50} water	St. (χ^2)	DT_{50} sed	St. (χ^2)	Method of calculation
Red Oak Stream	7.3	6.7	20	4.69	1.36	4.26	0.71	17.79	6.56	all SFO, decline fits
Town Park Pond	7.5	6.1	20	8.80	18.99	8.07	16.8	11.38	16.66	all SFO, decline fits
Geometric mean DT_{50} at 20°C				6.42		8.07		17.79		

IN-T2921	Modelling endpoints. Distribution (max in water 11.4 %AR after 14 d, max in sed 0.4 %AR after 14 d; Town Park Pond). Max in total system of 11.8 %AR after 14 days. Kinetic formation fraction (k_f/k_{dp}) in total system: from IN-N0079 of 1.00 (Red Oak Stream) and of 0.64 (Town Park Pond)									
Water/sediment system	pH water phase	pH sed	t.°C	DT_{50} whole sys.	St. (χ^2)	DT_{50} water	St. (χ^2)	DT_{50} sed	St. (χ^2)	Method of calculation
Red Oak Stream	7.3	6.7	20	27.31	19.67	na	-	na	-	HS-SFO
Town Park Pond	7.5	6.1	20	na	na	na	-	na	-	SFO-SFO
Single value DT_{50} at 20°C				27.31						

Mineralisation and non extractable residues (from parent dosed experiments)					
Water/sediment system	pH water phase	pH sed	Mineralisation (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Red Oak Stream	7.3	6.7	60.9	18 after 100 d	18
Town Park Pond	7.5	6.1	27.9	12 after 61 d	11

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT_{50} of 5.68 hours derived by the Atkinson model (version 1.83). OH (12) concentration assumed = 1.5 x 106
Volatilisation	Study not needed based on low measured vapour pressure
Metabolites	Oxamyl does not produce any volatile metabolites

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: IN-A2213, IN-N0079, and IN-D2708 Surface water: IN-A2213, IN-N0079, IN-D2708, IN-T2921 Sediment: IN-D2708 Ground water: IN-A2213, IN-N0079, and IN D2708 Air: none

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

Parent oxamyl

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	England and Wales groundwater monitoring (Environmental Agency, 2005–2011).
Air (indicate location and type of study)	-

PEC_{soil} (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3/9.3.1)

Parent Method of calculation	DT_{50} (d): 11.1/5.3 days Kinetics: SFO/SFO Worst case from lab studies for standard calculations/f geometric mean from lab studies for FOCUS PEARL 4.4.4.
Application data	Crop: potatoes at 1 × 1000 g a.s./ha (in-furrow) tobacco at 1 × 3000 g a.s./ha (in-furrow) tobacco at 1 × 5500 g a.s./ha (broadcast) Greenhouse uses * Depth of soil layer = evaluation depth: 5 cm for in-furrow application to tobacco 10 cm for in-furrow application to potatoes and broadcast application to tobacco Soil bulk density: 1.5 g/cm^3 % plant interception: no interception For calculations using FOCUS PEARL 4.4.4: Depth of soil layer and application dates: 10 cm, uniform distribution for potatoes (in-furrow) and application on 01-May 10 cm incorporation depth for tobacco (in-furrow) and application on 20-May 5 cm, uniform distribution for tobacco (broadcast) and application 20-May PEC_s is evaluated for 20 cm topsoil

* For indoor uses, no assessment on PEC_s is required (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): "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.

Standard calculations

Potatoes 1 × 1000 g a.s./ha **$PEC_{(s)}$** (mg/kg) 10 cm	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.667		-	
Short term	0.626	0.646	-	-
24h				
2d	0.588	0.627	-	-
4d	0.519	0.590	-	-
Long term	0.431	0.540	-	-
7d				
28d	0.116	0.315	-	-
50d	0.029	0.204	-	-
100d	0.001	0.107	-	-
Plateau concentration	Not accumulating			

Tobacco 1 × 3000 g a.s./ha **$PEC_{(s)}$** (mg/kg) 5 cm	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	4.000		-	
Short term			-	-
24h	3.758	3.878		
2d	3.530	3.760	-	-
4d	3.116	3.540	-	-
Long term			-	-
7d	2.584	3.240		
28d	0.696	1.890	-	-
50d	0.176	1.225	-	-
100d	0.008	0.639	-	-
Plateau concentration	Not accumulating			

Tobacco 1 × 500 g a.s./ha **$PEC_{(s)}$** (mg/kg) 10 cm	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	3.667		-	
Short term			-	-
24h	3.445	3.555		
2d	3.236	3.447	-	-
4d	2.856	3.245	-	-
Long term			-	-
7d	2.368	2.970		
28d	0.638	1.732	-	-
50d	0.162	1.123	-	-
100d	0.007	0.586	-	-
Plateau concentration	Not accumulating			

FOCUS PEARL 4.4.4 calculations

Potatoes 1 × 1000 g a.s./ha **PEC**$_{(s)}$ (mg/kg) 10 cm uniform distribution, EFSA CTC Scenario		Soil evaluation depth: 20 cm	
		Single application Actual	Single application Time weighted average
Initial	0 h	0.469	-
Long-term	7 d	-	0.450
	14 d	-	0.428
	21 d	-	0.405
	28 d	-	0.383
	56 d	-	0.310

Tobacco 1 × 3000 g a.s./ha **PEC**$_{(s)}$ (mg/kg) 10 cm uniform distribution, EFSA CTS Scenario		Soil evaluation depth: 20 cm	
		Single application Actual	Single application Time weighted average
Initial	0 h	1.199	-
Long-term	7 d	-	1.081
	14 d	-	0.953
	21 d	-	0.836
	28 d	-	0.742
	56 d	-	0.492

Tobacco 1 × 5500 g a.s./ha **PEC**$_{(s)}$ (mg/kg) 5 cm incorporation, EFSA CTS Scenario		Soil evaluation depth: 20 cm	
		Single application Actual	Single application Time weighted average
Initial	0 h	2.202	-
Long-term	7 d	-	2.001
	14 d	-	1.777
	21 d	-	1.567
	28 d	-	1.401
	56 d	-	0.934

Standard calculations

IN-A2213	Molecular weight relative to the parent: 0.740 (=162.2/219.3) DT_{50} (d): 5.8 days Kinetics: SFO Worst case from lab studies.
Application data	Application rate assumed: Potatoes 1 × 384.6 g/ha (in-furrow) Tobacco 1 × 1153.8 g/ha (in-furrow) Tobacco 1 × 2115.3 g/ha (broadcast)t (assumed IN-A2213 is formed at a maximum of 52.0 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Potatoes (in-furrow)		Tobacco (in-furrow)		Tobacco (broadcast)	
	Single application Actual	Single application Time weighted average	Single application Actual	Single application Time weighted average	Single application Actual	Single application Time weighted average
Initial	0.256		1.538		1.410	
Short term						
24h	0.228	0.242	1.365	1.450	1.251	1.329
2d	0.202	0.228	1.211	1.368	1.110	1.254
4d	0.159	0.204	0.954	1.223	0.874	1.121
Long term						
7d	0.111	0.174	0.666	1.042	0.611	0.955
28d	0.009	0.074	0.054	0.444	0.050	0.407
50d	0.001	0.043	0.004	0.257	0.004	0.235
100d	<0.001	0.021	<0.001	0.129	<0.001	0.118
Plateau concentration	Not accumulated					

IN-D2708	Molecular weight relative to the parent: 0.534 (=117.1/219.3) DT_{50} (d): 12.7 days Kinetics: SFO Worst case from lab studies.
Application data	Application rate assumed: Potatoes 420.2 g/ha (in-furrow) Tobacco 1260.7 g/ha (in-furrow) Tobacco 2311.3 g/ha (broadcast)t (assumed IN-D2708 is formed at a maximum of 78.7 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Potatoes (in-furrow)		Tobacco (in-furrow)		Tobacco (broadcast)	
	Single application Actual	Single application Time weighted average	Single application Actual	Single application Time weighted average	Single application Actual	Single application Time weighted average
Initial	0.280		1.681		1.541	
Short term						
24h	0.265	0.273	1.592	1.636	1.459	1.500
2d	0.251	0.265	1.507	1.592	1.382	1.460
4d	0.225	0.252	1.351	1.510	1.239	1.384
Long term						
7d	0.191	0.233	1.147	1.397	1.052	1.281
28d	0.061	0.144	0.365	0.861	0.334	0.790
50d	0.018	0.096	0.110	0.576	0.101	0.528
100d	0.001	0.051	0.007	0.307	0.007	0.281
Plateau concentration	Not accumulated					

IN-N0079	Molecular weight relative to the parent: 0.447 (=98.1/219.3) DT_{50} (d): 1 days Kinetics: SFO Conservative worst case.
Application data	Application rate assumed: Potatoes 45.6 g/ha (in-furrow) Tobacco 136.9 g/ha (in-furrow) Tobacco 251.0 g/ha (broadcast)t (assumed IN-N0079 is formed at a maximum of 10. 2 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Potatoes (in-furrow)		Tobacco (in-furrow)		Tobacco (broadcast)	
	Single application Actual	Single application Time weighted average	Single application Actual	Single application Time weighted average	Single application Actual	Single application Time weighted average
Initial	0.030		0.183		0.167	
Short term						
24h	0.015	0.022	0.091	0.132	0.084	0.121
2d	0.008	0.016	0.046	0.099	0.042	0.091
4d	0.002	0.010	0.011	0.062	0.010	0.057
Long term						
7d	<0.001	0.006	0.001	0.037	0.001	0.034
28d	<0.001	0.002	<0.001	0.009	<0.001	0.009
50d	<0.001	0.001	<0.001	0.005	<0.001	0.005
100d	<0.001	<0.001	<0.001	0.003	<0.001	0.002
Plateau concentration	Not accumulated					

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (modelling)	For $FOCUS_{gw}$ modelling, values used: Models used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4 Crop: potatoes at 1 × 1000 g a.s./ha (in-furrow) tobacco at 1 × 3000 g a.s./ha (in-furrow) tobacco at 1 × 5500 g a.s./ha (broadcast) Greenhouse uses: Tomatoes 2000 + 1000 + 1000 + 1000 g a.s./ha Solarisation 5500 g a.s./ha Crop uptake factor: 0.5 for oxamyl and 0 for all metabolites Water solubility (mg/L): 148100 at pH 4 and 20°C for oxamyl and metabolites Vapour pressure: 1.8×10^{-5} Pa at 20°C for oxamyl and metabolites Half-lives (normalised to pF2, 20°C with Q_{10} of 2.58 and Walker equation coefficient 0.7): Oxamyl $DT_{50\ lab}$ 5.3 d (geometric mean) IN-A2213 $DT_{50\ lab}$ 1.7 d (geometric mean) IN-D2708 $DT_{50\ lab}$ 5.7 d (geometric mean) IN-N0079: DT_{50} 1 d (conservative worst case) K_{FOC} and 1/n: Oxamyl 11.12 mL/g(geometric mean) and 0.92 (arithmetic mean) IN-A2213 6.37 mL/g(geometric mean) and 1.03 (arithmetic mean) IN-D2708 9.13 mL/g(geometric mean) and 0.67 (arithmetic mean) IN-N0079 5.18 mL/g(geometric mean) and 0.90 (arithmetic mean) Formation fraction of metabolites: IN-A2213 1.0 (from oxamyl) IN-D2708 1.0 (from IN-A2213 and IN-N0079) IN-N0079 0.35 (from oxamyl)

Application rate	Potatoes: 1 × 1000 g a.s./ha (in-furrow, at planting), 0% interception, incorporation into 10 cm, applications on 15-Apr (C), 01-May (H), 15-May (J), 01-May (K), 15-Apr (N), 01-Apr (P), 28-Feb (O), 15-Jan (S), 15-Feb (T) Tobacco: 1 × 3000 g a.s./ha (in-furrow, pre-planting), 0% interception, 5 cm incorporation depth, applications on 20-May (P) and 01-May (T) 1 × 5500 g a.s./ha (broadcast, at planting), 0% interception, incorporation into 10 cm, applications on 20-May (P) and 01-May (T) Tomatoes 2000 + 1000 + 1000 + 1000 g a.s./ha, 10-days interval, at planting, 0% interception, application to soil surface, first applications on 10-May (C,P), 15-Mar (O), 15-Apr (S), 10-Apr (T). Solarisation 5500 g a.s./ha – $FOCUS_{gw}$ crop tomatoes, 0% interception, application to soil surface, for all scenarios applications on 01-Jul and 01-Aug.

PEC_{gw} - FOCUS modelling results (80^{th} percentile annual average concentration at 1 m)

Potatoes (in-furrow)

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PEARL 4.4.4/Potatoes	Chateaudun	0.002	<0.001	<0.001	<0.001
	Hamburg	0.026	0.013	0.031	0.004
	Jokioinen	0.021	0.016	0.009	<0.001
	Kremsmunster	0.034	0.013	0.080	0.012
	Okehampton	0.028	0.015	0.043	0.004
	Piacenza	0.021	0.012	0.035	0.006
	Porto [a)]	0.105 (0.046)	0.077 (0.035)	0.018 (0.008)	0.002 (<0.001)
	Sevilla	0.023	0.018	0.011	0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

a) Values in brackets are reported for oxamyl applications every other year

	Scenario				
		Parent (µg/L)	IN-A2213	IN-D2708	IN-N0079
FOCUS PELMO 5.5.3/Potatoes	Chateaudun	0.001	0.001	<0.001	<0.001
	Hamburg	0.007	0.004	0.003	<0.001
	Jokioinen	0.036	0.035	0.008	0.002
	Kremsmunster	0.037	0.015	0.045	0.001
	Okehampton	0.046	0.033	0.031	0.002
	Piacenza	0.086	0.055	0.066	0.004
	Porto[a)]	0.250 (0.074)	0.226 (0.067)	0.033 (0.011)	0.012 (0.004)
	Sevilla[b)]	0.164 (0.057)	0.158 (0.056)	0.034 (0.010)	0.008 (0.003)
	Thiva	0.002	0.002	<0.001	<0.001

a) Values in brackets are reported for oxamyl applications every three years

b) Values in brackets are reported for oxamyl applications every other year

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOC US MAC	Chateaudun	0.001	0.001	<0.001	<0.001

Tobacco (in-furrow)

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PEARL 4.4.4/ Tobacco in-furrow	Piacenza	0.003	0.002	0.005	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PELMO 5.5.3/ Tobacco in-furrow	Piacenza	0.011	0.009	0.013	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

Tobacco (broadcast)

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PEARL 4.4.4/ Tobacco broadcast	Piacenza	0.009	0.004	0.024	0.003
	Thiva	<0.001	<0.001	<0.001	<0.001

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PELMO 5.5.3/ Tobacco broadcast	Piacenza	0.027	0.018	0.059	0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

Tomatoes (Tier 1 as open field and Tier 2 as greenhouse)

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PEARL 4.4.4 /Tomatoes	Tier 1, open field approach				
	Chateaudun	0.103	0.047	0.285	0.004
	Piacenza	0.023	0.010	0.047	0.001
	Porto [a)]	0.023	0.028	0.010	0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001
	Tier 2, increased daily temperature of 2°C				
	Chateaudun	0.024	0.011	0.035	0.001
	Piacenza	0.005	0.002	0.007	<0.001
	Porto	0.011	0.014	0.001	0.001

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PELMO 5.5.3/ Tomatoes	Tier 1, open field approach				
	Chateaudun	0.033	0.018	0.050	0.001
	Piacenza	0.156	0.127	0.136	0.007
	Porto [a)]	0.373	0.371	0.071	0.020
	Sevilla	0.001	0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001
	Tier 2, increased daily temperature of 2°C				
	Chateaudun	0.007	0.004	0.003	<0.001
	Piacenza	0.081	0.071	0.039	0.004
	Porto	0.232	0.244	0.032	0.012

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS MACRO 5.5.4 /Tomatoes	Chateaudun	0.019	0.012	0.018	0.002

Solarisation (Tier 1 as open field and Tier 2 as greenhouse), application on 1-Jul

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PEARL 4.4.4 /Solarisation (Tomatoes)	Tier 1, open field approach				
	Chateaudun	0.123	0.054	0.317	0.005
	Piacenza	0.021	0.010	0.024	<0.001
	Porto [a)]	0.003	0.003	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	0.002	<0.001	<0.001	<0.001
	Tier 2, increased daily temperature of 2°C				
	Chateaudun	0.029	0.013	0.045	0.001
	Piacenza	0.004	0.002	0.003	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PELMO 5.5.3/ Solarisation (Tomatoes)	Tier 1, open field approach				
	Chateaudun	0.084	0.043	0.190	0.003
	Piacenza	0.089	0.058	0.152	0.004
	Porto [a)]	0.003	0.003	0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	0.002	0.001	<0.001	<0.001
	Tier 2, increased daily temperature of 2°C				
	Chateaudun	0.019	0.010	0.023	0.001
	Piacenza	0.029	0.018	0.027	0.001
	Porto	<0.001	0.001	<0.001	<0.001

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS MACRO 5.5.4/ Solarisation	Chateaudun	0.031	0.021	0.032	0.003

Solarisation (Tier 1 as open field and Tier 2 as greenhouse), application on 1-Aug

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PEARL 4.4.4 /Solarisation (Tomatoes)	Tier 1, open field approach				
	Chateaudun	0.099	0.049	0.077	0.004
	Piacenza	0.284	0.142	0.979	0.011
	Porto [a)]	0.055	0.043	0.116	0.002
	Sevilla	0.001	<0.001	<0.001	<0.001
	Thiva	0.017	0.008	0.003	<0.001
	Tier 2, increased daily temperature of 2°C				
	Chateaudun	0.024	0.011	0.008	0.001
	Piacenza	0.077	0.043	0.218	0.003
	Porto	0.009	0.008	0.005	<0.001

	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
FOCUS PELMO 5.5.3 / Solarisation (Tomatoes)	Tier 1, open field approach				
	Chateaudun	0.038	0.021	0.007	0.002
	Piacenza	0.261	0.163	0.804	0.011
	Porto [a)]	0.051	0.049	0.042	0.002
	Sevilla	0.001	0.001	<0.001	<0.001
	Thiva	0.007	0.004	0.001	<0.001
	Tier 2, increased daily temperature of 2°C				
	Chateaudun	0.009	0.005	<0.001	<0.001
	Piacenza	0.077	0.058	0.198	0.003
	Porto	0.009	0.012	0.002	<0.001

FOCUS MACRO 5.5.4/ Solarisation	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			IN-A2213	IN-D2708	IN-N0079
	Chateaudun	0.038	0.030	0.014	0.004

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5/9.3.1)

Parent Parameters used in $FOCUS_{sw}$ step 1 and 2	Version control no. of FOCUS calculator: Steps 1-2 in FOCUS 2.1 Molecular weight (g/mol): 219.3 K_{foc} (mL/g): 11.12 (geometric mean) DT_{50} soil (d): 5.3 d (geometric mean, lab) DT_{50} water/sediment system (d): 2.5 d (worst case from sediment water studies) DT_{50} water (d): 2.5 d DT_{50} sediment (d): 1000 d
Parameters used in FOCUSsw step 3	Version control no. of FOCUS software: FOCUS SWASH 3.1, FOCUS MACRO 4.4.2, FOCUS PRZM 3.1.1, FOCUS TOXSWA 3.3.1, and SWAN 3.0.0 Water solubility (mg/L): 148100 at 20°C and pH 5 Vapour pressure: 1.8×10^{-5} Pa at 20°C K_{FOC} (mL/g): 11.12 (geometric mean) 1/n: Q_{10}=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0.5

Application rate	Crop and growth stage: potatoes at 1 × 1000 g a.s./ha (in-furrow, at planting) tobacco at 1 × 3000 g a.s./ha (in-furrow, pre-planting) tobacco at 1 × 5500 g a.s./ha (broadcast, at planting) Greenhouse uses: Tomatoes 2000 + 1000 + 1000 + 1000 g a.s./ha, 10-days interval (at planting) Solarisation 5500 g a.s./ha (no crop, application in July-August) Steps 1-2 Crop interception: 0% interception for all applications. Dust drift for Oxamyl 10GR: as a conservative worst case, spray drift values for the open field uses Spray drift for Oxamyl 10SL: zero drift Region/period: Southern Europe and March-May represents the worst case for all proposed oxamyl uses Step 3a Dust drift for Oxamyl 10GR: worst case estimates for spinning disks provided in EFSA (2004)[8]. Conservative values for "application method", CAM, and DEPI. Step 3b Dust drift for Oxamyl 10GR: no drift were performed for the in-furrow applications to potatoes and tobacco based on the evidence from an existing field study. Step 3c In-furrow application to potatoes: CAM = 5 for R scenarios. Step 3d: Application to tomatoes in greenhouses: increase of daily temperature by 2°C and introduction of daily irrigation at 4 mm/day for the period from 10-Apr to 10-Aug. Step 4a: In-furrow application to potatoes: 10 m VFS Step 4b: Broadcast application to tobacco: various NSZ

Potatoes (in-furrow)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	337.660		36.525	

[8] EFSA (2004) Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA on the appropriateness of using the current FOCUS surface water scenarios for estimating exposure risk assessment in aquatic ecotoxicology in the context of Council Directive 91/414/EEC. EFSA Journal 2004; 145. 31pp.

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	80.871		8.882	

FOCUS STEP 3a Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
D3	ditch	4.895	-	0.404	-
D4	pond	0.151	-	0.068	-
D4	stream	4.390	-	0.293	-
D6	ditch	4.851	-	0.333	-
D6	ditch	4.944	-	0.544	-
R1	pond	0.150	-	0.035	-
R1	stream	3.623	-	0.287	-
R2	stream	4.797	-	0.309	-
R3	stream	48.786	-	2.761	-

FOCUS STEP 3b Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
D3	ditch	0.001	-	0.001	-
D4	pond	0.121	-	0.053	-
D4	stream	0.737	-	0.289	-
D6	ditch	2.080	-	0.306	-
D6	ditch	0.707	-	0.128	-
R1	pond	0.020	-	0.004	-
R1	stream	3.601	-	0.273	-
R2	stream	3.096	-	0.300	-
R3	stream	48.786	-	2.714	-

FOCUS STEP 3c Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
R1	pond	0.001	-	<0.001	-
R1	stream	0.263	-	0.021	-
R2	stream	0.201	-	0.021	-
R3	stream	3.120	-	0.184	-

FOCUS STEP 4a Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
R3	stream	1.425	-	0.087	-

Tobacco (in-furrow)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1010.000		109.575	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	242.614		26.645	

FOCUS STEP 3a Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
R3	stream	15.376	-	0.853	-

FOCUS STEP 3b Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
R3	stream	1.941	-	0.200	-

Tobacco (broadcast)

FOCUS STEP 1 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1860.000		200.888	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	444.792		48.848	

FOCUS STEP 3a Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
R3	stream	28.189	-	1.543	-

FOCUS STEP 4b Scenario	Water body	NSZ	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R3	stream	10 m	5.459	-	0.310	-
R3	stream	20 m	2.838		0.210	
R3	stream	25 m	2.291		0.207	

Tomato (greenhouses)

FOCUS STEP 1 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1640.000		182.626	

FOCUS STEP 2 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	389.336		43.294	

FOCUS STEP 3a Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
D6	ditch	11.386	-	1.579	-

FOCUS STEP 3d Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
D6	ditch	0.002	-	0.002	-

Solarisation (greenhouses)

FOCUS STEP 1 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1810.000		200.888	

FOCUS STEP 2 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	428.270		47.624	

1-Jul

FOCUS STEP 3a Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
D6	ditch	0.002	-	0.001	-

1-Aug

FOCUS STEP 3a Scenario	Water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
D6	ditch	0.014	-	0.011	-

Metabolite IN-A2213 Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 162.2 Soil or water metabolite: soil and water K_{foc} (mL/g): 6.37 (geometric mean) DT_{50} soil (d): 1.7 (geometric mean lab, SFO) DT_{50} water/sediment system (d): 9.6 DT_{50} water (d): 9.6 DT_{50} sediment (d): 9.6 Maximum occurrence observed (% AR) Total Water and Sediment: 63.2 Soil: 52.0
Metabolite IN-D2708 Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 117.1 Soil or water metabolite: soil and water K_{foc} (mL/g): 9.13 (geometric mean) DT_{50} soil (d): 5.7 (geometric mean lab, SFO) DT_{50} water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% AR) Total Water and Sediment: 77.2 Soil: 78.7
Metabolite IN-N0079 Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 98.1 Soil or water metabolite: soil and water K_{foc} (mL/g): 5.18 (geometric mean) DT_{50} soil (d): 1.0 (conservative worst case) DT_{50} water/sediment system (d): 6.4 DT_{50} water (d): 6.4 DT_{50} sediment (d): 6.4 Maximum occurrence observed (% AR) Total Water and Sediment: 54.2 Soil: 10.2
Metabolite IN-T2921 Parameters used in spreadsheet calculations	Molecular weight (g/mol): 116.1 Soil or water metabolite: water DT_{50} water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% AR) Total Water and Sediment: 63.2 Soil: -
Application rate	Same as for parent

Potatoes (open field in-furrow)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	131.421		8.098	
IN-D2708	0h	142.185	-	12.968	-
IN-N0079	0h	17.335	-	0.805	-
IN-T2921[a)]	0h	20.379	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

FOCUS STEP 2 Scenario Southern EU	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	13.156		0.779	
IN-D2708	0h	37.785	-	3.446	-
IN-N0079	0h	2.230	-	0.084	-
IN-T2921[a)]	0h	4.881	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

Tobacco (open field in-furrow)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	394.263		24.293	
IN-D2708	0h	426.555	-	38.905	-
IN-N0079	0h	52.004	-	2.415	-
IN-T2921[a)]	0h	60.956	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

FOCUS STEP 2 Scenario Southern EU	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	39.468		2.337	
IN-D2708	0h	113.356	-	10.338	-
IN-N0079	0h	6.689	-	0.253	-
IN-T2921[a)]	0h	14.642	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

Tobacco (open field broadcast)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	722.816		44.537	
IN-D2708	0h	782.017	-	71.326	-
IN-N0079	0h	95.341	-	4.428	-
IN-T2921[a)]	0h	112.256	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

FOCUS STEP 2 Scenario Southern EU	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	72.358		4.285	
IN-D2708	0h	207.819	-	18.953	-
IN-N0079	0h	12.264	-	0.464	-
IN-T2921[a)]	0h	26.845	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

Tomato (greenhouses)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	635.611		40.488	
IN-D2708	0h	691.969	-	63.177	-
IN-N0079	0h	75.525	-	3.912	-
IN-T2921[a)]	0h	98.979	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

FOCUS STEP 2 Scenario Southern EU	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	49.768		3.170	
IN-D2708	0h	170.176	-	15.537	-
IN-N0079	0h	1.888	-	0.098	-
IN-T2921[a)]	0h	23.498	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

Solarisation (greenhouses)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	699.172		44.537	
IN-D2708	0h	761.166	-	69.495	-
IN-N0079	0h	83.077	-	4.303	-
IN-T2921[a)]	0h	109.239	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

FOCUS STEP 2 Scenario Southern EU	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
IN-A2213	0h	54.744		3.487	
IN-D2708	0h	187.193	-	17.091	-
IN-N0079	0h	2.077	-	0.108	-
IN-T2921[a)]	0h	25.847	-	-	-

a) The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation	FOCUS Step 3 for Oxamyl 10GR proposed uses
PEC Maximum concentration	Results are reported for the parent compound above.

Section 5: Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw/day)
Birds				
Mallard duck	Oxamyl	Acute	LD_{50}	3.16
Northern bobwhite quail	Oxamyl	Acute	LD_{50}	9.5
Northern bobwhite quail	Oxamyl 10GR	Acute	LD_{50}	12.5
Northern bobwhite quail	Oxamyl 10SL	Acute	LD_{50}	11.0
Mallard duck	Oxamyl	Short-term	LC_{50}	96.6 (766 mg a.s./kg feed)
Northern bobwhite quail	Oxamyl	Short-term	LC_{50}	85 (340 mg a.s./kg feed)
Mallard duck	Oxamyl	Long-term (Subchronic and reproductive)	NOEC	1.5 (10 mg a.s./kg feed)
Northern bobwhite quail	Oxamyl	Long-term (Subchronic and reproductive)	NOEC	4.36 (50 mg a.s./kg feed
Mammals				
Rat	Oxamyl	Acute	Lowest lethal dose LD50	2.5 2.5
Rat	Oxamyl 10GR	Acute	Lowest lethal dose LD50	3.5 3.4
Rat	IN-A2213	Acute	Acute lethal dose (ALD)	11000
Rat	IN-D2708	Acute	LD_{50}	3540
Rat	IN-L2953	Acute	LD_{50}	6675
Rat	IN-N0079	Acute	ALD	450
Rat	Oxamyl	Long-term	NOAEL	1.43 (25 mg a.s./kg feed)
Endocrine disrupting properties (Annex Part A, points 8.1.5) Oxamyl is not classified R2 or C2 for mammals, thus it does not qualify to be suspected to have endocrine properties. No endocrine effects were documented on the amphibian thyroid in this study.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): Not required				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): Oxamyl is a carbamate insecticide with a reversible cholinesterase inhibition mode of action. Acute single-dose exposures in oral toxicity tests to birds, mammals, and other terrestrial vertebrate wildlife elicit rapid onset of toxic responses with steep dose-response slopes and low LD_{50} values. Short-term dietary exposures to birds and mammals elicit moderate toxic responses with low dose-response slopes and moderate LC_{50} values. Long-term dietary exposures to birds and mammals elicit reproductive NOECs at doses that are toxic to parents. Birds and mammals are able to metabolize oxamyl after dietary exposures, thus reducing any toxic effects. Similar responses are anticipated for reptiles and amphibians				

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Risk Assessment for birds exposed to Oxamyl 10GR

Exposure scenario: 1 - Animals ingesting granules as source of food

Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. A granule has no nutritional value, and therefore is unlikely to be actively selected as a food source by birds. The granules do not look like food and would not be ingested by birds as a source of food. No risk assessment is required.

Exposure scenario: 2 - Birds ingesting granules with/as grit; focal species: small birds (25 g), LD50=0.079 mg a.s./small bird,

Tier 1 bird TER_a values after accidental ingestion of granules with soil (in the main field)

Use	Potato	Tobacco in-furrow	Tobacco broadcast
Application rate (kg a.s./ha)	1.0	3.0	5.5
Soil surface granule density ($G_{density}$) [granules/m^2]	4	12	65.6
Soil surface small granule density ($G_{density}$) [granules/m^2] (69.4% of granules)	2.77	8.32	45.52
Acute risk			
Daily grit dose ($DGritD_{acute}$) = $651 \times (G_{density}/[15200 + G_{density}]) \times 0.0264$	0.0031	0.0094	0.0513
TER_a	25.5	8.4	1.5
Acute risk refinement based on LD50 of Oxamyl 10GR = 0.31mg a.s./kg bw/d.small bird.			
Daily grit dose ($DGritD_{acute}$) = $651 \times (G_{density}/[15200 + G_{density}]) \times 0.0264$	-	0.0094	0.0513
TERa (= small bird LD50/ DGritDacute)	-	33.0	**6.0**
Chronic risk			
Daily grit dose ($DGritD_{chronic}$) = $386 \times (G_{density}/ (15200 + G_{density}) \times 0.0140$	0.001	0.003	0.0161
TER_{lt} ($LD_{50}/DGritD_{chronic}$)	7.9	2.6	0.5

Exposure scenario: 3-Birds ingesting granules when seeking seeds as food

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.

Exposure scenario: 4 - Animals ingesting granules when eating soil-contaminated food

Tier TER_a values after accidental ingestion of granules with soil

Parameter	Potatoes (1 × 1000 kg a.s./ha)	Tobacco (1 × 3000 kg a.s./ha)	Tobacco (1 × 5500 kg a.s./ha)
Application rate (kg a.s./ha)	1.0	3.0	5.5
Shortcut–	0.283 (0.028 for incorporation at 10cm)		
Exposure Daily dry soil dose - acute (mg a.s./kg bw/d)	0.283	0.849	1.55
Toxicity endpoint (mg a.s./kg bw)	0.316		
TER_a	11.1	3.7	20
Trigger	10	10	10

[a] Maximum instantaneous PECs resulting from maximum application of oxamyl at 5.5 kg a.s./ha and 10 cm incorporation depth

Refined Tier 1 TER_a values after accidental ingestion of granules with soil

Refinement: The acute toxicity of the formulated product to birds is lower than that of the active substance.

Parameter	Tobacco (1 × 3000 kg a.s./ha)	
Application rate (kg a.s./ha)	3.0	
Shortcut	0.283	
Exposure Daily dry soil dose - acute (mg a.s./kg bw/d)	0.849	
Toxicity endpoint – Oxamyl 10GR (mg a.s./kg bw)	12.5	
TER_a	14.7	
Trigger	10	

Refined bird TERa values after accidental ingestion of granules with soil - tobacco (5.5 kg a.s./ha)

Refinement: A maximum of 11.6 granules/m^2 could remain on the surface to pass the acute grit intake risk assessment for the 5.5 kg a.s./ha broadcast-soil incorporation. The label provides clear stewardship guidelines for mitigating and documenting risk to wildlife and birds. Users are required to cover all granules with soil so they are completely buried and to remove spills. A higher tier field study was conducted and documented safe use to birds in potato fields after broadcast application of 5.5 kg a.s./ha.

Tier 1 bird TER_{lt} values after accidental ingestion of granules with soil

Exposure scenario	Potato	Tobacco in-furrow	Tobacco broadcast
Application rate (kg a.s./ha)	1.0	3.0	5.5
Shortcut– x twa Shortcut at 10 cm depth incorporation*	0.025 x 0.53 0.012 x 0.53		
Exposure Daily dry soil dose - chronic (mg a.s./kg bw/d)	0.013	0.040	0.035
Toxicity endpoint (mg a.s./kg bw/d)	0.316		
TER_{lt}	24.3	7.9	9.0*
Trigger	5	5	5

Exposure scenario: 5 - Animals consuming other food items with residues from granular applications

Herbivores: Acute and chronic risk assessment

Pre-cropping weed control with herbicides is a best agricultural practice in commercial potato and tobacco fields to reduce competition between crops and emergent weeds during germination and growth. Potatoes and tobacco are considered to be unpalatable to birds. Thus, the scenario of acute or chronic exposure to herbivorous birds immediately after application is considered to be not relevant to the risk assessment.

Vermivores:

Acute risk assessment

The worst case exposure value is 1.544 mg/kg worms after a 2 kg a.s./ha application, which is equivalent to an RUD of 0.772 mga.s./kg worm after 1 kg a.s./ha //ha application.

Tier 1 worst-case bird TER_a for exposure to residues in earthworms

Parameter	Potatoes (1 × 1 kg a.s./ha)	Tobacco (1 × 3kg a.s./ha)	Tobacco (1 × 5.5 kg a.s./ha)
Maximum PEC_{worm} (mg a.s./kg)	0.772	2.316	3.87
Small bird FIR/bw (100 g thrush; 100% insects)	0.96		
Daily Dietary Dose (mg a.s./Kg)	0.74	2.22	3.71
LD_{50} for birds (mg a.s./kg bw/d)	3.16		
TER_a	4.2	1.4	0.8
Trigger	10	10	10

Refined bird TER_a values after consumption of worms with residues from granular application

The refined Tier 1 assessment considers a RUD of 0.26 mg a.s./kg worm calculated as mean value of the three plots at day 0 for the acute exposure assessment.

Refined Tier 1 bird TER_a for exposure to residues in earthworms

Parameter	Potatoes (1 × 1 kg a.s./ha)	Tobacco (1 × 3 kg a.s./ha)	Tobacco (1 × 5.5 kg a.s./ha)
Mean PEC_{worm} (mg a.s./kg)	0.26	0.78	1.43
Small bird FIR/bw (100g thrush; 100% insects)	0.96		
Daily Dietary Dose (mg a.s./bird)	0.2496	0.7488	1.3728
LD_{50} for birds (mg a.s./kg bw/d)	3.16		
TER_a	12.6	4.2	2.3
Trigger	10	10	10

Refinement: Higher tier field studies documented 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.

Chronic risk assessment

Tier 1 bird TER_{lt} for exposure to residues in earthworms

Parameter	Potatoes (1 × 1000 g a.s./ha)	Tobacco (1 × 3000 g a.s./ha)	Tobacco (1 × 5500 g a.s./ha)
PEC_{soil} (mg a.s./kg)	0.667	4.000	3.667
BAF	0.03	0.03	0.03
PEC_{worm} (mg a.s./kg bw)	0.02	0.12	0.11
Daily dose for birds (PEC_{worm} × 1.1)	0.022	0.132	0.121
NOEL for birds (mg a.s./kg bw/d)	0.316	0.316	0.316
TER_{lt}	14.4	2.4	2.6

The long-term risk to birds from secondary poisoning occurring by feeding on earthworms result in TER_{lt} values that exceed 5 for potato scenario. For tobacco after in-furrow and broadcast applications, the risk based on initial PECsoil is not acceptable.

Exposure scenario: 6 - Exposure *via* Drinking Water

Acute drinking water risk assessment

Drinking water risk assessment - ratio of effective application rate to bird acute toxicity endpoints for birds exposed to Oxamyl 10GR in tobacco or potatoes

Scenario	Species	LD_{50} (dietary) (mg a.s./kg bw/d)	Rate applied (g a.s./ha)	MAF_m [a]	AR_{eff} [b]	HQ [c]	Trigger value [d]
Tobacco, 5.5 kg a.s/ha	Bird	3.16	5500	1	5500	1740	50
Tobacco, 3.0 kg a.s/ha	Bird	3.16	3000	1	3000	949	50
Potato, 1.0 kg a.s/ha	Bird	3.16	1000	1	1000	316	50

[a] Multiple application factor

[b] Effective application rate

[c] Hazard quotient (ratio of effective application rate to relevant endpoint)

[d] Trigger based on a K_{FOC} of 16 mL/g (mean; Oxamyl Renewal Dossier, Document M-CP, Section 5 for Oxamyl 10GR, DuPont-40934 EU)

Tier 1 bird acute drinking water TER_a for Oxamyl 10GR – puddle scenario

Crop	Focal species	LD_{50} (mg/kg bw/day)	DWR [a] in L/kg bw/d	PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous bird	3.16	0.46	14.99	6.90	0.46	10
Tobacco, 3.0 kg a.s/ha	Granivorous bird	3.16	0.46	8.18	3.76	0.84	10
Potato, 1.0 kg a.s/ha	Granivorous bird	3.16	0.46	2.73	1.26	2.52	10

[a] Drinking water rates as published by DEFRA (Department for Environment, Food and Rural Affairs), 2007. Improved estimates of

daily food and water requirements for use in risk assessments – DEFRA Project Code PS2308.

Refined bird acute drinking water TER_a for Oxamyl 10GR – puddle scenario

Scenario	Species	LD_{50} (mg/kg bw/day)	DWR[a] in L/kg bw/d	FOCUS Step 3a PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous bird	3.16	0.46	0.028	0.0128	246	10
Tobacco, 3.0 kg a.s/ha	Granivorous bird	3.16	0.46	0.015	0.0069	457	10
Potato, 1.0 kg a.s/ha	Granivorous bird	3.16	0.46	0.048	0.0220	143	10

[a] Drinking water rates as published by DEFRA (Department for Environment, Food and Rural Affairs), 2007. Improved estimates of daily food and water requirements for use in risk assessments – DEFRA Project Code PS2308.

Chronic drinking water risk assessment

Tier 1 bird chronic drinking water TER_{lt} for Oxamyl 10GR – puddle scenario

Scenario	Species	LD50/10 (mg/kg bw/day)	DWR[a] in L/kg bw/d	PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous bird	0.316	0.46	14.99	6.90	0.046	5
Tobacco, 3.0 kg a.s/ha	Granivorous bird	0.316	0.46	8.18	3.76	0.084	5
Potato, 1.0 kg a.s/ha	Granivorous bird	0.316	0.46	2.73	1.26	0.252	5

[a] Drinking water rates as published by DEFRA (Department for Environment, Food and Rural Affairs), 2007. Improved estimates of daily food and water requirements for use in risk assessments – DEFRA Project Code PS2308.

Refinement: run off concentrations directly from relevant FOCUS Step 3 scenarios
Refined bird chronic drinking water TER_{lt} for Oxamyl 10GR – puddle scenario

Scenario	Species	LD50/10 (mg/kg bw/day)	DWR[a] in L/kg bw/d	FOCUS Step 3a PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous bird	0.316	0.46	0.028	0.0128	25	5
Tobacco, 3.0 kg a.s/ha	Granivorous bird	0.316	0.46	0.015	0.0069	46	5
Potato, 1.0 kg a.s/ha	Granivorous bird	0.316	0.46	0.048	0.0220	14	5

[a] Drinking water rates as published by DEFRA (Department for Environment, Food and Rural Affairs), 2007. Improved estimates of daily food and water requirements for use in risk assessments – DEFRA Project Code PS2308.

Overview: Avian risk assessment conclusions for Oxamyl 10GR

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: Potentially poses a risk because thorough incorporation of granules in soil is required. TER_a and TER_{lt} are >trigger values, indicating risks are acceptable in the main field. The Applicant should address the risk also at the row ends. **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	TER_{acute} are >trigger value for potato scenario indicating risks are acceptable. For the tobacco scenarios TER < trigger indicating potential risk.
Birds consuming food contaminated with a.s. residues – soil residue bioconcentration in earthworms	Exposure calculated with measured worm BAF. TER_{lt} are >trigger value for potato scenario (risk acceptable). TERlt based on initial PECsoil are < trigger for the in-furrow and broadcast tobacco scenario (risks not acceptable). Refinement needed.
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.

Risk Assessment for mammals exposed to Oxamyl 10GR

Exposure scenario: Mammals ingesting granules as source of food

Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. They do not look like food and would not be ingested by mammals as a source of food.

Exposure scenario: Mammals ingesting granules when eating soil-contaminated food

Acute risk assessment

Tier 1 mammal TER_a values after ingesting granules with soil contaminated food

Exposure scenario	Potato	Tobacco in-furrow	Tobacco broadcast
Application rate (kg a.s./ha)	1.0	3.0	5.5
Shortcut value– Shortcut value for incorporation of 10 cm*		0.097 0.010	
Exposure Daily dry soil dose - acute (mg a.s./kg bw/d)	0.097	0.291	0.055
Toxicity endpoint (mg a.s./kg bw)		2.5	
TER_a	25	8.59	45.1
Trigger	10	10	10
Refinement: The acute toxicity of the formulated product to birds is lower than that of the active substance			
Refined toxicity endpoint (mg a.s./kg bw)		3.5	
TER_a		12	
Trigger		10	

Refinement: A higher tier field study documented safe use after broadcast application of 5.5 kg a.s./ha, supporting a conclusion of safe use at the highest application rate.

Chronic risk assessment

Exposure scenario	Potato	Tobacco in-furrow	Tobacco broadcast
Application rate (kg a.s./ha)	1.0	3.0	5.5
–Shortcut value Shortcut value for incorporation of 10 cm*		0.005 x 0.53 0.004 x 0.53	
Exposure Daily dry soil dose – chronic (mg a.s./kg bw/d)	0.0027	0.0079	0.012*
Toxicity endpoint (mg a.s./kg bw)		1.43	
TER_{lt}	529	181	119

Exposure scenario: Mammals consuming other food items with residue from granular applications

Acute and chronic risk assessments – herbivores

Pre-cropping weed control with herbicides is a best agricultural practice in commercial potato and tobacco fields to reduce competition between crops and emergent weeds during germination and growth. Potatoes and tobacco are considered to be unpalatable to mammals. Thus, the scenarios of acute and chronic exposures to herbivorous mammals immediately after application are considered to be not relevant to the risk assessment.

Vermivore assessment

Parameter	Potatoes (1 × 1000 g a.s./ha)	Tobacco (1 × 3000 g a.s./ha)	Tobacco (1 × 5500 g a.s./ha)
PECsoil (mg a.s./kg)*	0.667	4.000	3.667
BAF	0.03	0.03	0.03
PECworm (mg a.s./kg bw/d)	0.02	0.12	0.11
Daily dose for mammals (PECworm 1.28)	0.0256	0.1536	0.1408
NOEL for mammals (mg a.s./kg bw/d)	1.43	1.43	1.43
TERlt	55.8	9.3	10.1

* Maximum instantaneous PECs as calculated in Vol 3 B8 for each scenario.

Exposure scenario: Drinking water risk assessment -

Mammal tier 1 acute drinking water TER_a for Oxamyl 10GR– puddle scenario
Granivorous mammal

Scenario	Species	LD_{50} (mg/kg bw/day)	DWR[a] in L/kg bw/d	PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous mammal	2.5	0.24	14.99	3.6	0.69	10
Tobacco, 3.0 kg a.s/ha	Granivorous mammal	2.5	0.24	8.18	1.96	1.28	10
Potato, 1.0 kg a.s/ha	Granivorous mammal	2.5	0.24	2.73	0.65	3.85	10

[a] EFSA 2009.

Refinement: Using run off concentrations directly from relevant FOCUS Step 3 scenarios.
Refined mammal tier 1 acute drinking water TER_a for Oxamyl 10GR – puddle scenario

Scenario	Species	LD_{50} (mg/kg bw/day)	DWR[a] in L/kg bw/d	FOCUS Step 3a PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous mammal	2.5	0.24	0.028	0.00672	372	10
Tobacco, 3.0 kg a.s/ha	Granivorous mammal	2.5	0.24	0.015	0.0036	694	10
Potato, 1.0 kg a.s/ha	Granivorous mammal	2.5	0.24	0.048	0.01152	217	10

[a] EFSA 2009.

Chronic drinking water risk assessment

Granivorous mammal **Tier 1 mammal chronic drinking water TER_a for Oxamyl 10GR – puddle scenario**							
Scenario	**Species**	**NOEL (mg/kg bw/day)**	**DWR[a] in L/kg bw/d**	**PEC_{pool}/ PEC_{puddle} (mg a.s./L)**	**DDD**	**TER**	**Trigger**
Tobacco, 5.5 kg a.s/ha	Granivorous mammal	1.43	0.24	14.99	3.6	0.40	5
Tobacco, 3.0 kg a.s/ha	Granivorous mammal	1.43	0.24	8.18	1.96	0.73	5
Potato, 1.0 kg a.s/ha	Granivorous mammal	1.43	0.24	2.73	0.65	2.2	5

[a] EFAS 2009.

Refinement: Using run off concentrations directly from relevant FOCUS Step 3 scenarios **Refined mammal tier 1 chronic drinking water TER_a for Oxamyl 10GR – puddle scenario**							
Scenario	**Species**	**NOEL (mg/kg bw/day)**	**DWR[a] in L/kg bw/d**	**FOCUS Step 3a PEC_{pool}/ PEC_{puddle} (mg a.s./L)**	**DDD**	**TER**	**Trigger**
Tobacco, 5.5 kg a.s/ha	Granivorous mammal	1.43	0.24	0.028	0.00672	213	5
Tobacco, 3.0 kg a.s/ha	Granivorous mammal	1.43	0.24	0.015	0.0036	397	5
Potato, 1.0 kg a.s/ha	Granivorous mammal	1.43	0.24	0.048	0.01152	124	5

[a] EFSA 2009.

Overview: 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 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); therefore, birds and mammals are considered to be not exposed to residues of the formulated product, the active substance oxamyl, or its metabolites.

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[a]
Laboratory tests				
Fish				
Oncorhynchus mykiss Rainbow trout	Oxamyl	Acute 96 hr (static)	Mortality, LC_{50}	3.13 (mg a.s./L)$_{mm}$
Lepomis macrochirus Bluegill sunfish	Oxamyl	Acute 96 hr (semi-static)	Mortality, LC_{50}	6.12 (mg a.s./L)$_{mm}$
Oncorhynchus mykiss Rainbow trout	Oxamyl 10GR	Acute 96 hr (static)	Mortality, LC_{50}	3.6 (mg a.s./L)$_{nom}$
Lepomis macrochirus Bluegill sunfish	Oxamyl 10GR	Acute 96 hr (semi-static)	Mortality, LC_{50}	4.7 (mg a.s./L)$_{nom}$
Oncorhynchus mykiss Rainbow trout	Oxamyl 10SL	Acute 96 hr (static)	Mortality, LC_{50}	27 (mg prep./L)$_{nom}$
Lepomis macrochirus Bluegill sunfish	Oxamyl 10SL	Acute 96 hr (static)	Mortality, LC_{50}	51 (mg prep./L)$_{nom}$
Fathead minnow	Oxamyl	early life stage (28d)	NOEC	0.500 (mg a.s./L) $_{nom*}$ Supportive information
Oncorhynchus mykiss Rainbow trout	Oxamyl	early life stage (90 d)	NOEC	Not valid
Cyprinodon variegatus Sheepshead minnow	Oxamyl	early life stage (29 d)	NOEC	0.356 (mg a.s./L) $_{mm}$
Oncorhynchus mykiss Rainbow trout	IN-A2213	96 hr (static,)	LC_{50}	>132 (mg met/L) $_{mm}$
Oncorhynchus mykiss Rainbow trout	IN-D2708	96 hr (static,)	LC_{50}	93.8 (mg met/L) $_{mm}$ Supportive information
Oncorhynchus mykiss Rainbow trout	IN-N0079	96 hr (static, renewal)	LC_{50}	22.4 (mg met/L) $_{mm}$
Oncorhynchus mykiss Rainbow trout	IN-T2921	96 hr (static,)	LC_{50}	>127 (mg met/L) $_{mm}$
Aquatic invertebrates				
Daphnia magna	Oxamyl	48 h (static)	EC_{50}	0.319 (mg a.s./L)
Daphnia magna	Oxamyl 10GR	48 h (semi-static)	EC_{50}	0.33 (mg a.s./L)$_{nom}$
Daphnia magna	Oxamyl 10SL	48 h (static)	EC_{50}	3.0 (mg prep./L)$_{nom}$
Chimarra atterima	Oxamyl	48 h (static, or semi-static or flow-through)	EC_{50}	0.096 (mg a.s./L)
Centroptilum triangulifer	Oxamyl	48 h (static, or semi-static or flow-through)	EC_{50}	0.067 (mg a.s./L)
Hyalella azteca	Oxamyl	48 h (static, or semi-static or flow-through)	EC_{50}	0.320 (mg a.s./L)
Daphnia pulex	Oxamyl			Not valid

Group	Test substance	Time-scale (Test type)	End point	Toxicity[a]
Ceriodaphnia dubia	Oxamyl	48 h (static, or semi-static or flow-through)	EC_{50}	0.094 (mg a.s./L)

[a] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance

*nominal concentrations not confirmed analytically. Results should be recalculated based on mean measured concentration.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[a]
Group	**Test substance**	**Time-scale (Test type)**	**End point**	**Toxicity[a]**
Aquatic invertebrates (continued)				
Americamysis bahia	Oxamyl	48 h (static, or semi-static or flow-through)	EC_{50}	0.0465 (mg a.s./L)
Crassostrea virginica	Oxamyl	acute (96 h)	EC_{50}	27.5 (mg a.s./L)
Daphnia magna	Oxamyl	21 d (static, or semi-static or flow-through)	NOEC	0.0268 (mg a.s./L)
Americamysis bahia	Oxamyl	28 d (static, or semi-static or flow-through)	NOEC	0.0189 (mg a.s./L)
Daphnia magna	IN-A2213	48 h (static, or semi-static or flow-through)	EC_{50}	>125(mg met/L)
Daphnia magna	IN-D2708	48 h (static, or semi-static or flow-through)	EC_{50}	>134 (mg met/L)
Daphnia magna	IN-D2708	21 d (static, or semi-static or flow-through)	NOEC	66.1 (mg met/L)
Daphnia magna	IN-N0079	48 h (static, or semi-static or flow-through)	EC_{50}	>128 (mg met/L)
Daphnia magna	IN-T2921	48 h (static, or semi-static or flow-through)	EC_{50}	>123(mg met/L)
Sediment-dwelling organisms				
Chironomus tentans	Oxamyl	48 h (static, or semi-static or flow-through)	EC_{50}	0.350 (mg a.s./L)
Algae				
Pseudokirchneriella subcapitata	Oxamyl			Data gap
	Oxamyl 10GR			Data gap
Pseudokirchneriella subcapitata	Oxamyl 10SL	72 h (static)	E_bC_{50} E_rC_{50} NOEC	16 (mg prod./L) 34 (mg prod./L) 4.0 (mg prod./L)
Pseudokirchneriella subcapitata	IN-A2213	72 h (static)	E_rC_{50}	>122 Supportive information
Pseudokirchneriella subcapitata	IN-D2708			Data gap
Pseudokirchneriella subcapitata	IN-N0079			Data gap
Pseudokirchneriella subcapitata	IN-T2921	72 h (static)	E_rC_{50}	>113

[a] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance

Group	Test substance	Time-scale (Test type)	End point	Toxicity[a]
Group	**Test substance**	**Time-scale (Test type)**	**End point**	**Toxicity[a]**
Aquatic invertebrates (continued)				
Americamysis bahia	Oxamyl	48 h (static, or semi-static or flow-through)	EC_{50}	0.0465 (mg a.s./L)
Crassostrea virginica	Oxamyl	acute (96 h)	EC_{50}	27.5 (mg a.s./L)
Daphnia magna	Oxamyl	21 d (static, or semi-static or flow-through)	NOEC	0.0268 (mg a.s./L)
Americamysis bahia	Oxamyl	28 d (static, or semi-static or flow-through)	NOEC	0.0189 (mg a.s./L)
Daphnia magna	IN-A2213	48 h (static, or semi-static or flow-through)	EC_{50}	>125(mg met/L)
Daphnia magna	IN-D2708	48 h (static, or semi-static or flow-through)	EC_{50}	>134 (mg met/L)
Daphnia magna	IN-D2708	21 d (static, or semi-static or flow-through)	NOEC	66.1 (mg met/L)
Daphnia magna	IN-N0079	48 h (static, or semi-static or flow-through)	EC_{50}	>128 (mg met/L)
Daphnia magna	IN-T2921	48 h (static, or semi-static or flow-through)	EC_{50}	>123(mg met/L)
Sediment-dwelling organisms				
Chironomus tentans	Oxamyl	48 h (static, or semi-static or flow-through)	EC_{50}	0.350 (mg a.s./L)
Algae				
Pseudokirchneriella subcapitata	Oxamyl			Data gap
Pseudokirchneriella subcapitata	Oxamyl 10SL	72 h (static)	E_bC_{50} E_rC_{50} NOEC	16 (mg prod./L) 34 (mg prod./L) 4.0 (mg prod./L)
Pseudokirchneriella subcapitata	IN-A2213	72 h (static)	E_rC_{50}	>122 Supportive information
Pseudokirchneriella subcapitata	IN-D2708			Data gap
Pseudokirchneriella subcapitata	IN-N0079			Data gap
Pseudokirchneriella subcapitata	IN-T2921	72 h (static)	E_rC_{50}	>113

[a] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance

Group	Test substance	Time-scale (Test type)	End point	Toxicity[a]
Higher plant				
Lemna gibba Duckweed	Oxamyl	chronic (7-d)	E_bC_{50} frond count	3.57 (mg a.s./L)
			E_yC_{50} frond count	3.16 (mg a.s./L)
			E_rC_{50} frond count	>7.17 (mg a.s./L)
			E_bC_{50} dry weight	2.20 (mg a.s./L)
			E_bC_{50} dry weight	1.67 (mg a.s./L)
			E_rC_{50} dry weight	3.30 (mg a.s./L)
			NOEC overall	0.640 (mg a.s./L)

[a] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance

Further testing on aquatic organisms Additional testing with aquatic invertebrates was conducted, please refer to endpoints listed in table above.
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) Two studies with vertebrates are available, i.e., "[redacted] (2015), 21-D amphibian metamorphosis assay (AMA) with south African clawed frog, Xenopus laevis" and "[redacted] (2012); Oxamyl technical (DPX-D1410): Short term reproduction assay with the fathead minnow, *Pimephales promelas*, determined under flow-through conditions". The NOEC for *X. laevis* exposed to oxamyl in a 21 day amphibian metamorphosis assay (AMA) was 130.1 µg a.s./L based on time-weighted mean measured concentrations and AMA apical endpoints. The prevalence and severity of this finding were slightly increase in frogs of the 120 dose group as compared to controls, but the magnitude of the increased prevalence and severity was insufficient to conclude that this necessarily represented a treatment effect. The results of the 21d short term reproduction assay with fish provided a NOEC based on the endocrine-relevant endpoints (*i.e.*, reproductive parameters, VTG, GSI, gonad histopathology) of 0.989 mg a.s./L. The overall study NOEC based on the most sensitive endpoint, female wet weight, was 0.305 mg a.s./L. There is no indication of endocrine activity in fish from this test.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

The triggers for this study are log P_{ow} ≥3 and potential exposure that may lead to bioconcentration where the DT_{90} is ≤24 hours *via* hydrolysis. The log P_{ow} for oxamyl is -0.44.

Oxamyl 10GR:

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS$_{sw}$ step 1-3 - TERs for oxamyl

Scenario	PEC global max (µg L)	Fish acute	Fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Rainbow trout	*Fathead minnow*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		3130 µg/L	356 µg/L	319 µg/L	26.8 µg/L		3300µg/L
FOCUS Step 1	1860						
FOCUS Step 2							
South Europe	444.792	7.54	1.12	0.72	0.06		7.4
FOCUS Step 3a (potatoes)[a]							
D3/ditch	4.895	646	73	65.2	5		-
D4/pond	0.151	20927	2357	2113	177		-
D4/stream	4.390	720	81	72.7	6		-
D6/pond	4.851	651	73	65.8	6		-
D6/ditch	4.944	639	72	64,5	5		-
R1/pond	0.150	21067	2373	2126	179		-
R1/stream	3.623	872	98	88.0	7		-
R2/stream	4.797	659	74	66.5	6		-
R3/stream	48.786	65	7.3	6.5	1		-
FOCUS Step 3b (potatoes)							
D3, ditch	0.001	-	-	31900	26800		-
D4, stream	0.737	-	-	433	36		-
D6, ditch	2.080	-	-	153	13		-
D6, ditch	0.707	-	-	451	38		-
R1, stream	3.601	-	-	89	7		-
R2, stream	3.096	-	-	103	9		-
R3, stream	48.786	65	7.3	6.5	1		-

FOCUS Step 3c (potatoes)

R1, stream	0.263	-	-	1212	101	-
R2, stream	0.201	-	-	-	133	-
R3, stream	3.120	997	114	102	**8.5**	-

FOCUS Step 3a (tobacco, 5.5 kg/ha)[a]

R3/stream	28.189	112	13	11.3	0.9	117
Trigger[b]		100	10	100	10	10

[a] Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.

[b] If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, *i.e.*, what the AF value is and for which organism and endpoint it refers.

FOCUS$_{sw}$ step 4 - TERs oxamyl –

Potatoes 1 × 1000 g a.s./ha

Organisms *Daphnia magna*
chronic:
Toxicity endpoint: 26.8 µg/L

Mitigation options	**10 m vegetated buffer strip (corresponding to ≤90 % run-off reduction)**	**TER**	**Trigger**
FOCUS Step 4[a]			
R3/stream	1.425	19	10

[a] Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4.

Tobacco broadcast, 1 x 5.5 kg/haOrganisms: *Daphnia magna* acute
Toxicity endpoint: EC50= 319µg/L

Mitigation options	20 m non-spray buffer zone (corresponding to ≤95 % drift reduction)	TER	Trigger
FOCUS Step 4[a] 20m NSZ			
R3/stream	2.838	112	100

Tobacco broadcast, 1 x 5.5 kg/ha

Organisms *Daphnia magna* chronic:
Toxicity endpoint: NOEC = 26.8 µg/L

Mitigation options	25 m vegetated buffer strip (corresponding to ≤90 % run-off reduction)	TER	Trigger
FOCUS Step 4[a]			
R3/stream	2.291	12	10

[a] Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4.

Oxamyl 10SL:

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

$FOCUS_{sw}$ step 1-3 - TERs for oxamyl

Scenario	PEC global max (µg L)	Fish acute	Fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant
		Rainbow trout	*Fathead minnow*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}
		2700µg/L	356 µg/L	300 µg/L	26.8 µg/L	931 µg/L	3300 µg/L
FOCUS Step 1 (solarisation)	1810		-	0.18	0.015		1.82
			-				
FOCUS Step 2							
Tomato,	389.336	6.93	0.91	0.77	0.069		8.47
Solarization, South Europe	428.270	6.3	0.83	0.7	0.015		7.71
FOCUS Step 3[a]							
Tomato, D6/ditch	11.386	237	31	26.3	2.4		290
Solarisation, D6/ditch	0.014	192857	25428	21428	1914		235714
FOCUS Step 3 d[a]							
Tomato, D6/ditch	0.002	-		150000	13400		
Trigger[b]		100	10	100	10	10	10

[a] Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.

[b] If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, *i.e.*, what the AF value is and for which organism and endpoint it refers.

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	Oxamyl	48-hr Oral	LD_{50}	0.38 µg a.s./bee
Apis mellifera	Oxamyl	48-hr Contact	LD_{50}	0.47 µg a.s./bee
Apis mellifera	Oxamyl 10SL	48-hr Oral	LD_{50}	0.26 µg a.s./bee
Apis mellifera	Oxamyl 10SL	48-hr Contact	LD_{50}	0.23 µg a.s./bee
Apis mellifera	Oxamyl	10-d adult oral	LDD_{50} NOED	0.14 µg a.s./bee/d 0.07µg a.s./bee
Apis mellifera	Oxamyl	7d larvae	LD_{50} NOED	0.81 µg a.s./ larva/d 0.18µg a.s./larva/d
Bombus terrestris	Oxamyl	48-hr Oral	LD_{50}	0.36 µg a.s./bee
Bombus terrestris	Oxamyl	48-hr Contact	LD_{50}	39.3 µg a.s./bee
Bombus terrestris	Oxamyl 10SL	6 drip irrigation x 1 Kg a.s./ha at 14 day intervals	mortality of bumble bee larvae and adults, crop pollination, hive weight, and sugar consumption or brood development. .	No effects

Potential for accumulative toxicity: No
Semi-field test (Cage and tunnel test) Bombus terrestris (Oxamyl 10GR) Tunnel test with at 1.0 or 3.5 kg a.s./ha in potatoes with brood observations mortality, flight intensity, condition of colonies, behaviour. Oxamyl 10GR was applied once during planting of Solanum tuberosum.. In the Solanum tuberosum pollen samples taken from the forager bumblebees, a maximum value of 0.008 mg oxamyl/kg was found; and in the flower samples, a maximum value of 0.019 mg oxamyl/kg could be found in the treatment group of 3.5 kg oxamyl a.s./ha. Biological results are judged not valid. Residues could be used for risk refinement. Apis mellifera (Oxamyl 10GR) Tunnel test with honey bees exposed to Phacelia tanacetifolia treated with Oxamyl 10GR at 8.625 in-furrow or 5.5 kg a.s./ha broadcast during seeding.. The study was judged not reliable.
Field tests: None

Risk assessment for toxicity of Oxamyl 10GR at 5500 g a.s./ha

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Honey bees	a.s.	HQoral	**14500**	50
Bumble bees	a.s.	HQoral	**15300**	50
Honey bees	a.s.	HQcontact	**11700**	50
Bumble bees	a.s.	HQcontact	**140**	50

TER for soil treatment of Oxamyl 10GR

Species	Exposure scenario	Exposure route	Endpoint	Exposure	TER	EPPO trigger
Honeybees, adult	Plants in soil treated field	Oral acute	0.38 µg a.s./bee			≥10
Honeybees, adult		Oral chronic	0.14 µg a.s./bee/day			≥1
Honeybees, larva		Oral chronic	0.81 µg/larva			≥1
Bumblebees, adult		Oral acute	0.36 µg a.s./bee			≥10
Honeybees, adult	Dust drift in field margin	Oral acute	0.38 µg a.s./bee			≥10
Honeybees, adult		Oral chronic	0.14 µg a.s./bee/day			≥1
Honeybees, larva		Oral chronic	0.81 µg/larva			≥1
Bumblebees, adult		Oral acute	0.36 µg a.s./bee			≥10

Values in bold are below the relevant trigger.

Refined oral exposure of Oxamyl 10GR to bumblebees (*Bombus terrestris*) in field margins after dust drift

Species	Residue levels in pollen and nectar (µg a.s./mg)	Food consumption (mg/bee/day)	Exposure (µg a.s./bee/day)	Endpoint (µg a.s./bee)	TER	EPPO trigger
Bumble bees, adult	0.000505	149[a]	0.06464	0.36	**4.8**	≥10

Values in bold are below the relevant trigger

[a] estimated from EFSA opinion (2012) Tasei *et al.* (1994) and Tasei *et al.* (2000)

Risk assessment for toxicity of Oxamyl 10SL

Refined oral exposure of Oxamyl 10SL to bumblebees (*Bombus terrestris*) in glass houses

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test substance	End point	Toxicity
Aphidius rhopalosiphi	Oxamyl 10SL Glass plate dose response (48 h)	Not valid	
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
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: 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 %
Orius levigatus			Not reliable

Species	Test substance	End point	Toxicity
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)

First tier risk assessment for non-target arthropods exposed to Oxamyl 10GR

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[a]	Trigger
Oxamyl 10GR	*Typhlodromus pyri*				
	Aphidius rhopalosiphi				2

[a] 1.49% (drift value for granule broadcast application, 1.5 m distance according to EFSA 2004

In-field risk assessment for 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

*An acceptable risk can be concluded based on the fact that ER50 (EC50) 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 would permit a rapid recolonization.

Off-field risk assessment for Tobacco at 1 × 55 kg Oxamyl 10GR/ha, broadcast, based on extended lab test or aged residue tests

Species	ER_{50} (g/ha)	Off-field rate[1]
Poecilus cupreus, *Aleochara bilineata*, and *Pardosa* spp	>55000	40.98

[1]1.49% (drift value for granule broadcast application, 1.5 m distance according to EFSA 2004. Exposure in soil. Vegetative distribution factor of 10.

Risk assessment for solarization in glass house at 1 x 55 kg Oxamyl 10SL/ha with drip irrigation.
Although oxamyl is 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.
Extended studies three ground-dwelling species (Poecilus cupreus, Aleochara bilineata, and Pardosa spp) 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 PECsoil equivalent to 3.85 mg a.s./kg dry soil (5.5 kg a.s./ha, 10-cm soil depth). Reproduction of staphilinid beetles Aleochara bilineata 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.

Risk assessment for tomato in glass house at 20 + 10 +10+10 kg Oxamyl 10SL/ha with drip irrigation based on extended lab test or aged residue tests.

Although oxamyl is 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

Species	ER_{50}	In-field rate	Off-field rate[1]
Typhlodromus pyri,	> 6 × 1.0 kg a.s./ha	2 + 1 +1+1 kg a.s/ha	n.a.
Aphidius rhopalosiphi	> 6 × 1.0 kg a.s./ha	2 + 1 +1+1 kg a.s/ha	n.a.
Orius laevigatu	> 6 × 1.0 kg a.s./ha	2 + 1 +1+1 kg a.s/ha	n.a.
Aleochara bilineata,	>3 mg a.s/kg dw soil		n.a.
Pardosa spp,	>33 mg a.s/kg dw soil		n.a.
Poecilus cupreus	>6 mg a.s/kg dw soil		n.a.

[1]indicate distance assumed to calculate the drift rate and if 3D or 2D.

Semi-field tests
None
Field studies
None
Additional specific test
None

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Time scale	End point	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

Higher tier testing Three earthworm field studies in Germany (DuPont-9157), United Kingdom (DuPont-14076), and The Netherlands (DuPont-14075) were performed but not submitted. A population modelling study was performed to evaluate potential effects of oxamyl on Collembola following applications to potato and tobacco, but its reliability is questionable.			
Nitrogen transformation (nitrate formation rate)	Oxamyl	28-day laboratory	<25% effect at doses of 12.0 and 60.0 mg a.s./kg d.w.soil
	Oxamyl 10GR	Not valid	
	Oxamyl 10SL	28-day laboratory	<25% effect at day 28 1.5 and 15 Kg a.s./ha and 23 mg a.s/Kg soil dw (0.6%, +15.3%, +7.2%)
	IN-A2213	56-day laboratory	<25% effect at day 56 at 4.9 mg a.s./kg d.w.soil (+3.54%)
	IN-D2708	Not valid	
	IN-N0079	56-day laboratory	<25% effect at day 56 at 3.0 and 15 mg a.s./kg d.w.soil (+6%, +15%)
	IN-T2921	Not reliable	

Toxicity/exposure ratios for soil organisms

Oxamyl 10GR applied on potato at 1000 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	a.s.	Acute	0.667	168	10
Eisenia fetida	10GR	Acute	0.667	>150	10
Eisenia fetida	10GR	Chronic	0.667	9.6	5
Eisenia fetida	IN-A2213	Acute	0.256	>3906	5
Eisenia fetida	IN-D2708	Acute	0.280	>3571	5
Eisenia fetida	IN-N0079	Acute	0.030	21333	5
Eisenia fetida	IN-A2213	Chronic	0.256	104	5
Eisenia fetida	IN-D2708	Chronic	0.280	357	5
Eisenia fetida	IN-N0079	Chronic	0.030	1667	5
Other soil macro-organisms					
Folsomia candida	a.s.	Chronic	0.469 [a]	**0.53**	5
Hypoaspis aculeifer	a.s.	Chronic	0.469 [a]	34	5
Folsomia candida	IN-A2213	Chronic	0.256	391	5
Hypoaspis aculeifer	IN-A2213	Chronic	0.256	391	5
Folsomia candida	IN-D2708	Chronic	0.280	357	5
Hypoaspis aculeifer	IN-D2708	Chronic	0.280	357	5
Folsomia candida	IN-N0079	Chronic	0.030	417	5
Hypoaspis aculeifer	IN-N0079	Chronic	0.030	833	5

[a] refined PECs calculations were conducted for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios.

Oxamyl 10GR applied on tobacco at 3000 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	a.s.	Acute	4.000	28	10
Eisenia fetida	10GR	Acute	4.000	>25	10
Eisenia fetida	10GR	Chronic	1.199 [a]	5.3	5
Eisenia fetida	IN-A2213	Acute	1.538	650	5
Eisenia fetida	IN-D2708	Acute	1.681	595	5
Eisenia fetida	IN-N0079	Acute	0.183	3497	5
Eisenia fetida	IN-A2213	Chronic	1.538	17	5
Eisenia fetida	IN-D2708	Chronic	1.681	59	5
Eisenia fetida	IN-N0079	Chronic	0.183	273	5
Other soil macroorganisms					
Folsomia candida	a.s.	Chronic	1.199 [a]	**0.21**	5
Hypoaspis aculeifer	a.s.	Chronic	1.199 [a]	13	5
Folsomia candida	IN-A2213	Chronic	1.538	65	5
Hypoaspis aculeifer	IN-A2213	Chronic	1.538	65	5
Folsomia candida	IN-D2708	Chronic	1.681	59	5
Hypoaspis aculeifer	IN-D2708	Chronic	1.681	59	5
Folsomia candida	IN-N0079	Chronic	0.183	68	5
Hypoaspis aculeifer	IN-N0079	Chronic	0.183	137	5

[a] refined PECs calculations were conducted for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios.

Oxamyl 10GR applied on tobacco at 5500 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	a.s.	Acute	3.667	31	10
Eisenia fetida	10GR	Acute	3.667	>27	10
Eisenia fetida	10GR	Chronic	2.202 [a]	**2.9**	5
Eisenia fetida	IN-A2213	Acute	1.410	709	5
Eisenia fetida	IN-D2708	Acute	1.541	649	5
Eisenia fetida	IN-N0079	Acute	0.167	3832	5
Eisenia fetida	IN-A2213	Chronic	3.667	7	5
Eisenia fetida	IN-D2708	Chronic	1.541	65	5
Eisenia fetida	IN-N0079	Chronic	0.167	299	5
Other soil macroorganisms					
Folsomia candida	a.s.	Chronic	2.202 [a]	**0.11**	5
Hypoaspis aculeifer	a.s.	Chronic	2.202 [a]	7.3	5
Folsomia candida	IN-A2213	Chronic	1.410	71	5
Hypoaspis aculeifer	IN-A2213	Chronic	1.410	71	5
Folsomia candida	IN-D2708	Chronic	1.541	65	5
Hypoaspis aculeifer	IN-D2708	Chronic	1.541	65	5
Folsomia candida	IN-N0079	Chronic	0.167	75	5
Hypoaspis aculeifer	IN-N0079	Chronic	0.167	150	5

[a] refined PECs calculations were conducted for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios.

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not availbale. ER_{50} tests have been provided.

Laboratory dose response tests

Risk for Oxamyl 10GR applied broadcast on tobacco at 5500 g a.s./ha.

Species	Test substance	ER_{50} (kg a.s./ha) vegetative vigour	ER_{50} (kga.s./ha) emergence	Exposure (kg a.s./ha)[a]	TER	Trigger
Zea mays	Oxamyl 24SL	>2.24	>2.24	81.25	27	5
Avena sativa		>2.24	>2.24	81.25	27	5
Allium cepa		>2.24	>2.24	81.25	27	5
Lolium perenne		>2.24	-	81.25	27	5
Sorghum bicolor		-	>2.24	81.25	27	5
Cucumis sativus		>2.24	>2.24	81.25	27	5
Brassica napus		>2.24	>2.24	81.25	27	5
Pisum sativum		>2.24	>2.24	81.25	27	5
Glycine max		>2.24	>2.24	81.25	27	5
Beta vulgaris		>2.24	>2.24	81.25	27	5
Lycopersicon esculentum		>2.24	>2.24	81.25	27	5

[a] Drift estimates are based on EFSA (2004) drift values for granular application with spinning disk, worst-case value.

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	Respiration rate
Activated sludge	EC_{50} >100mg/L

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s. No monitoring data is available for this active substance Available monitoring data concerning effect of the PPP. No monitoring data is available for Oxamyl 10SL and Oxamyl 10GR

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds

Compartment	
soil	Parent (Oxamyl)
water	Parent (Oxamyl)
sediment	Parent (Oxamyl)
groundwater	Parent (Oxamyl)

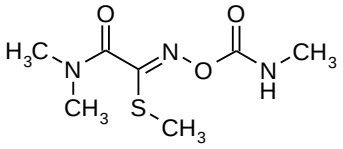
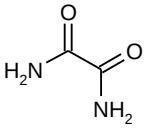
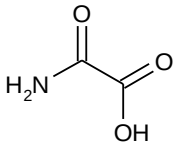
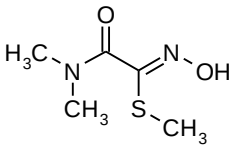
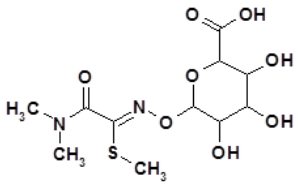
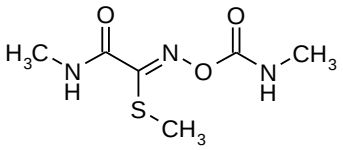
Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

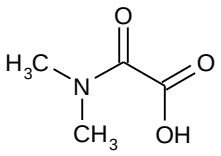
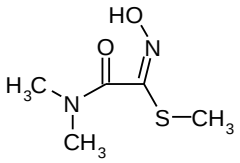
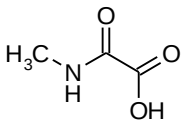
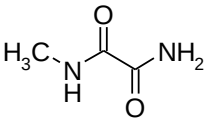
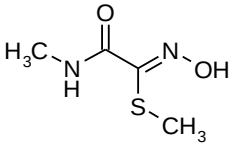
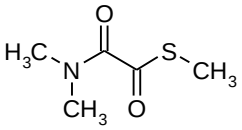
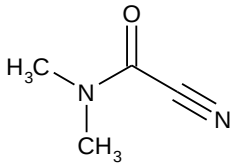
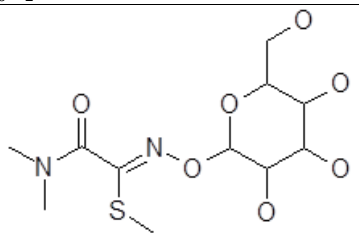
Substance	Oxamyl 42%TK
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][9]:	H411: Toxic to aquatic life with long lasting effects Aquatic Chronic 2
Peer review proposal[10] for harmonised classification according to Regulation (EC) No 1272/2008:	Oxamyl is already classified according to regulation 1272/2008

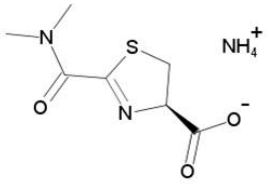
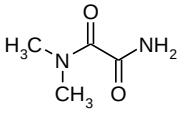
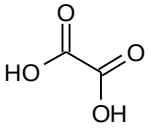
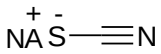
9 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

10 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Appendix

Code Number (Synonyms)	Description	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	 $C_7H_{13}N_3O_3S$
IN-00699	**CAS name:** Ethanediamide **Common name:** Oxamide **CAS number**: 471-46-5 **Molecular weight:** 88.07 g/mole	 $C_2H_4N_2O_2$
IN-18474	**CAS name:** Aminooxoacetic acid **Common name:** Oxamic acid **CAS number**: 471-47-6 **Molecular weight:** 89.05 g/mole	 $C_2H_3NO_3$
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	 $C_5H_{10}N_2O_2S$
A2213 glucuronide	**CAS name:** Not applicable **Common name:** Not applicable **CAS number**: Not applicable **Molecular weight:** 338.34 g/mole	 $C_{11}H_{18}N_2O_8S$
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	 $C_6H_{11}N_3O_3S$

Code Number (Synonyms)	Description	Structure
IN-D2708	**CAS name:** (Dimethylamino)oxoacetic acid **Common name:** DMOA **CAS number**: 32833-96-8 **Molecular weight:** 117.105 g/mole	 $C_4H_7NO_3$
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	 $C_5H_{10}N_2O_2S$
IN-KP532	**CAS name:** (Methylamino)oxoacetic acid **CAS number**: 29262-58-6 **Molecular weight:** 103.08 g/mole	 $C_3H_5NO_3$
IN-KV998	**CAS name:** *N*-Methylethanediamide **CAS number**: 22509-04-2 **Molecular weight:** 102.09 g/mole	 $C_3H_6N_2O_2$
IN-L2953	**CAS name:** Methyl *N*-hydroxy-2-(methylamino)-2-oxoethanimidothioate **CAS number**: 66157-67-3 **Molecular weight:** 148.18 g/mole	 $C_4H_8N_2O_2S$
IN-M2583	**CAS name:** *S*-Methyl (dimethylamino)oxoethanethioate **CAS number**: Not available **Molecular weight:** 147.20 g/mole	 $C_5H_9NO_2S$
IN-N0079	**CAS name:** Dimethylcarbonocyanidic amide **Common name:** DMCF **CAS number**: 16703-51-8 **Molecular weight:** 98.10 g/mole	 $C_4H_6N_2O$
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	 $C_{11}H_{20}N_2O_7S$

Code Number (Synonyms)	Description	Structure
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	 $C_7H_{13}N_3O_3S$
IN-T2921	**CAS name:** *N*,*N*-Dimethylethanediamide **Common name:** DMEA (also DMO) **CAS number**: 600-39-5 **Molecular weight:** 116.12 g/mole	 $C_4H_8N_2O_2$
N/A	**CAS name:** Ethanedioic acid **Common name:** Oxalic Acid **CAS number**: 144-62-7 **Molecular weight:** 90.04 g/mole	 $C_2H_2O_4$
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	 NaSCN