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Oxamyl 10GR

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ANNEX B.8
Environmental fate and behaviour and environmental exposure assessment

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B.8 ENVIRONMENTAL FATE AND BEHAVIOUR AND ENVIRONMENTAL EXPOSURE ASSESSMENT

Environmental fate studies using the formulation Oxamyl 10GR were not conducted as data from studies with the active substance, oxamyl, are available and adequate to enable extrapolation to the behaviour of the formulated product. A summary of the environmental fate parameters of oxamyl can be found in Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU. Neither the type of plant protection product nor its ingredients and physical properties were expected to affect the fate and behaviour in soil, ground water, surface water, and sediment.

The primary degradation pathway of oxamyl in aerobic soils is microbial and hydrolytic degradation to yield IN-A2213 and subsequently IN-D2708. Further degradation leads to extensive mineralization to carbon dioxide and non-extractable residues. Maximum occurrences of IN-A2213 and IN-D2708 in the laboratory studies were 52 and 78.7% AR, respectively. Maximum occurrences of IN-A2213 and IN-D2708 in field and greenhouse dissipation studies were lower: 25.5 and 26% for IN-A2213 and 25.8 and 5.2% for IN-D2708, respectively (Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU). Results from the laboratory and field degradation studies consistently support the conclusion that oxamyl is readily degraded in aerobic topsoils to carbon dioxide with IN-A2213 and IN-D2708 as major intermediates.

The secondary degradation pathway of oxamyl takes place in the presence of ferrous ions to form IN-N0079 (Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU). This route of degradation is expected to occur under anaerobic, reducing conditions and where sufficient Fe^{II} is present. Under aerobic conditions, this degradation pathway is unlikely to occur unless *via* indirect photolysis. Maximum occurrence of IN-N0079 in the soil photolysis study was 10.2% AR (Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU). IN-N0079 degrades further to IN-D2708.

As a conclusion, two distinct pathways of oxamyl degradation could be distinguished;

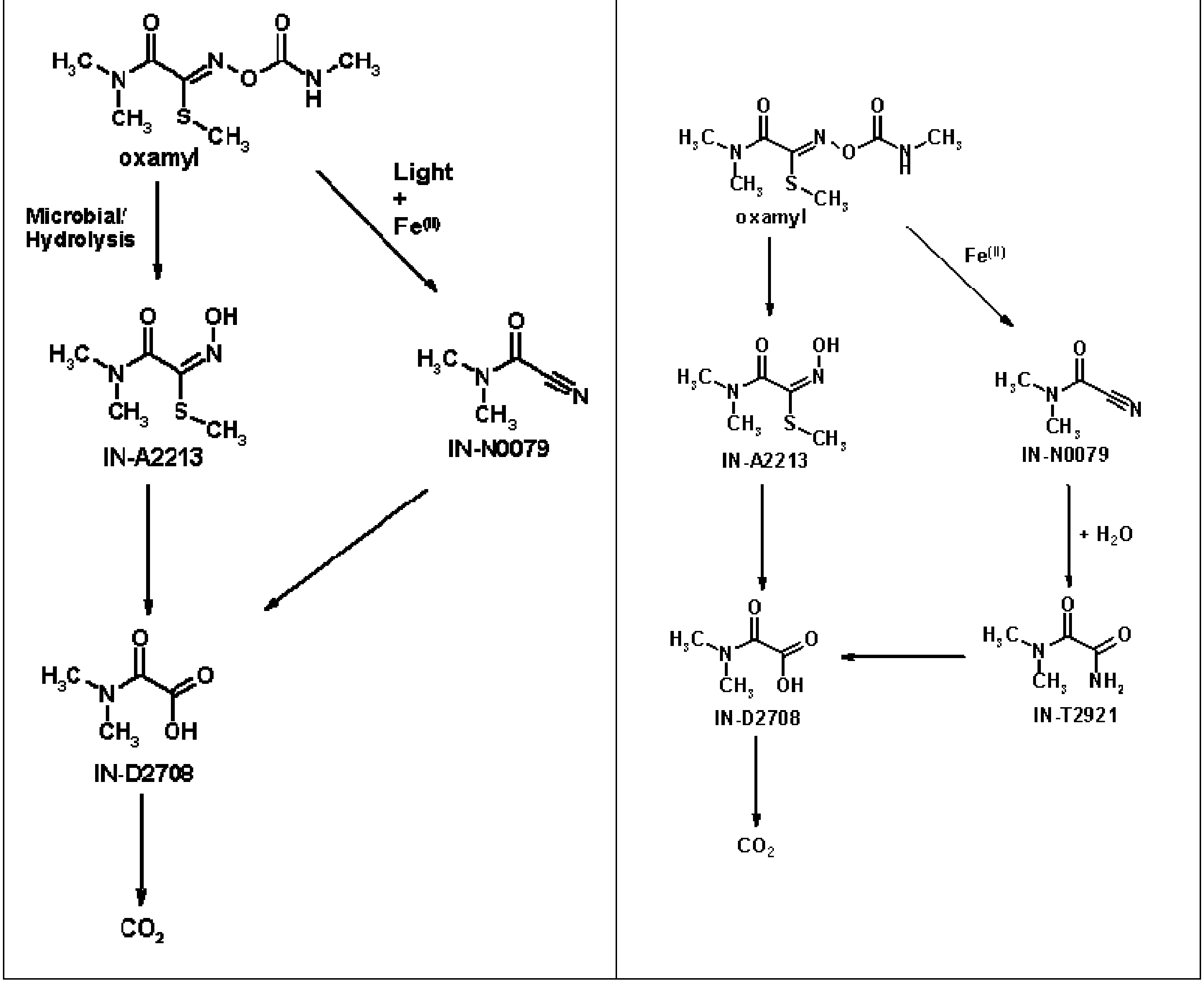
- Oxamyl → IN-A2213 → IN-D2708 in aerobic soils;
- Oxamyl → IN-N0079 → IN-D2708 under submerged conditions at presence of Fe^{II} ions or as a result of indirect photolysis.

Degradation of oxamyl in natural water/sediment systems occurred *via* four water/sediment metabolites, IN–A2213, IN-D2708, IN-N0079, and IN-T2921, which were observed at levels >10% AR.

Based on these studies, a schematic degradation pathway was proposed, as depicted in Figure 1.

Figure 1 Proposed pathway of transformation of oxamyl

Degradation pathway for oxamyl in aerobic soil	Degradation pathway for oxamyl in water/sediment system



Endpoints considered relevant in assessing the fate of oxamyl and its metabolites are shown under Points B.8.1.1, B.8.1.2, B.8.2, B.8.3 and B.8.4) in this document. Simulations of PEC_{soil}, PEC_{gw}, and PEC_{sw} have been presented on the basis of endpoints derived according to FOCUS Working Group on Degradation Kinetics (2006) and were subjected to visual and statistical checks as outlined by the FOCUS Working Group on Degradation Kinetics (summarised under B.8.1.1 and B.8.4.2 in this document). The residue definitions for the exposure assessment are summarized in Table 1.

Table 1 Oxamyl and metabolites considered in the assessment

Code number/name[a]	Compartment(s)
Oxamyl (DPX-1410)	Soil, groundwater, surface water
IN-A2213	Soil, groundwater, surface water
IN-D2708	Soil, groundwater, surface water
IN-N0079	Soil, groundwater, surface water
IN-T2921	Surface water

[a] A complete list of active substances and metabolites with their chemical names and structures are included in Oxamyl EU Renewal Dossier, Document N, Part 3, DuPont-40940 EU.

Context surrounding representative use(s)

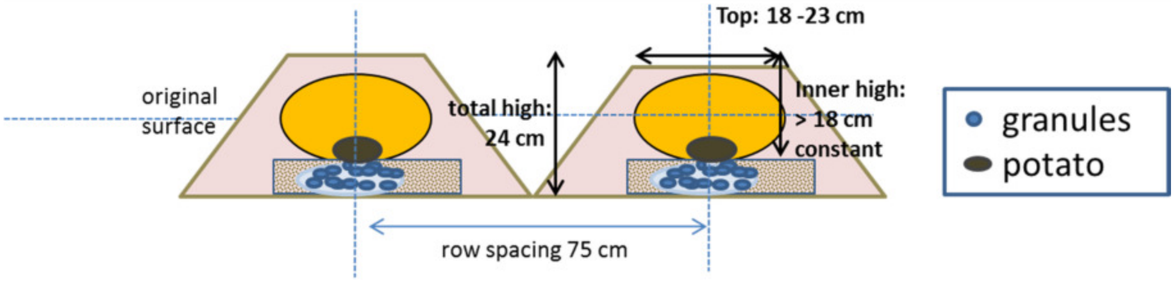
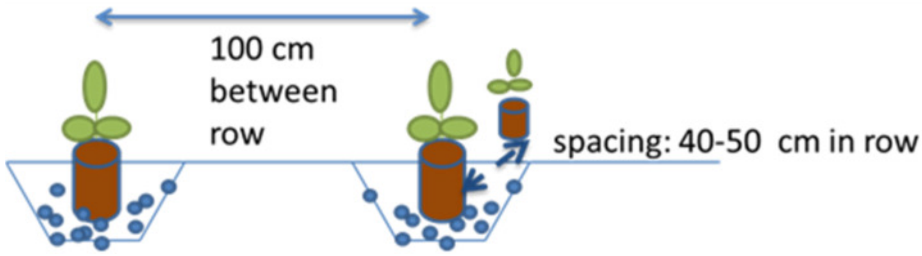
Oxamyl is an insecticide and nematicide used to control a wide range of varieties of nematodes and arthropods. It is the active substance in DuPont nematicide/insecticide Oxamyl 10GR and Oxamyl 10L, two representative formulations. The intended uses for the granular formulation include application to potatoes and tobacco. The following proposed uses of oxamyl in the open field were considered:

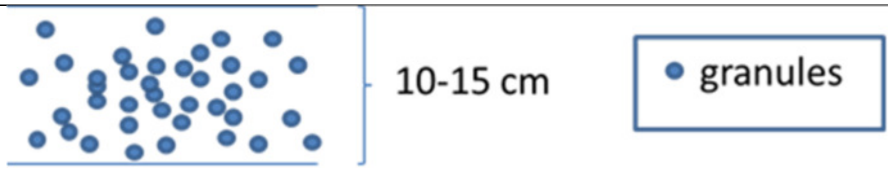
Open field uses (Oxamyl 10G, Table 2):

- Potatoes at 1000 g a.s./ha in-furrow at planting
- Tobacco at 3000 g a.s./ha in-furrow at planting;
- Tobacco at 5500 g a.s./ha broadcast before planting;

The application of Oxamyl 10GR is made into the soil using tractor-mounted, ground-directed broadcast, or with in-furrow equipment.

Table 2 Representative uses of Oxamyl 10GR formulation (open field uses)

In-furrow application to potatoes at 1 × 1000 g a.s./ha

Typical application depth for this use is >9 cm relative to the original soil surface and >18 cm relative to the ridge surface. This application regime results in essentially no granules on the soil surface.
In-furrow application to tobacco at 1 × 3000 g a.s./ha

Typical application depth for this use is about 5 cm relative to the original soil surface. This application regime results in relatively small number of granules on the soil surface.

Broadcast and incorporation application to tobacco at 1 × 5500 g a.s./ha

Granules are evenly distributed between the topsoil and 10 to 15 cm soil depth.

For the purpose of supporting protective exposure PEC_{soil}, PEC_{gw}, and PEC_{sw} assessments summarised in this document, modelling has been carried out based upon the representative uses considering usage in potato and tobacco.

Unless specifically indicated, all reports in this section are submitted to address mandatory data requirements for the approval of the active substance.

B.8.1 Fate and behaviour in soil

B.8.1.1 Rate of degradation in soil

B.8.1.1.1 Laboratory studies

Study submitted to the EU for the first time in this submission.

B.8.1.1.1/01

Reference: CP 9.1.1.1/01	**Report:**	Ghafoor, A., Zillgens, B. (2015); Estimation of kinetic endpoints for oxamyl and its metabolites oxamyl oxime (IN-A2213), DMOA (IN-D2708), DMCF (IN-N0079) from laboratory soil degradation studies **DuPont Report No.:** DuPont-41859 EU **Guidelines:** Not applicable **Deviations:** None **Testing Facility:** Dr. Knoell Consult GmbH, Mannheim, Germany **Testing Facility Report No.:** DuPont-41859 EU **GLP:** No **Certifying Authority:** Not applicable

Four aerobic soil degradation studies in nine soils for oxamyl under laboratory conditions (DuPont-2957, AMR1851-90, DuPont-2958, and DuPont-39014), one aerobic degradation study for metabolite IN-D2708 (DMOA) in three soils under laboratory conditions (DuPont-2675), one aerobic degradation study for metabolite IN-N0079 (DMCF) in three soils under laboratory conditions (DuPont-2674), and one photodegradation study for oxamyl and its metabolite IN-N0079 (DMCF) in one soil under laboratory conditions (DuPont-31501) were carried out. Since the studies do not contain a kinetic evaluation of the data according to recent FOCUS recommendations (FOCUS, 2006[1], 2011[2]), residue data of these studies were re-evaluated to derive persistence

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

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

and modelling endpoints for oxamyl and its metabolites IN-A2213, IN-D2708, and IN-N0079 under aerobic soil conditions, and for oxamyl and its photolytic metabolite IN-N0079 under irradiated conditions (photodegradation).

The results of the kinetic evaluations of persistence endpoints of the active substance and its metabolites are reported in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU and are summarised below rather than being distributed in different subsections. This was done for the sake of clarity and easier reading. The persistence and modelling endpoints, derived from laboratory (photo-) degradation

Table 3 Summary of degradation parameters as persistence endpoints for oxamyl

Study[a]	Soil/Condition	$DegT_{50}$ (days)	$DegT_{90}$ (days)	Model
DuPont-2957	Commerce 20°C	2.8	9.3	SFO
	Commerce 10°C	15.8	52.3	SFO
	Gross-Umstadt 20°C	3.7	13.9	DFOP
AMR 1851-90	Madera 25°C	11.1	36.8	SFO
DuPont-2958	Nijmegen 20°C	7.8	25.8	SFO
DuPont-39014	Goch 597 20°C	0.6	2.0	SFO
	LRA-D 588 20°C	9.7	79.5	DFOP
	Speyer 582 20°C	7.2	24.0	SFO
	Tama 583 20°C	7.8	48.5	FOMC

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

Table 4 Summary of degradation parameters as persistence endpoints for oxamyl degradation in light (photolysis study)

Study[a]	Soil/Condition	DT_{50}	DT_{90}	Model
		(Days)		
DuPont-31501	Tama 20°C	4.6	15.2	SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

Table 5 Summary of degradation parameters as persistence endpoints for IN-A2213

Study[a]	Soil/Condition	$DegT_{50}$ (days)	$DegT_{90}$ (days)	Model
DuPont-2957	Commerce 20°C	5.8	19.1	SFO-SFO
	Commerce 10°C	22.1	73.3	SFO-SFO
	Gross-Umstadt 20°C	1.7	5.7	DFOP-SFO
DuPont-2958	Nijmegen 20°C	1.7	5.5	SFO-SFO
DuPont-39014	Speyer 582 20°C	1.4	4.5	SFO-SFO
	Tama 583 20°C	1.8	5.9	FOMC-SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

Table 6 Summary of degradation parameters as persistence endpoints for IN-D2708

Study[a]	Soil/Condition	$DegT_{50}$ (days)	$DegT_{90}$ (days)	Model
DuPont-2957	Commerce 20°C	3.5	11.8	SFO-SFO
	Gross-Umstadt 20°C	3.2	10.8	DFOP-SFO
DuPont-2958	Nijmegen 20°C	8.8	29.4	SFO-SFO
DuPont-2675[b]	Commerce 20°C	7.6	25.3	SFO
	Gross-Umstadt 20°C	9.5	31.6	SFO
	Drummer 20°C	12.7	42.2	SFO
DuPont-39014	Tama 583 20°C	6.8	22.4	FOMC-SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

[b] IN-D2708 was directly dosed into the soils.

Table 7 Summary of degradation parameters as persistence endpoints for IN-N0079 (applied as parent)

Study[a]	Soil/Condition	$DegT_{50}$	$DegT_{90}$	Model
		(Minutes)		
DuPont-2674[b]	Commerce 23°C	49.5	164.4	SFO
	Gross-Umstadt 23°C	4.0	13.2	SFO
	Drummer #6 23°C	23.0	76.5	SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

[b] IN-N0079 was directly dosed into the soils.

Table 8 Summary of degradation parameters as persistence endpoints for IN-N0079 (derived from oxamyl photolysis study)

Study[a]	Soil/Condition	DT_{50} (days)	DT_{90} (days)	Model
DuPont-31501	Tama 20°C	2	6.5	SFO-SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934EU

Table 9 Summary of degradation parameters as modelling endpoints for oxamyl

Study[a]	Soil/Condition	$DegT_{50}$ at 20°C (days)	Moisture content (w/w %)			$DegT_{50}$ at 20°C & 10 kPa[c] (days)	Model at MWHC
			At MWHC	During study	At 10 kPa		
DuPont-2957	Commerce 20°C	2.8	33.3	13.3	26	1.8	SFO
	Commerce 10°C[b]	6.1	33.3	13.3	26	3.8	SFO
	Gross-Umstadt 20°C	4.0	50	20	26	3.3	SFO
AMR 1851-90	Madera 25°C[b]	17.8	15.4	11.6	22	11.4	SFO
DuPont-2958	Nijmegen 20°C	7.8	33.3	13.3	25	5.0	SFO
DuPont-39014	Goch 597 20°C	0.6	-	pF2	-	0.6	SFO
	LRA-D 588 20°C	19.4	-	pF2	-	19.4	FOMC $DegT_{90}$/ 3.32
	Speyer 582 20°C	7.2	-	pF2	-	7.2	SFO
	Tama 583 20°C	14.3	-	pF2	-	14.3	FOMC $DegT_{90}$/ 3.32

a All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

b Corrected to 20°C

c Correction factor = $(\theta_{study}/\theta_{pf2})^{0.7}$

Table 10 Summary of degradation parameters as modelling endpoints for oxamyl in light (photolysis study)

Study[a]	Soil/Condition	DT_{50} at 20°C (days)	Moisture content (w/w %)			DT_{50} at 20°C & 10 kPa[b] (days)	Model
			At MWHC	During study	At 10 kPa		
DuPont-31501	Tama 20°C	4.6	30	22.5	30	3.8	SFO

a All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

b Correction factor = $(\theta_{study}/\theta_{pf2})^{0.7}$

Table 11 Summary of degradation parameters as modelling endpoints for IN-A2213

Study[a]	Soil/Condition	$DegT_{50}$ at 20°C (days)	Moisture content (w/w %)			$DegT_{50}$ at 20°C & 10 kPa[c] (days)	Model
			At MWHC	During study	At 10 kPa		
DuPont-2957	Commerce 20°C	5.8	33.3	13.3	26	3.6	SFO-SFO
	Commerce 10°C[b]	8.6	33.3	13.3	26	5.4	SFO-SFO
	Gross-Umstadt 20°C	1.6	50	20	26	1.3	SFO-SFO
DuPont-2958	Nijmegen 20°C	1.7	33.3	13.3	25	1.1	SFO-SFO
DuPont-39014	Speyer 582 20°C	1.4	-	pF2	-	1.4	SFO-SFO
	Tama 583 20°C	1.8	-	pF2	-	1.8	FOMC-SFO

a All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

b Corrected to 20°C

c Correction factor = $(\theta_{study}/\theta_{pf2})^{0.7}$

Table 12 Summary of degradation parameters as modelling endpoints for IN-D2708

Study[a]	Soil/Condition	$DegT_{50}$ at 20°C (days)	Moisture content (w/w %) At MWHC	During study	At 10 kPa	$DegT_{50}$ at 20°C & 10 kPa[b] (days)	Model
DuPont-2957	Commerce 20°C	3.5	33.3	13.3	26	2.2	SFO-SFO
	Gross-Umstadt 20°C	3.1	50	20	26	2.6	SFO-SFO
DuPont-2958	Nijmegen 20°C	8.8	33.3	13.3	25	5.7	SFO-SFO
DuPont-2675[c]	Commerce 20°C	7.6	33.3	13.3	26	4.8	SFO
	Gross-Umstadt 20°C	9.5	50	22	26	8.5	SFO
	Drummer 20°C	12.7	49.4	23.2	30	10.6	SFO
DuPont-39014	Tama 583 20°C	6.8	-	pF2	-	6.8	FOMC-SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

[b] Correction factor = $(\theta_{study}/\theta_{pf2})^{0.7}$

[c] IN-D2708 was dosed directly into the soils

Table 13 Summary of degradation parameters as modelling endpoints for IN-N0079 (applied as parent)

Study[a]	Soil/Condition	$DegT_{50}$ at 20°C (minutes)	Moisture content (w/w %) At MWHC	During study	At 10 kPa	$DegT_{50}$ at 20°C & 10 kPa[b] (minutes)	Model
DuPont-2674[c]	Commerce 23°C	65.8	33.3	13.3	26	41.2	SFO
	Gross-Umstadt 23°C	5.3	50	20	26	4.4	SFO
	Drummer #6 23°C	30.8	49.4	19.9	30	23.0	SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

[b] Correction factor = $(\theta_{study}/\theta_{pf2})^{0.7}$

[c] IN-N0079 was dosed directly into the soils

Table 14 Summary of degradation parameters as modelling endpoints for IN-N0079 (derived from oxamyl photodegradation study)

Study[a]	Soil/Condition	DT_{50} at 20°C (days)	Moisture content (w/w %) At MWHC	During study	At 10 kPa	DT_{50} at 20°C & 10 kPa[b] (days)	Model
DuPont-31501	Tama 20°C	2	30	22.5	30	1.6	SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

[b] Correction factor = $(\theta_{study}/\theta_{pf2})^{0.7}$

Table 15 Summary of IN-A2213 formation fractions from the best-fit kinetic models for use in PEC_{soil} evaluations

Study[a]	Soil/Condition	Oxamyl → IN-A2213	Model
DuPont-2957	Commerce 20°C	0.98	SFO-SFO
	Commerce 10°C	0.74	SFO-SFO
	Gross-Umstadt 20°C	0.98	DFOP-SFO
AMR 1851-90	Madera 25°C	1.00	SFO-SFO
DuPont-2958	Nijmegen 20°C	1.00	SFO-SFO
DuPont-39014	LRA-D 588 20°C	1.00	DFOP-SFO
	Speyer 582 20°C	0.75	SFO-SFO
	Tama 583 20°C	0.86	FOMC-SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

Table 16 Summary of IN-D2708 formation fractions from the best-fit kinetic models for use in PEC_{soil} evaluations

Study[a]	Soil/Condition	IN-A2213 → IN-D2708	Model
DuPont-2957	Commerce 10°C	0.88	SFO-SFO
DuPont-2958	Nijmegen 20°C	0.73	SFO-SFO
DuPont-39014	Speyer 582 20°C	1.00	SFO-SFO
	Tama 583 20°C	1.00	FOMC-SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

Table 17 Summary of formation fractions for use in groundwater and surface water modelling assessments

Study[a]	Proposed formation fraction for	Maximum reliable formation fraction	Model
DuPont-2957	Oxamyl → IN-A2213	1.0	see Table 15
DuPont-39014	IN-A2213 → IN-D2708	1.0	see Table 16

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

Table 18 Summary of IN-N0079 formation fractions from the best-fit kinetic models (derived from oxamyl photodegradation study)

Study[a]	Soil/Condition	Oxamyl → IN-N0079	Model
DuPont-31501	Tama 20°C	0.35	SFO-SFO

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

RMS comments and conclusion

This study is considered corrected to harmonize the derivation of degradation parameters from soil metabolism. Residue data of aerobic soil degradation studies in 6 soils for metabolite IN-A2213 under laboratory conditions (DuPont-2957, DuPont-2958, and DuPont-39014); 7 soils for metabolite IN-D2708 under laboratory conditions (DuPont-2957, DuPont-2958, DuPont-2675 and DuPont-39014) and 3 soils for metabolite IN-N0079 under laboratory conditions (DuPont-2674) were re-evaluated to derive persistence and modelling endpoints for oxamyl under aerobic soil conditions. One photodegradation study for metabolite IN-N0079 in one soil under laboratory conditions (DuPont-31501) was re-evaluated to derive persistence and modelling endpoints for metabolite IN-N0079 under irradiated conditions (photodegradation).
The kinetic assessments conducted are in full compliance with the FOCUS kinetics guidance and the imput parameters can be used for ground water and surface water risk assessment.

B.8.1.1.2 Field studies

B.8.1.1.2.1 Soil dissipation studies

Discussion of the rate of degradation of oxamyl and its soil metabolites IN-A2213 and IN-D2708 in soil dissipation studies can be found in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU. The field dissipation studies reported therein were conducted with the Oxamyl 10GR formulation containing oxamyl. Oxamyl 10GR is not designed as a slow release formulation and there are no formulation specific properties or formulation ingredients used that could be expected to cause the active substance in oxamyl to degrade differently when applied as unformulated technical product. Therefore, data generated with the active substance in the context of the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU are considered to be applicable to the formulation.

Study submitted to the EU for the first time in this submission.

B.8.1.1.2.1/01

Reference: CP 9.1.1.2.1/01	**Report**	Partsch, S., Zillgens, B. (2015); Estimation of kinetic endpoints for oxamyl and its metabolites oxamyl oxime (IN-A2213) and DMOA (IN-D2708) from field soil dissipation studies **DuPont Report No.:** DuPont-41859 EU, Supplement No. 1 **Guidelines:** Not applicable **Deviations:** None **Testing Facility:** Dr. Knoell Consult GmbH, Mannheim, Germany **Testing Facility Report No.:** DuPont-41859 EU, Supplement No. 1 **GLP:** No **Certifying Authority:** Not applicable

Residue data from soil dissipation studies (DuPont-2815, DuPont-3026) were reevaluated to meet the requirements of the current FOCUS (2006, 2011, 2014a3) and EFSA (2014)4 guidelines on degradation kinetics. The results of the kinetic evaluations of the active substance and its metabolites are reported in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU and are summarised below rather than being distributed in different subsections. This was done for the sake of clarity and easier reading.

Two field dissipation studies for oxamyl were conducted at European trial sites in Ottersum in the Netherlands (DuPont-2815) and Spalding in the UK (DuPont-3026). In both field dissipation studies, the Oxamyl 10GR (granule, 10% oxamyl) was applied at 4 (NL) and 5.5 kg a.s./ha (UK) onto bare ground and the granules were further incorporated into the topsoil. Persistence endpoints and modelling endpoints were then calculated for comparison against trigger values and for use in exposure modelling, respectively.

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

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

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

All persistence and modelling endpoints, derived from field dissipation studies are summarised in Table 19 to Table 24. DT_{xx} is used as a general term in all tables, it represents both dissipation and degradation time.

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

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

Degradation model of oxamyl in the field

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

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

Oxamyl → IN-A2213 → IN-D2708

Estimation of the kinetic endpoints

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

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

Normalisation of field dissipation data

Soil temperature and moisture are important factors that may affect degradation rates in the field. Hence, it is important to normalise degradation rates according to local weather conditions which are subjected to daily and seasonal changes. Here, normalisation was performed by adjusting the individual day lengths as a function of fluctuating temperature and moisture. The following equation was used for this so called "time-step normalisation". It results in a value >1 for warmer and wetter conditions and a value <1 for cooler and drier conditions:

$$Day_{norm} = Day \times Q_{10}^{[(Tact\ -\ Tref)/10]} \times (Moist_{act}/FC)^{0.7}$$

where

Day_{norm}	=	Normalised Day Length (NDL)
Day	=	1 d
Q_{10}	=	Standard Q_{10} factor of 2.58
Tact	=	Daily soil temperature at measured depth
Tref	=	Reference temperature, 20°C
$Moist_{act}$	=	Daily soil water content at measured depth
FC	=	Reference soil water content (field capacity)

Based on this equation, cumulative corrected day lengths were calculated between each sampling interval to result in the normalised day lengths (NDL) which were used for the determination of modelling endpoints.

For both sites no measured soil temperature and soil moisture data were available. Therefore, daily values of these variables were calculated with the well-established environmental fate model FOCUS PEARL 4.4.4 (Leistra *et al.,* 2001[5]). Site-specific soil, crop and weather data were used as input parameters.

[5] Leistra, M., van der Linden, A.M.A, Boesten, J.J.T.I., Tiktak, A., van den Berg, F. (2001) PEARL model for pesticide behaviour and emissions in soil-plant systems - Descriptions of the processes in FOCUS PEARL v 1.1.1, Bilthoven, National Institute of Public Health and the Environment. Wageningen, Alterra, Green World Research. RIVM report 711401009/Alterra-rapport 013.

Table 19 Summary of persistence endpoints for oxamyl

Study	Soil/Condition	DT_{50} (days)	DT_{90} (days)	Model
DuPont-2815	Ottersum (NL) non-normalised data	9.5	31.4	SFO
DuPont-3026	Spalding (UK) non-normalised data	0.7	30.6	DFOP

NOTE: All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

Table 20 Summary of persistence endpoints for IN-A2213

Study[a]	Soil/Condition	DT_{50} (days)	DT_{90} (days)	Formation fraction from oxamyl	Model
DuPont-2815	Ottersum (NL) non-normalised data	1.4	4.6	0.83	SFO-SFO
DuPont-3026	Spalding (UK) non-normalised data	17.5	58.0	Calculation not possible[b]	SFO[b]

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU
[b] Determined from decline fit

Table 21 Summary of persistence endpoints for IN-D2708

Study[a]	Soil/Condition	DT_{50} (days)	DT_{90} (days)	Formation fraction from IN-A2213	Model
DuPont-2815	Ottersum (NL), non-normalised data	5.0	16.6	1 (fixed)	SFO-SFO
DuPont-3026	Spalding (UK), non-normalised data	9.1	30.1	Calculation not possible[a]	SFO[b]

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU
[b] Determined from decline fit

Table 22 Summary of modelling endpoints for oxamyl according to FOCUS

Study[a]	Soil/Condition	DT_{50} (days)	Model
DuPont-2815	Ottersum (NL), normalised data	5.0	SFO
DuPont-3026	Spalding (UK), normalised data	6.9	DFOP

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

Table 23 Summary of modelling endpoints for IN-A2213 according to FOCUS

Study[a]	Soil/Condition	DT_{50} (days)	Formation fraction from oxamyl	Model
DuPont-2815	Ottersum (NL), normalised data	0.8	0.77	SFO-SFO
DuPont-3026	Spalding (UK), normalised data	8.8	Calculation not possible [a]	SFO[b]

[a] All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU
[b] Determined from decline fit

Table 24 Summary of modelling endpoints according to FOCUS for IN-D2708

Study[a]	Soil/Condition	DT_{50} (days)	Formation fraction from IN-A2213	Model
DuPont-2815	Ottersum (NL), normalised data	2.9	1 (fixed)	SFO-SFO
DuPont-3026	Spalding (UK), normalised data	4.7	Calculation not possible [a]	SFO[b]

a All studies are cited or summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

b Determined from decline fit

RMS comments and conclusion

This study is considered corrected to harmonize the derivation of degradation parameters from soil metabolism. Residue data of aerobic soil degradation field studies in two soils for oxamyl and its metabolites under field conditions (DuPont-2815 and DuPont-3026) were re-evaluated to derive persistence and modelling endpoints for oxamyl and its metabolites from field dissipation studies.
The kinetic assessments conducted are in full compliance with the FOCUS kinetics guidance and the imput parameters can be used for ground water and surface water risk assessment.

B.8.1.1.2.2 Soil accumulation testing

Soil residue testing

Soil residue studies are not required for oxamyl since the DT50 lab is less than one third of the interval between application and harvest of potatoes (PHI = 90 days).

Soil accumulation testing

Soil accumulation studies were not done with oxamyl since the DT_{90} was much less than one year. The soil equilibrium concentration or soil PEC_{soil} estimates reliably indicate no potential for accumulation after repeated applications in potatoes (see the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934EU).

B.8.1.2 Mobility in the soil

B.8.1.2.1 Laboratory studies

Discussion of the soil mobility of oxamyl and its major soil metabolites can be found in the corresponding dossier for the active substance (see the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU).

The type of formulation and inert substances used in Oxamyl 10GR are not expected to affect the mobility of the active substance in soil. Therefore, data generated with the active substance in the context of CA 7.1.4 are considered to be applicable to the formulation. Therefore, Oxamyl 10GR was not specifically tested for soil mobility.

B.8.1.2.2 Lysimeter studies

Lysimeter studies were not performed with oxamyl.

No further specific formulation testing was required, as Oxamyl 10GR is not designed as a slow release formulation and there are no formulation specific properties or formulation ingredients used that could be expected to affect the mobility of oxamyl in soil when formulated as Oxamyl 10GR.

B.8.1.2.3 Field leaching studies

A field leaching study with Oxamyl 10GR was not conducted.

B.8.2 Predicted environmental concentrations in soil (PEC$_S$)

Study submitted to the EU for the first time in this submission.

B.8.2/01

Reference: CP 9.1.3/01	**Report:**	Juraske, R., Zillgens, B. (2015); Predicted enviromental concentrations of oxamyl and its major metabolites in soil after the application to various crops - a modelling assessment for Europe **DuPont Report No.:** DuPont-40857 EU **Guidelines:** Not applicable **Deviations:** None **Testing Facility:** Dr. Knoell Consult GmbH, Mannheim, Germany **Testing Facility Report No.:** DuPont-40857 EU **GLP:** No **Certifying Authority:** Not applicable

Predicted environmental concentrations in soil (PEC$_S$) of oxamyl and its major soil metabolites (IN-A2213, IN-D2708, and IN-N0079) after application to various crops in Europe were calculated based upon recommendations of the FOCUS group (FOCUS, 1997[6]; EU, 2000[7]). Key input parameters are summarised in Table 25.

6 FOCUS (1997): Soil Persistence Models and EU Registration. Final Report of the Soil Modeling Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their Use).

7 EU (2000): Guidance Document on Persistence in Soil, EC Document Reference Sanco/9188/VI/97 rev. 8, 17 pp.

Table 25 Key input parameters used in simulation of PEC_s for oxamyl and its soil metabolites

Parameter	Value	Units	Reference
Molecular weight Oxamyl IN-A2213 IN-D2708 IN-N0079	 219.3 162.2 117.1 98.1	 g/mol	 Oxamyl EU Renewal Dossier, Document N, Part 3, DuPont–40940 EU
Laboratory soil $DegT_{50}$ (non-normalised) Oxamyl (lab) IN-A2213 (lab) IN-D2708 (lab) IN-N0079 (worst case)	 11.1[a]/ 5.3[c] 5.8[a] 12.7[a] 1[b]	 days	DuPont-40857 EU, which is summarised in this document
Sorption coefficient K_{FOM} Oxamyl	 6.40	 -	DuPont-40857 EU, which is summarised in this document
Freundlich exponent Oxamyl	 0.92	 -	Calculated based on data presented in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU
Plant uptake Oxamyl	 0.5	 -	 default value
Maximum occurrence in soil Oxamyl (default) IN-A2213 (lab) IN-D2708 (lab) IN-N0079 (soil photolysis)	 100 52.0 78.7 10.2	 % AR	 Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU

a SFO kinetic endpoints.
b Conservative worst case.
c Geometric mean normalised modelling endpoint used in FOCUS PEARL 4.4.4 simulations.

The application framework for oxamyl include in-furrow application to potatoes at 1 × 1000 g a.s./ha, in-furrow application to tobacco at 1 × 3000 g a.s./ha, and broadcast application to tobacco at 1 × 5500 g a.s./ha.

PEC_s calculations for oxamyl and all metabolites were performed using persistence endpoints (worst case laboratory $DegT_{50}$ values obtained for soils at ≥20°C). For IN-N0079, the worst case $DegT_{50}$ is 49.5 min, therefore a conservative value of 1 day was used in calculation. The maximum levels of the degradation products IN-A2213 and IN-D2708 were derived from the laboratory soil degradation studies and IN-N0079 was derived from the soil photodegradation study. They were found to be 52.0, 78.7, and 10.2% AR, respectively.

A soil bulk density of 1.5 g/cm^3 and a soil depth of 5 cm (in-furrow application to tobacco tobacco at 1 × 3000 g a.s./ha) or 10 cm (in-furrow application to potatoes at 1 × 1000 g a.s./ha and a broadcast application to tobacco at 1 × 5500 g a.s./ha) were assumed. Using these assumptions, the concentration of test substance in soil immediately after a single application was calculated as follows:

$$PEC_{s,ini,1} = \frac{(A_1 - (A_1 * p_1))*10}{d*bd}$$

[Equation 1]

Where: $PEC_{s,ini,1}$ = Predicted initial environmental concentration in soil after first appl. (mg/kg)
A_1 = Application rate (g/ha)
P_1 = Plant interception (fraction)
d = Depth of soil layer (cm)
bd = Bulk density (g/cm^3)

The concentration of test substance in soil immediately after the nth application is calculated as shown in Equation 2. Initial PEC_s values are calculated after each application and the maximum of these values is used in the soil risk assessment.

$$PEC_{s,ini,n} = PEC_{s,ini,n-1} * e^{-k*(t_n - t_{n-1})} + \frac{(A_n - (A_n * p_n))*10}{d*bd}$$

[Equation 2]

Where: $PEC_{s,ini,n}$ = Predicted initial environmental concentration in soil after n^{th} application (mg/kg)
$PEC_{s,ini,n-1}$ = Predicted initial environmental concentration in soil after $n^{th\ -1}$ appl. (mg/kg)
A_n = n^{th} Application rate (g/ha)
p_n = n^{th} Plant interception (fraction)
d = Depth of soil layer (cm)
bd = Bulk density (g/cm^3)
k = Degradation rate (1/d)
t_n = Day of n^{th} application
t_{n-1} = Day of $n^{th\ -1}$ application

The actual concentration at a Day t is simulated as given in Equation 3:

$$PEC_{s,actual,t} = PEC_{s,ini} * e^{-k*t}$$

[Equation 3]

Where: $PEC_{s,act,t}$ = Actual predicted environmental concentration at time t after $PEC_{s,ini}$ (mg/kg)
$PEC_{s,ini}$ = Initial predicted environmental concentration in soil (mg/kg)
k = Degradation rate (1/d)
t = Time after $PEC_{s,\ ini}$

Finally, the maximum time-weighted average concentration is calculated, giving the average in a certain time period (Equation 4).

$$TWA_x = \frac{(PEC_{s,act,t-x} + ... + PEC_{act,t})}{x}$$

[Equation 4]

Where: TWA_x = Time-weighted average over x days (mg/kg)
x = Time period of TWA calculation (days)
t = Day of observed time period
$PEC_{s,act}$ = Actual predicted environmental concentration at described time (mg/kg)

Furthermore, refined PEC_s calculations were conducted for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios (EFSA, 2012a[8], 2012b[9]). The geometric mean modelling $DegT_{50}$ was employed in simulations for the parent substance. The refined calculations were performed for the open field uses of oxamyl, *i.e.* for the repeated annual applications on potatoes and tobacco. Potatoes were modelled using the CTC EFSA scenario (central zone) and crop parametrisation for potato in Kremsmünster. Tobacco was modelled using the EFSA CTS scenario (southern zone) and the FOCUS crop parametrisation for tobacco in Piacenza.

FOCUS PEARL 4.4.4 was parameterised as follows. For in-furrow and broadcast applications, a uniform distribution in the 10 cm (potatoes) or 5 cm (tobacco) of topsoil was assumed in modelling. A 10 cm incorporation depth for an in-furrow application on tobacco (1 × 5500 g a.s./ha) was considered. The application dates used were 1-May for application to potatoes (representing planting date in Hamburg and Kremsmünster scenarios) and 20-May for both applications to tobacco (representing a transplanting date in Piacenza scenario).

8 EFSA (2012a). Tier-1 and Tier-2A Scenario Parameterisation and Example Calculations. EFSA Journal 10(1):2433 [64 pp.]. doi:10.2903/j.efsa.2012.2433. Available at http://www.efsa.europa.eu/en/efsajournal/pub/2433.htm

9 EFSA (2012b). Scientific Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations in soil. EFSA Journal 10(2):2562. doi:10.2903/j.efsa.2012.2562. Available at: http://www.efsa.europa.eu/en/efsajournal/pub/2562.htm

Concentrations in total soil (adsorbed plus that dissolved in the soil water) were evaluated for the top 20 cm of soil for various time windows.

Initial PEC_s value

Active substance

Table 26 Summary of PEC_{soil} values of oxamyl following application to potatoes (1 × 1000 g a.s./ha)

Time		Oxamyl	
		Soil depth: 10 cm	
		Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)
Initial	0 h	0.667	-
Short-term	24 h	0.626	0.646
	2 d	0.588	0.627
	4 d	0.519	0.590
Long-term	7 d	0.431	0.540
	14 d	0.278	0.444
	21 d	0.180	0.371
	28d	0.116	0.315
	50 d	0.029	0.204
	100 d	0.001	0.107

Table 27 Summary of PEC_{soil} values of oxamyl following application to tobacco (1 × 3000 g a.s./ha)

Time		Oxamyl	
		Soil depth: 5 cm	
		Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)
Initial	0 h	4.000	-
Short-term	24 h	3.758	3.878
	2 d	3.530	3.760
	4 d	3.116	3.540
Long-term	7 d	2.584	3.240
	14 d	1.669	2.667
	21 d	1.078	2.228
	28d	0.696	1.890
	50 d	0.176	1.225
	100 d	0.008	0.639

Table 28 Summary of PEC_{soil} values of oxamyl in soil following application to tobacco (1 × 5500 g a.s./ha)

Time		Oxamyl Soil depth: 10 cm Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)
Initial	0 h	3.667	-
Short-term	24 h	3.445	3.555
	2 d	3.236	3.447
	4 d	2.856	3.245
Long-term	7 d	2.368	2.970
	14 d	1.530	2.444
	21 d	0.988	2.043
	28d	0.638	1.732
	50 d	0.162	1.123
	100 d	0.007	0.586

Table 29 Actual and time-weighted average (TWA) concentrations of oxamyl in soil following application to potato (1 × 1000 g a.s./ha) in Europe (EFSA CTC Scenario)

Time		Oxamyl Soil evaluation depth: 20 cm PEC_s actual (mg/kg)	PEC_s TWA (mg/kg)
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

Table 30 Actual and time-weighted average (TWA) concentrations of oxamyl in soil following application to tobacco (1 × 3000 g a.s./ha) in Europe (EFSA CTS Scenario)

Time		Oxamyl Soil evaluation depth: 20 cm PEC_s actual (mg/kg)	PEC_s TWA (mg/kg)
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

Table 31 Actual and time-weighted average (TWA) concentrations of oxamyl in soil following application to tobacco (1 × 5500 g a.s./ha) in Europe (EFSA CTS Scenario)

Time		Oxamyl	
		Soil evaluation depth: 20 cm	
		PEC_s actual (mg/kg)	PEC_s TWA (mg/kg)
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

Metabolites

Table 32 Summary of PEC_{soil} values of IN-A2213, IN-D2708, and IN-N0079 following application to potato (1 × 1000 g a.s./ha)

Time		IN-A2213		IN-D2708		IN-N0079	
		Soil depth: 10 cm		Soil depth: 10 cm		Soil depth: 10 cm	
		Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)	Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)	Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)
Initial	0 h	0.256	-	0.280	-	0.030	-
Short-term	24 h	0.228	0.242	0.265	0.273	0.015	0.022
	2 d	0.202	0.228	0.251	0.265	0.008	0.016
	4 d	0.159	0.204	0.225	0.252	0.002	0.010
Long-term	7 d	0.111	0.174	0.191	0.233	<0.001	0.006
	14 d	0.048	0.124	0.130	0.196	<0.001	0.003
	21 d	0.021	0.094	0.089	0.167	<0.001	0.002
	28d	0.009	0.074	0.061	0.144	<0.001	0.002
	50 d	0.001	0.043	0.018	0.096	<0.001	0.001
	100 d	<0.001	0.021	0.001	0.051	<0.001	<0.001

Table 33 Summary of PEC_{soil} values of IN-A2213, IN-D2708, and IN-N0079 following application to tobacco (1 × 3000 g a.s./ha)

		IN-A2213		IN-D2708		IN-N0079	
		Soil depth: 5 cm		Soil depth: 5 cm		Soil depth: 5 cm	
Time		Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)	Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)	Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)
Initial	0 h	1.538	-	1.681	-	0.183	-
Short-term	24 h	1.365	1.450	1.592	1.636	0.091	0.132
	2 d	1.211	1.368	1.507	1.592	0.046	0.099
	4 d	0.954	1.223	1.351	1.510	0.011	0.062
Long-term	7 d	0.666	1.042	1.147	1.397	0.001	0.037
	14 d	0.289	0.747	0.783	1.175	<0.001	0.019
	21 d	0.125	0.563	0.534	1.000	<0.001	0.013
	28d	0.054	0.444	0.365	0.861	<0.001	0.009
	50 d	0.004	0.257	0.110	0.576	<0.001	0.005
	100 d	<0.001	0.129	0.007	0.307	<0.001	0.003

Table 34 Summary of PEC_{soil} values of IN-A2213, IN-D2708, and IN-N0079 following application to tobacco (1 × 5500 g a.s./ha)

		IN-A2213		IN-D2708		IN-N0079	
		Soil depth: 10 cm		Soil depth: 10 cm		Soil depth: 10 cm	
Time		Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)	Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)	Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)
Initial	0 h	1.410	-	1.541	-	0.167	-
Short-term	24 h	1.251	1.329	1.459	1.500	0.084	0.121
	2 d	1.110	1.254	1.382	1.460	0.042	0.091
	4 d	0.874	1.121	1.239	1.384	0.010	0.057
Long-term	7 d	0.611	0.955	1.052	1.281	0.001	0.034
	14 d	0.265	0.685	0.718	1.077	<0.001	0.017
	21 d	0.115	0.516	0.490	0.917	<0.001	0.011
	28d	0.050	0.407	0.334	0.790	<0.001	0.009
	50 d	0.004	0.235	0.101	0.528	<0.001	0.005
	100 d	<0.001	0.118	0.007	0.281	<0.001	0.002

Short-term PEC_s values – 24 hours, 2 and 4 days after last application

Active substance

See Table 26 to Table 31 for values.

Metabolites

See Table 32 to Table 34 for values.

Long-term PEC_s values – 7, 28, 50, and 100 days after last application

Active substance

See Table 26 to Table 31 for values.

Metabolites

See Table 32 to Table 34 for values.

RMS comments and conclusion

PECsoil of oxamyl and its major soil metabolites (IN-A2213, IN-D2798, and IN-N0079) were calculated on the basis of the recommendations of FOCUS Soil guidance document, assuming the longest DT_{50} value from labratory studies ($DegT_{50}$ non-normalised). Results presented above are accepted.
The maximum initial PECs value for oxamyl was calculated to be 0.667 mg/kg for application to potatoes, 4.000 mg/kg and 3.667 mg/kg for application to tobacco at 1 × 3000 g a.s./ha and 1 × 5500 g a.s./ha respectively, 2.839 mg/kg for application to tomatoes, and 7.333 mg/kg for application in combination with solarisation. The overall maximum initial PECs values for IN-A2213, IN-D2708 and IN-N0079 were calculated to be 2.820, 3.082 and 0.335 mg/kg, all calculated for the solarisation use.
Using the refined calculation approach with FOCUS PEARL 4.4.4 and Tier-2a EFSA scenarios, the maximum PECs value for oxamyl was calculated to be 0.469 mg/kg for application to potatoes, 1.199 mg/kg and 2.202 mg/kg for application to tobacco at 1 × 3000 g a.s./ha and 1 × 5500 g a.s./ha respectively.

B.8.3 Predicted environmental concentrations in ground water (PEC_{GW})

Study submitted to the EU for the first time in this submission.

B.8.3/01

Reference: CP 9.2.4/01	**Report**	Anyusheva, M., Zillgens, B. (2015); Predicted environmental concentrations of oxamyl and its metabolites in groundwater following applications to various crops - a modelling assessment for Europe using the FOCUS groundwater scenarios **DuPont Report No.:** DuPont-40858 EU **Guidelines:** Not applicable **Deviations:** None **Testing Facility:** Dr. Knoell Consult GmbH, Mannheim, Germany **Testing Facility Report No.:** DuPont-40858 EU **GLP:** No **Certifying Authority:** Not applicable

The predicted groundwater concentrations (PECgw) of oxamyl and its soil metabolites IN-A2213, IN-D2708, and IN-N0079 were determined following recommendations of the FOCUS workgroup (FOCUS, 2000[10], 2009[11], European Commission, 2014[12]). The most current versions of FOCUS models, FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3, were used to generate PECgw values in order to assess potentially safe European use regions in the context of Annex I positive listing consideration. Each scenario involves a fixed combination of crop, soil, and climatic parameters to represent the range of conditions across Europe. The application framework for oxamyl included in-furrow application to potatoes at 1 × 1000 g a.s./ha, in-furrow application to tobacco at 1 × 3000 g a.s./ha, and broadcast application to tobacco at 1 × 5500 g a.s./ha.

Key input parameters for oxamyl and metabolites are summarised in Table 35.

The PEC_{gw} calculations for oxamyl and degradation products were based on the geometric mean $DegT_{50}$ values determined from the laboratory degradation studies. The $DegT_{50}$ values from the laboratory studies were normalised for a temperature of 20°C and moisture content of pF = 2 before calculating the geometric mean value, according to the FOCUS guidance. Geometric mean organic carbon normalised sorption coefficients were taken forward where possible. The simulations were performed for two separate pathways. Pathway A represented main degradation pathway of oxamyl in aerobic soils resulting in formation of IN-A2213 and

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

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

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

IN–D2708. Pathway B represented a minor degradation pathway resulting in formation of IN-N0079 and IN–D2708. Using the FOCUS methodology, the 80th percentile PEC_{gw} values of oxamyl and its soil degradation products were generated assuming repeated annual applications of the active substance. For potatoes, applications every other year and every three years were assumed for the Porto and Sevilla scenarios.

Potential annual average concentrations of active substance (PEC_{gw}) and relevant degradation products in soil pore water at a depth of one meter were calculated. The predicted concentration is a conservative estimate of what may actually be expected in groundwater used for drinking water as soil pore water at 1 m depth is not a likely source of drinking water.

Simulated application regime is presented in Table 36 and Table 37.

Table 35 Key input parameters used in simulation of PEC_{gw} for oxamyl and its soil metabolites

Parameter	Value	Units	Reference
Molecular weight Oxamyl IN-A2213 IN-D2708 IN-N0079	 219.3 162.2 117.1 98.1	 g/mol	 Oxamyl EU Renewal Dossier, Document N, Part 3, DuPont-40940 EU
Water Solubility (20°C, pH 5) Oxamyl and all metabolites	 148100	 mg/L	 Oxamyl EU Renewal Dossier, Document M-CA, Section 2, DuPont-40929 EU
Vapour Pressure (20°C) Oxamyl and all metabolites	 1.8×10^{-5}	 Pa	 Oxamyl EU Renewal Dossier, Document M-CA, Section 2, DuPont-40929 EU
Laboratory soil $DegT_{50}$ (normalised) Oxamyl IN-A2213 IN-D2708 IN-N0079	 5.3[a] 1.7[a] 5.7[a] 1.0[c]	 days	 DuPont-40858 EU, which is summarised in this document
Freundlich Organic Carbon/Matter Sorption Coefficients (K_{FOC}/K_{FOM}) Oxamyl[a] IN-A2213[a] IN-D2708[a] IN-N0079[a]	 11.12/ 6.40 6.37/ 3.69 9.13/ 5.31 5.18/ 3.00	 -	 DuPont-40858 EU, which is summarised in this document; Calculated based on data presented in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU
Freundlich sorption exponent (1/n) Oxamyl[b] IN-A2213[b] IN-D2708[b] IN-N0079[c]	 0.92 1.03 0.67 0.90	 -	 DuPont-40858 EU, which is summarised in this document; Calculated based on data presented in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU
Formation fractions (laboratory studies) oxamyl → IN-A2213 oxamyl → IN-N0079 IN-A2213 → IN-D2708 IN-N0079 → IN-D2708	 1.0 0.35 1.0 1.0	 -	 DuPont-40858 EU, which is summarised in this document
Plant uptake			

Oxamyl all metabolites	0.5 0.0	-	
Q10 Oxamyl and all metabolites	2.58	-	

a Geometric mean values.
b Arithmetic mean values.
c Conservative worst case.

Table 36 Simulated application regime of oxamyl used in the modelling study

Crop/Use	FOCUS crop	Application rate (g a.s./ha)	Interval (days)	Inter-ception (%)	Soil deposit (g a.s./ha)	Appl. depth[a] (cm)	Recommended application time[a]
Potatoes	Potatoes	1000	-	0	1000	10	At planting
Tobacco	Tobacco	3000	-	0	3000	5	Pre-planting
Tobacco	Tobacco	5500	-	0	5500	10	At planting

a For in-furrow application to potatoes (1000 g a.s./ha) and tobacco (5500 kg a.s./ha, broadcast with incorporation), "incorporation into 10 cm soil depth" was assumed. For application to tobacco (3000 g a.s./ha, in-furrow), a 5 cm incorporation depth was taken forward in modelling.

Table 37 Application dates of oxamyl used in the modelling study

FOCUS scenario	1st application
Potatoes 1 × 1000 g a.s./ha	
Châteaudun	15-Apr
Hamburg	01-May
Jokioinen	15-May
Kremsmünster	01-May
Okehampton	15-Apr
Piacenza	01-Apr
Porto	28-Feb
Sevilla	15-Jan
Thiva	15-Feb
Tobacco 1 × 3000 and 1 × 5500 g a.s./ha	
Piacenza	20-May
Thiva	01-May

Calculation of concentrations in groundwater

Active substance and metabolites

On the basis of simulations carried out with the realistic worst-case scenarios represented in FOCUS GW (FOCUS, 2000 and European Commission, 2014) the predicted concentration of oxamyl in soil pore water at one-meter depth was less than 0.1 µg/L for applications every year beside the FOCUS Porto and Sevilla scenario passing with applications every other year or every three years. Results obtained by FOCUS PEARL and FOCUS PELMO are summarised in Table 38 to Table 40.

Table 38 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following applications to potatoes at 1 × 1000 g a.s./ha

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708[a]	IN-N0079
FOCUS PEARL 4.4.4				
Annual applications				
Châteaudun	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
Kremsmünster	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	0.105	0.077	0.018	0.002
Sevilla	0.023	0.018	0.011	0.001
Thiva	<0.001	<0.001	<0.001	<0.001
Applications every other year				
Porto	0.046	0.035	0.008	<0.001
FOCUS PELMO 5.5.3				
Annual applications				
Châteaudun	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
Kremsmünster	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	0.250	0.226	0.033	0.012
Sevilla	0.164	0.158	0.034	0.008
Thiva	0.002	0.002	<0.001	<0.001
Applications every other year				
Porto	0.115	0.104	0.015	0.006
Sevilla	0.057	0.056	0.010	0.003
Applications every three years				
Porto	0.074	0.067	0.011	0.004

[a] Values as calculated in pathway A are presented, as maximum of both pathways.

Table 39 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following applications to tobacco at 1 × 3000 g a.s./ha

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

[a] Values as calculated in pathway A are presented, as maximum of both pathways.

Table 40 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following applications to tobacco at 1 × 5500 g a.s./ha

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

a Values as calculated in pathway A are presented, as maximum of both pathways.

The predicted concentrations of oxamyl (DPX-D1410) in groundwater were estimated using FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3. Simulations were based on proposed usage regimes in the open field uses on potatoes and tobacco.

The simulation runs resulted in concentrations below 0.1 µg/L for oxamyl when using parameterisation drawn upon the laboratory degradation studies and applications either every year, every other year, and/or every three years. Predicted concentrations for the metabolite IN-A2213 exceeded the threshold value of 0.1 µg/L in some of the scenarios, whereas PEC_{gw} for IN-D2708 and IN-N0079 were always lower than 0.1 µg/L.

Additional PEC_{gw} calculations for scenario Châteaudun:

In addition to the PEC_{gw} simulations presented in DuPont-40858 EU and summarised above, the potential of oxamyl and its metabolites to reach groundwater by macropore/preferential flow was simulated for the standard FOCUS scenario Châteaudun as implemented in the leaching model FOCUS MACRO 5.5.4 According to FOCUS groundwater guidance (FOCUS, 2014[13]) simulations are required for each crop that is defined for the Châteaudun scenario. Consequently, simulations were conducted for the in-furrow application of oxamyl to potatoes at a rate of 1 × 1000 g a.s./ha.

Input parameters were identical to the simulations with FOCUS PEARL and PELMO (Table 35). The Walker Exponent for moisture response was set to 0.49 within the MACRO tool. As a worst case assumption, formation fractions of the metabolites were not corrected for molar mass differences of metabolites and parent and all metabolites (IN-A2213, IN-D2708, and IN-N0079) were assumed to directly form from degradation of the parent. Application was assumed to take place at 15-April to be in line with FOCUS PEARL and PELMO simulations (Table 37).

Results of the FOCUS MACRO 5.5.4 simulations are summarised in Table 41. The calculated 80th percentile PEC_{gw} values (at 1 m soil depth) for oxamyl (DPX-D1410) and its soil metabolites IN-A2213, IN-D2708, and IN-N0079, were below the regulatory threshold value of 0.1 µg/L for the intended application to potatoes.

Table 41 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following annual applications to potatoes at 1 × 1000 g a.s./ha

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708	IN-N0079
FOCUS MACRO 5.5.4				
Châteaudun	0.001	0.001	<0.001	<0.001

13 FOCUS (2014): Generic Guidance for Tier 1 FOCUS Ground Water Assessments, version 2.2. May 2014. 66 pp.

Additional field testing

As the results from the modelling clearly show, major European use regions exist where predicted 80th percentile PEC_{gw} values are <0.1 µg/L.

The results of groundwater monitoring in the UK support conclusions of the modelling exercise that oxamyl potential to pollute groundwater above 0.1 µg/L levels is very low. The monitoring was performed by the Environmental Agency in England and Wales in 2010 and 2011. The monitoring sites were relevant for potato growing areas and covered areas vulnerable to pesticide leaching in terms of soil and hydrological characteristics. In total, oxamyl was monitored in 2768 sites and in all cases, the detections were below the regulatory threshold of 0.1 µg/L.

Field monitoring results are described in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU.

RMS comments and conclusion
Predicted concentrations for oxamyl and its metabolite IN-A2213, based on proposed usage regimes in the open field used on potatoes and tobacco, exceeded the threshold value of 0.1 µg/L in some of the scenarios, in the annual application use, whereas PECgw for IN D2708 and IN N0079 were always lower than 0.1 µg/L However, based on the available results of groundwater monitoring in the UK support conclusions, oxamyl potential to pollute groundwater above 0.1 µg/L levels is very low.

B.8.4 Fate and behaviour in water and sediment

B.8.4.1 Aerobic mineralisation in surface water

See DuPont-40441, summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU.

B.8.4.2 Water/sediment study

Study submitted to the EU for the first time in this submission.

B.8.4.2/01

Reference: CP 9.2.2/01	**Report:**	Ghafoor, A., Zillgens, B. (2015); Estimation of kinetic endpoints of oxamyl and its metabolites oxamyl oxime (IN-A2213), DMOA (IN-D2708), DMCF (IN-N0079) and IN-T2921 in water/sediment systems - kinetic calculations following FOCUS kinetics guidelines **DuPont Report No.:** DuPont-44046 EU **Guidelines:** Not applicable **Deviations:** None **Testing Facility:** Dr. Knoell Consult GmbH, Mannheim, Germany **Testing Facility Report No.:** DuPont-44046 EU **GLP:** No **Certifying Authority:** Not applicable

One aquatic degradation study has been conducted to investigate the rate of degradation of oxamyl and its metabolites in two water/sediment systems (AMR 3143-94; cited in the Oxamyl EU Renewal Dossier, Document M–CA, Section 7, DuPont-40934 EU). Since the study does not contain a kinetic evaluation according to recent FOCUS recommendations (FOCUS, 2006, 2011), residue data of this study were re-evaluated to derive persistence and modelling endpoints for oxamyl and its metabolites IN-A2213, IN–D2708, IN-N0079, and IN-T2921 under aerobic conditions in water/sediment systems.

The kinetic evaluation of the water/sediment study was carried out using the one-compartmental approach (level I) as described in FOCUS guidance documents. For oxamyl, level I consisted of the derivation of a total-system degradation half-life and dissipation half-lives for sediment and the water phase. For metabolites, level I analysis consisted of the derivation of a degradation half-life for the total-system and dissipation half-lives for total system, sediment, and water phase. The sediment level I analysis for oxamyl and the level I dissipation analyses for metabolites were conducted based upon the decline from the maximum occurrence.

The results of the evaluation referring to either the active substance or one of its aerobic metabolites are summarised below rather than being split into different subsections. This was done for the sake of clarity and easier reading. The persistence and modelling endpoints, derived from a laboratory water/sediment study and chosen according to FOCUS (2006, 2011) guidelines, are summarised in Table 42 through Table 49.

Table 42 Summary of water/sediment study persistence endpoints for oxamyl

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

Table 43 Summary of water/sediment study persistence endpoints for IN-A2213

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

Table 44 Summary of water/sediment study persistence endpoints for IN-D2708

System	Water/sediment system	Values in days	Best fit model	Type of endpoint and comments
Red Oak Stream	System	DT_{50} = - DT_{90} = -	-	M-I, No Decline, Default DT_{50}
	Water	DT_{50} = - DT_{90} = -	-	M-I, No Decline, Default DT_{50}
	Sediment	DT_{50} = - DT_{90} = -	-	M-I, No Decline, Default DT_{50}
Town Park Pond	System	$DegT_{50}$ = 185.73 $DegT_{90}$ = 617.0	SFO-SFO	M-I, System degradation endpoint
	Water	$DegT_{50}$ = 185.73 $DegT_{90}$ = 617.0	SFO-SFO	M-I, System degradation endpoint
	Sediment	$DegT_{50}$ = 185.73 $DegT_{90}$ = 617.0	SFO-SFO	M-I, System degradation endpoint

Table 45 Summary of water/sediment study persistence endpoints for IN-N0079

System	Water/sediment system	Values in days	Best fit model	Type of endpoint and comments
Red Oak Stream	System	DT_{50} = 4.69 DT_{90} = 15.58	SFO	System decline endpoint
	Water	DT_{50} = 4.26 DT_{90} = 14.15	SFO	Water decline endpoint
	Sediment	DT_{50} = 17.79 DT_{90} = 59.08	SFO	Sediment decline endpoint
Town Park Pond	System	$DegT_{50}$ = 8.53 $DegT_{90}$ = 28.34	SFO-SFO	System degradation endpoint
	Water	DT_{50} = 8.07 DT_{90} = 26.82	SFO	Water decline endpoint
	Sediment	DT_{50} = 11.38 DT_{90} = 37.81	SFO	Sediment decline endpoint

Table 46 Summary of water/sediment study persistence endpoints for IN-T2921

System	Water/sediment system	Values in days	Best fit model	Type of endpoint and comments
Red Oak Stream	System	DT_{50} = 27.31 DT_{90} = 90.71	HS-SFO	M-I, system degradation
	Water	DT_{50} = - DT_{90} = -	-	M-I, No Decline, Default DT_{50}
	Sediment	DT_{50} = - DT_{90} = -	-	M-I, No Decline, Default DT_{50}
Town Park Pond	System	$DegT_{50}$ = - $DegT_{90}$ = -	-	M-I, No Decline, Default DT_{50}
	Water	DT_{50} = - DT_{90} = -	-	M-I, No Decline, Default DT_{50}
	Sediment	DT_{50} = - DT_{90} = -	-	M-I, No Decline, Default DT_{50}

Table 47 Summary of water/sediment study modeling endpoints for oxamyl

System	FOCUS Step	Values in days	Kinetic level and type
Red Oak Stream	Step 1	$DegT_{50}$ = 2.50	P-I Total System; HS $DegT_{90}$/3.32
	Step 2	$DegT_{50}$ = 2.50	P-I Total System; HS $DegT_{90}$/3.32
	Step 3	Water: $DegT_{50}$ = 2.50 Sediment: DT_{50} = 1000	P-I Total System; HS $DegT_{90}$/3.32 Default assumption
Town Park Pond	Step 1	$DegT_{50}$ = 0.69	P-I Total System; SFO
	Step 2	$DegT_{50}$ = 0.69	P-I Total System; SFO
	Step 3	Water: 0.69 Sediment: 1000	P-I Total System; SFO Default assumption

Table 48 Summary of water/sediment study modeling endpoints for IN-A2213

System	FOCUS Step	Values in days	Kinetic level and type
Red Oak Stream	Step 1	DT_{50} = 13.95	M-I System decline, SFO
	Step 2	DT_{50} = 13.95	M-I System decline, SFO
	Step 3	Water: $DegT_{50}$ = 8.24 Sediment: DT_{50} = 1000	M-I System degradation, HS-SFO Default assumption
Town Park Pond	Step 1	DT_{50} = 6.65	M-I System decline, SFO
	Step 2	DT_{50} = 6.65	M-I System decline, SFO
	Step 3	Water: $DegT_{50}$ = 5.67 Sediment: DT_{50} = 1000	M-I System degradation, SFO-SFO Default assumption

Table 49 Summary of water/sediment study modeling endpoints for IN-D2708

System	FOCUS Step	Values in days	Kinetic level and type
Red Oak Stream	Step 1	DT_{50} = 1000	M-I, No Decline observed, Default DT_{50}
	Step 2	DT_{50} = 1000	M-I, No Decline, Default DT_{50}
	Step 3	Water: DT_{50} = 1000 Sediment: DT_{50} = 1000	No Decline observed Default assumption
Town Park Pond	Step 1	DT_{50} = 1000	M-I, No Decline, Default DT_{50}
	Step 2	DT_{50} = 1000	M-I, No Decline, Default DT_{50}
	Step 3	Water: $DegT_{50}$ = 185.73 Sediment: DT_{50} = 1000	M-I System degradation, SFO-SFO Sediment: Default assumption

Table 50 Summary of water/sediment study modeling endpoints for IN-N0079

System	FOCUS Step	Values in days	Kinetic level and type
Red Oak Stream	Step 1	DT_{50} = 4.69	M-I System decline, SFO
	Step 2	DT_{50} = 4.69	M-I System decline, SFO
	Step 3	Water: $DegT_{50}$ = 1000 Sediment: DT_{50} = 1000	M-I System degradation not reliable, use default DT_{50} SFO-SFO Default assumption
Town Park Pond	Step 1	DT_{50} = 8.80	M-I System decline, SFO
	Step 2	DT_{50} = 8.80	M-I System decline, SFO
	Step 3	Water: $DegT_{50}$ = 8.53 Sediment: DT_{50} = 1000	M-I System degradation, SFO-SFO Default assumption

Table 51 Summary of water/sediment study modeling endpoints for IN-T2921

System	FOCUS Step	Values in days	Kinetic level and type
Red Oak Stream	Step 1	DT_{50} = 1000	M-I, No decline observed, Default DT_{50}
	Step 2	DT_{50} = 1000	M-I, No Decline, Default DT_{50}
	Step 3	Water: $DegT_{50}$ = 27.31 Sediment: DT_{50} = 1000	M-I System degradation; HS-SFO Default assumption
Town Park Pond	Step 1	DT_{50} = 1000	M-I, No decline observed, Default DT_{50}
	Step 2	DT_{50} = 1000	M-I, No Decline, Default DT_{50}
	Step 3	Water: DT_{50} = 1000 Sediment: DT_{50} = 1000	M-I, No Decline, Default DT_{50} Default assumption

RMS comments and conclusion

This study is considered corrected to harmonize the derivation of degradation parameters from water.
Residue data of aerobic degradation in one water-sediment study for oxamyl under laboratory conditions with a total of two sediment test systems, (DuPont-AMR 3143-94) were re-evaluated to derive persistence and modelling endpoints for oxamyl and its metabolites
The kinetic assessments conducted are in full compliance with the FOCUS kinetics guidance and the imput parameters can be used for surface water risk assessment.

B.8.4.3 Irradiated water/sediment study

An irradiated water/sediment study was not run with oxamyl. This higher tier study was not required and would not provide additional information above what has been demonstrated in the aqueous photolysis study and the water/sediment study.

B.8.5 Predicted environmental concentrations in surface water and sediment (PEC_{SW}, PEC_{SD})

Study submitted to the EU for the first time in this submission.

B.8.5/01

Reference: CP 9.2.5/01	**Report**	Anyusheva, M., Zillgens, B. (2015); Predicted evniromental concentrations of oxamyl and its metabolites in surface water following applications to various crops -- a modelling assessment for Europe using the FOCUS surface water scenarios **DuPont Report No.:** DuPont-40859 EU **Guidelines:** Not applicable **Deviations:** None **Testing Facility:** Dr. Knoell Consult GmbH, Mannheim, Germany **Testing Facility Report No.:** DuPont-40859 EU **GLP:** No **Certifying Authority:** Not applicable

Predicted surface water (PEC_{sw}) and sediment (PEC_{sed}) concentrations of oxamyl and relevant soil and aquatic metabolites IN-A2213, IN-D2708, IN-N0079, and IN-T2921 were generated in a stepwise approach to simulate applications of oxamyl to potatoes and tobacco. Step 1 and 2 calculations were performed for oxamyl and its metabolites, while Step 3 and 4 calculations were performed for the parent substance oxamyl alone. All simulations at Steps 1-4 were conducted with the tools Steps 1-2 in FOCUS 2.1, FOCUS SWASH 3.1, FOCUS MACRO 4.4.2, FOCUS PRZM 3.1.1, FOCUS TOXSWA 3.3.1, and SWAN 3.0.0 and recommendations of EFSA and the FOCUS surface water workgroup.

The application of Vydate 10GR was assumed to be made into the soil using tractor-mounted, ground-directed broadcast or in-furrow equipment. The application framework included in-furrow application to potatoes at 1 × 1000 g a.s./ha, in-furrow application to tobacco at 1 × 3000 g a.s./ha, and broadcast application to tobacco at 1 × 5500 g a.s./ha (Table 52).

Table 52 Overview of the simulated application regime of oxamyl

Crop/Use	FOCUS crop/ technique	Application rate (g a.s./ha)	Interval (days)	Inter-ception (%)	Soil deposit (g a.s./ha)	Recommended application time
Potatoes	Potatoes	1000	-	0	1000	At planting
Tobacco	Tobacco	3000	-	0	3000	Pre-planting
Tobacco	Tobacco	5500	-	0	5500	At planting

Substance parameters

For all substances, geometric mean $DegT_{50}$ values derived from laboratory aerobic degradation studies and geometric means of organic carbon normalised sorption coefficients were taken forward where possible. For metabolite IN-N0079, a conservative $DegT_{50}$ in soil of 1 day was used in modelling as the actual half-lives derived from aerobic soil degradation studies were less than 1 day. Since oxamyl is a root systemic compound, a plant uptake factor of 0.5 was employed. Key substance input parameters for oxamyl and its metabolites are summarised in Table 53.

Table 53 Key input parameters used in simulation of PEC_{sw} and PEC_{sed} for oxamyl and its soil and aquatic metabolites

Parameter	Value	Units	Reference
Molecular weight Oxamyl IN-A2213 IN-D2708 IN-N0079	 219.3 162.2 117.1 98.1	 g/mol	 Oxamyl EU Renewal Dossier, Document N, Part 3, DuPont–40940 EU
Water solubility (20°C, pH 5) Oxamyl	 148100	 mg/L	 Oxamyl EU Renewal Dossier, Document M-CA, Section 2, DuPont-40929 EU
Vapour pressure (20°C) Oxamyl	 1.8×10^{-5}	 Pa	 Oxamyl EU Renewal Dossier, Document M-CA, Section 2, DuPont-40929 EU
Laboratory soil $DegT_{50}$ Oxamyl IN-A2213 IN-D2708 IN-N0079	 5.3[a] 1.7[a] 5.7[a] 1.0[c]	 days	 DuPont-40859 EU, which are summarised in this document
Freundlich organic carbon sorption coefficients (K_{FOC}) Oxamyl IN-A2213 IN-D2708 IN-N0079	 11.12[a] 6.37[a] 9.13[a] 5.18[a]	 -	 Calculated based on data presented in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU
Freundlich sorption exponent (1/n) Oxamyl	 0.92[b]	 -	 Calculated based on data presented in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU
Water/sediment half-life (total system) Oxamyl IN-A2213 IN-D2708 IN-N0079 IN-T2921	 2.5 9.6 1000 6.4 1000	 days	 DuPont-40859 EU, which is summarised in this document
Water half-life (total system) Oxamyl IN-A2213 IN-D2708 IN-N0079 IN-T2921	 2.5 9.6 1000 6.4 1000	 days	 DuPont-40859 EU, which is summarised in this document
Sediment half-life (total system) Oxamyl IN-A2213 IN-D2708 IN-N0079 IN-T2921	 2.5/1000[d] 9.6 1000 6.4 1000	 days	 DuPont-40859 EU, which is summarised in this document

Table 53 Key input parameters used in simulation of PECsw and PECsed for oxamyl and its soil and aquatic metabolites (continued)

Parameter	Value	Units	Reference
Maximum occurrence in soil Oxamyl IN-A2213 IN-D2708 IN-N0079	 100 52.0 78.7 10.2	 %	 Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU
Maximum occurrence in water-sediment system Oxamyl IN-A2213 IN-D2708 IN-N0079 IN-T2921	 100 63.2 77.2 54.2 11.4[e]	 %	 Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU
Plant uptake Oxamyl	 0.5	 -	 default
Q_{10} Oxamyl and all metabolites	 2.58	 -	 default
Wash-off: Oxamyl MACRO PRZM	 0.05 0.50	 1/mm 1/cm	 default

a Geometric mean values.
b Arithmetic mean value.
c Conservative worst case.
d Values for Step 2/Step 3 calculations.
e Maximum occurrence in water was employed in calculations, since PEC values for IN-T2921 metabolite were calculated from those of oxamyl.

Modelling strategy

Steps 1 and 2

At Step 1, inputs of spray drift, run-off, erosion, and drainage are evaluated as a single loading, *i.e.* all entries into the water body occur at the same time. Therefore, Step 1 calculations represent the most conservative assessment and include a large margin of safety. At Step 2, calculations are refined as drift events, followed by a run-off, erosion, or drainage event occurring four days after the application. Further refinements are introduced by considering crop interception and by assigning variable quantities of pesticide loss for Southern and Northern Europe and different seasons.

Step 1 and 2 calculations were performed for oxamyl and its metabolites for the uses on potatoes and tobacco using drift percentages defined for spray applications and zero interception. The calculated PEC_{sw} and PEC_{sed} values could therefore be considered as worst case estimates. In all cases, a combination of Southern Europe and March-May was taken forward, as it is characterised by the most conservative parameterisation of run-off, drainage, and erosion losses into surface water for the application period early spring to early autumn (March–September). PEC_{sw} for the aquatic metabolite IN-T2921 were estimated based on the respective PEC_{sw} values for oxamyl.

Step 3

At Step 3, the transport and environmental fate of test substances are simulated by means of complex environmental fate models to more realistically represent natural and agronomic conditions. Step 3 scenarios represent the range of major agricultural areas across the European Union and are thus used for the assessment of surface water risk within the framework of pesticide registration in the EU. The scenarios do not mimic specific catchment areas, nor are they necessarily representative of agriculture at the location or country after which they are named.

At Step 3a, all proposed oxamyl uses were considered in simulations employing conservative parameterisation. Dust drift was considered based on the worst case estimates for spinning disks provided in EFSA (2004)[14]. Conservative values for "application method", CAM and DEPI parameters were also taken forward in modelling.

At Step 3b, drift entries into surface water were refined based on the evidence from an existing field study, DuPont–38691 EU. Simulations considering no drift were performed for the in-furrow applications to potatoes and tobacco.

At Step 3c, a CAM value of 5 (instead of 6) was employed to the Step 3b simulations for the oxamyl application to potato to reflect a more realistic distribution of the parent compound in soil. Only R scenarios were considered in these simulations.

Step 4

Vegetative filter strips and grassed rows in perennial crops have a high potential to reduce pesticide loads transported to surface water bodies *via* run-off water or eroding particles. FOCUS (2007a)[15] assumes that a 10 m vegetative filter strip (VFS) reduces the run-off volume and flux by 60% and the erosion volume and flux by 85%, and a 20 m buffer zone reduces the run-off volume and flux by 80% and the erosion volume and flux by 95%. The concentration in run-off water and eroding soil particles remains constant but run-off volumes and thus pesticide masses change. As a result, 60% filter efficiency of a 10 m VFS does not equate to a 60% reduction of the PEC_{sw} but to a smaller reduction.

At Step 4a, a vegetative filter strip of 10 m was introduced as run-off buffer to the potato R3 stream scenario, based on reduction efficiencies provided in FOCUS (2007a). The simulation was based on Step 3c results.

At Step 4b, no-spray zones (NSZ) were introduced to estimate oxamyl concentrations following application to tobacco at 1 × 5500 g a.s./ha. The simulations were based on Step 3a simulations, which considered dust drift into a FOCUS stream as defined in EFSA (2004). This dust drift percentage was defined for the distance from the edge of the filed to the edge of stream of 1.5 m. No dust drift percentage was reported for greater distances. In order to predict oxamyl concentrations in surface water at greater distances (*e.g.* 10, 20, and 25 m) the reduction of drift loadings with distance was assumed to be the same as that of spray application. The amount of spray usually corresponds to the percentage of fine droplets (<150 μm, FOCUS; 2007b)[16]. The smaller the droplet, the longer it stays airborne and has the possibility to travel further. A granular formulation considered in EFSA (2004) contains 4% (by weight) particles smaller than 250 μm and only 0.1% smaller than 150 μm (dust fraction). Percentage of the fine droplets in sprays is much higher (FOCUS, 2007b). Therefore, it was assumed that spray drift reduction factors with distance are conservative estimates for dust drift reduction. The reduction factors and mass loadings used in TOXSWA calculations are shown in Table 56. All estimated dust drift percentages were based on the dust drift of 1.24% defined for the FOCUS stream scenario and 1.5 m distance from the edge of the field to water (EFSA; 2004). This corresponds to 8.184 mg/m^2 dust drift load at 1.5 m distance (at an application rate of 5500 g a.s./ha and considering +20% drift from the upstream catchment). NSZ of 10, 20, and 25 m were simulated at Step 4b.

Based on the above discussions, detailed parameterisation of the application scenarios and application dates at FOCUS Steps 1-3 are provided in Table 54 toTable 57.

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14 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.

15 FOCUS (2007a): Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. EC Document Reference SANCO/10422/2005, v2.0, 169 pp.

16 FOCUS (2007b): Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 2. Detailed Technical Reviews. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. EC Document Reference SANCO/10422/2005, v2.0, 436 pp.

Table 54 Simulated application scenarios for oxamyl in Europe in FOCUS Steps 1-2

Target crop (zone)	FOCUS crop/ technique[a]	Application rate (g a.s./ha)	Drift (%)	Interception for Step 1-2	Application timing for Step 1-2
Potatoes (CEU) in-furrow	Potatoes	1 × 1000	2.759[b]	No	SEU: Mar - May[c]
Tobacco (SEU) in-furrow	Tobacco	1 × 3000	2.759[b]	No	SEU: Mar – May[d]
Tobacco (SEU) broadcast	Tobacco	1 × 5500	2.759[b]	No	SEU: Mar – May[d]

[a] FOCUS crops were chosen following FOCUS (2001, 2014).
[b] Oxamyl is applied as granulate to potatoes and tobacco. Therefore, as a worst case, dust drift percentage was considered to be equal to the spray drift
[c] Application timing for potatoes use is at planting, which ranges from April to June in CEU+NEU and from January to April in SEU. One combination, namely, SEU and March – May results in the highest run-off, drainage and erosion percentage (FOCUS, 2001[17], 2014b[18]).Hence represents the conservative worst case application timing at Steps 1-2 for this use.
[d] This combination was defined to be characterised by the highest run-off, drainage and erosion loadings in SEU.

Table 55 Simulated application scenarios for oxamyl in Europe in Step 3

Target crop	FOCUS crop	Application rate (g a.s./ha)	Application method in SWASH	CAM (-)	DEPI (-)	Drift (%)
Potatoes in-furrow	Potatoes	1 × 1000	Granular	6[d]/5[d]	10	Ditch 1.49[a], Pond 0.15[a], Stream 1.488[a] 0[b] for all
Tobacco in-furrow	Tobacco	1 × 3000	Granular	6	5	Ditch 1.49[a], Pond 0.15[a], Stream 1.488[a] 0[c] for all
Tobacco broadcast	Tobacco	1 × 5500	Granular	6	10	Ditch 1.49[a], Pond 0.15[a], Stream 1.488

[a] EFSA (2004) drift values for granular application with spinning disk, worst case values. For stream, a 20%-drift from the upstream catchment was accounted for. These drift values were used in Step 3a simulations.
[b] Based on the results of field measurements, dust drift during an in-furrow application on potatoes was zero. Drift percentages were used in Step 3b simulations.
[c] Value extrapolated (due to the same type of equipment) from the results of the field measurements for potato in-furrow planting.
[d] At Steps 3a and 3b CAM = 6 (linearly decreasing to DEPI) was employed. At Step 3c, CAM of 5 was deployed (linearly increasing to DEPI).

Table 56 The estimated dust drift percentages and mass loadings for different widths of no-spray zones for oxamyl application to tobacco (broadcast) at Step 4 simulations

Distance[a] (m)	FOCUS spray drift[b] (%)	Drift reduction factor with distance[c]	Estimated dust drift load[d] (mg/m^2)
1.5	1.4304	1	8.184
2	1.1413	1.25	6.530
10	0.2771	5.16	1.585
20	0.1440	9.93	0.824
25	0.1163	12.30	0.665

[a] Distance from the edge of the field to the edge of the FOCUS stream.

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17 FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 rev. 2, 245 pp.
18 FOCUS (2014b): Generic guidance for FOCUS surface water Scenarios, version 1.3.

[b] Areic mean value for FOCUS crop tobacco and FOCUS stream scenario with FOCUS drift calculator.
[c] Relative to 1.5 m distance.
[d] Dust drift loading (at x m) = Dust drift loading (at 1.5 m)/drift reduction factor (for x m).

Table 57 Application dates for oxamyl in the FOCUS Step 3 and Step 4 scenarios

Crop (use)	Location[a]	Application window	Julian days	Application dates found by PAT[b]
Potatoes (1 × 1000 g/ha)	D3	26-Apr - 26-May	116-146	4-May
	D4	8-May - 7-Jun	128-158	17-May
	D6	27-Mar - 26-Apr	86-116	2-Apr
	D6	22-Jul - 21-Aug	203-233	25-Jul
	R1	21-Apr - 21-May	111-141	26-Apr
	R2	1-Mar - 31-Mar	60-90	1-Mar
	R3	27-Mar - 26-Apr	86-116	28-Mar
Tobacco (1 × 3000 g/ha, 1 × 5500 g/ha)	R3	20-May - 19-Jun	140-170	1-Jun

[a] Scenarios are intended to represent agricultural regions of Europe, not specific locations.
[b] PAT is pesticide application timing calculator in MACRO and PRZM model. Selects application date as a function of proximity to rainfall events as defined in the FOCUS surface water report (FOCUS, 2001, 2014).

Results

Predicted concentrations of oxamyl in surface water (PEC_{sw}) and sediment (PEC_{sed}) after in-furrow application to potatoes at 1 × 1000 g a.s./ha, in-furrow application to tobacco at 1 × 3000 g a.s./ha, and broadcast application to tobacco at 1 × 5500 g a.s./ha are presented in Table 58 to Table 66 for all simulated steps.

Predicted concentrations of oxamyl metabolites in surface water (PEC_{sw}) and sediment (PEC_{sed}) are presented in Table 58 for Step 1-2 simulations.

Initial PEC_{sw} values for static and slow moving water bodies

Active substance and metabolites

Table 58 Summary of Step 1 and 2 calculations for oxamyl and its metabolites

Compound	Step 1		Step 2 Southern Europe Mar-May	
	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)	PEC_{sw} (µg/L)	PEC_{sed} (µg/kg)
	Potatoes 1 × 1000 g a.s./ha[b]			
Oxamyl	337.660	36.525	80.871	8.882
IN-A2213	131.421	8.098	13.156	0.779
IN-D2708	142.185	12.968	37.785	3.446
IN-N0079	17.335	0.805	2.230	0.084
IN-T2921[a]	20.379	-	4.881	-
	Tobacco 1 × 3000 g a.s./ha[b]			
Oxamyl	1010.000	109.575	242.614	26.645
IN-A2213	394.263	24.293	39.468	2.337
IN-D2708	426.555	38.905	113.356	10.338
IN-N0079	52.004	2.415	6.689	0.253
IN-T2921[a]	60.956	-	14.642	-
	Tobacco 1 × 5500 g a.s./**ha[b]**			
Oxamyl	1860.000	200.888	444.792	48.848
IN-A2213	722.816	44.537	72.358	4.285
IN-D2708	782.017	71.326	207.819	18.953
IN-N0079	95.341	4.428	12.264	0.464
IN-T2921[a]	112.256	-	26.845	-

[a] The results represent predicted concentrations of IN-T2921 after formation in the water body. 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.

[b] As a worst case, spray drift values were considered in calculations. They are expected to be higher than dust drift resulting from application of granules in the field.

Table 59 Summary of maximum Step 3a PEC_{sw} and PEC_{sed} values for oxamyl following application to potatoes at 1 × 1000 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	7 days TWA PEC_{sw} (µg/L)	14 days TWA PEC_{sw} (µg/L)	Maximum PEC_{sw} caused by	Maximum PEC_{sed} (µg/kg ds)
D3, ditch	4.895	0.645	0.323	Drift	0.404
D4, pond	0.151	0.113	0.101	Drift	0.068
D4, stream	4.390	0.637	0.612	Drift	0.293
D6, ditch	4.851	0.748	0.612	Drift	0.333
D6, ditch	4.944	1.544	0.798	Drift	0.544
R1, pond	0.150	0.106	0.080	Drift	0.035
R1, stream	3.623	0.221	0.160	Drift	0.287
R2, stream	4.797	0.308	0.184	Drift	0.309
R3, stream	48.786	3.069	1.648	Run-off	2.761

Application parameterisation: application mode “granular”, dust drift as defined in EFSA (2004) for spinning disks, CAM 6, and DEPI 10.

Table 60 Summary of maximum Step 3a PEC_{sw} and PEC_{sed} values for oxamyl following application to tobacco at 1 × 3000 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	7 days TWA PEC_{sw} (µg/L)	14 days TWA PEC_{sw} (µg/L)	Maximum PEC_{sw} caused by	Maximum PEC_{sed} (µg/kg ds)
R3, stream	15.376	0.796	0.398	Drift	0.853

Application parameterisation: application mode "granular", dust drift as defined in EFSA (2004) for spinning disks, CAM 6, and DEPI 5.

Table 61 Summary of maximum Step 3a PEC_{sw} and PEC_{sed} values for oxamyl following application to tobacco at 1 × 5500 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	7 days TWA PEC_{sw} (µg/L)	14 days TWA PEC_{sw} (µg/L)	Maximum PEC_{sw} caused by	Maximum PEC_{sed} (µg/kg ds)
R3, stream	28.189	1.459	0.729	Drift	1.543

Application parameterisation: application mode "granular", dust drift as defined in EFSA (2004) for spinning disks, CAM 6, and DEPI 10.

Table 62 Summary of maximum Step 3b PEC_{sw} and PEC_{sed} values for oxamyl following application to potatoes at 1 × 1000 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	7 days TWA PEC_{sw} (µg/L)	14 days TWA PEC_{sw} (µg/L)	Maximum PEC_{sw} caused by	Maximum PEC_{sed} (µg/kg ds)
D3, ditch	0.001	0.001	0.001	Drainage	0.001
D4, pond	0.121	0.112	0.099	Drainage	0.053
D4, stream	0.737	0.637	0.612	Drainage	0.289
D6, ditch	2.080	0.748	0.612	Drainage	0.306
D6, ditch	0.707	0.345	0.249	Drainage	0.128
R1, pond	0.020	0.013	0.009	Run-off	0.004
R1, stream	3.601	0.221	0.112	Run-off	0.273
R2, stream	3.096	0.308	0.154	Run-off	0.300
R3, stream	48.786	3.069	1.536	Run-off	2.714

Application parameterisation: application mode "granular", zero drift, CAM 6, and DEPI 10.

Table 63 Summary of maximum Step 3b PEC_{sw} and PEC_{sed} values for oxamyl following application to tobacco at 1 × 3000 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	7 days TWA PEC_{sw} (µg/L)	14 days TWA PEC_{sw} (µg/L)	Maximum PEC_{sw} caused by	Maximum PEC_{sed} (µg/kg ds)
R3, stream	1.941	0.234	0.118	Run-off	0.200

Application parameterisation: application mode "granular", zero drift, CAM 6, and DEPI 5.

Table 64 Summary of maximum Step 3c PEC_{sw} and PEC_{sed} values for oxamyl following application to potatoes at 1 × 1000 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	7 days TWA PEC_{sw} (µg/L)	14 days TWA PEC_{sw} (µg/L)	Maximum PEC_{sw} caused by	Maximum PEC_{sed} (µg/kg ds)
R1, pond	0.001	0.001	0.001	Run-off	<0.001
R1, stream	0.263	0.016	0.008	Run-off	0.021
R2, stream	0.201	0.020	0.010	Run-off	0.021
R3, stream	3.120	0.196	0.098	Run-off	0.184

Application parameterisation: application mode "granular", zero drift, CAM 5, and DEPI 10.

Table 65 Summary of maximum Step 4a PEC_{sw} and PEC_{sed} values for oxamyl following application to potatoes at 1 × 1000 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	7 days TWA PEC_{sw} (µg/L)	14 days TWA PEC_{sw} (µg/L)	Maximum PEC_{sw} caused by	Maximum PEC_{sed} (µg/kg ds)
	10 m VFS				
R3, stream	1.425	0.090	0.045	Run-off	0.087

Step 4a calculations are based on the results of Step 3c

Table 66 Summary of maximum Step 4b PEC_{sw} and PEC_{sed} values for oxamyl following application to tobacco at 1 × 5500 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	7 days TWA PEC_{sw} (µg/L)	14 days TWA PEC_{sw} (µg/L)	Maximum PEC_{sw} caused by	Maximum PEC_{sed} (µg/kg ds)
	10 m NSZ				
R3, stream	5.459	0.282	0.141	Drift	0.310
	20 m NSZ				
R3, stream	2.838	0.227	0.114	Drift	0.210
	25 m NSZ				
R3, stream	2.291	0.227	0.114	Drift	0.207

Step4b calculations are based on the result of Step 3a.

Long-term PEC_{sw} values – 7, 14, 21, 28, and 42 days after last application

See Table 59 to Table 66 for values.

Additional field testing

No additional field testing was conducted.

RMS comments and conclusion
Predicted environmental concentrations were generated to simulate applications of oxamyl to potatoes, tobacco and tomatoes use in the EU. PECsw and PECsed concentrations of oxamyl and relevant soil and aquatic metabolites IN-A2213, IN-D2708, IN-N0079, and IN-T2921 were determined following recommendations of the FOCUS workgroup (FOCUS, 2001 and 2014) Corrected FOCUS Step 1-2 calculations to evaluate PECsw and PECsed values were performed for oxamyl and its metabolites using conservative parameterization and show in Table 58.

FOCUS Step 3 and 4 were performed for the parent substance only. For the open field uses, stepwise refinements were performed using dust drift values from the field study (see Table 59-64), more realistic distribution in the soil profile and employing VFS or NSZ of varying depth (Table 65 and 66).

B.8.6 Fate and behaviour in air

B.8.6.1 Route and rate of degradation in air and transport via air

The route and rate of degradation in air and transport *via* air study DuPont-7929 EU was originally submitted under EU Rev8 Point IIA 9.3.1. No EU agreed guideline is available for the estimation of the predicted environmental concentrations of chemicals in air.

Oxamyl is applied to the soil surface and incorporated into the upper soil layer. The application method and the low vapour pressure (1.8 × 10^{-5} Pa at 20°C) of oxamyl indicate a low potential for volatilisation of the active substance from soil under practical conditions of use.

B.8.6.2 Predicted environmental concentrations from airborne transport

Please refer above to point B.8.6.1

B.8.7 Predicted environmental concentrations from other routes of exposure

No other studies are required or conducted.

B.8.8 References relied on

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval of the active substance.

Studies marked in yellow are submitted for the first time.

Sorted by Annex Point

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Owner
B.8.1.1.1/01	Ghafoor, A., Zillgens, B.	2015	Estimation of kinetic endpoints for oxamyl and its metabolites oxamyl oxime (IN-A2213), DMOA (IN-D2708), DMCF (IN-N0079) from laboratory soil degradation studies Dr. Knoell Consult GmbH DuPont-41859 EU GLP: No Published: No	N	N	DuPont
B.8.1.1.2.1/01	Partsch, S., Zillgens, B.	2015	Estimation of kinetic endpoints for oxamyl and its metabolites oxamyl oxime (IN-A2213) and DMOA (IN-D2708) from field soil dissipation studies Dr. Knoell Consult GmbH DuPont-41859 EU, Supplement No. 1 GLP: No Published: No	N	N	DuPont
B.8.2/01	Juraske, R., Zillgens, B.	2015	Predicted enviromental concentrations of oxamyl and its major metabolites in soil after the application to various crops - a modelling assessment for Europe Dr. Knoell Consult GmbH DuPont-40857 EU GLP: No Published: No	N	N	DuPont

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Owner
B.8.4.2/01	Ghafoor, A., Zillgens, B.	2015	Estimation of kinetic endpoints of oxamyl and its metabolites oxamyl oxime (IN-A2213), DMOA (IN-D2708), DMCF (IN-N0079) and IN-T2921 in water/sediment systems - kinetic calculations following FOCUS kinetics guidelines Dr. Knoell Consult GmbH DuPont-44046 EU GLP: No Published: No	N	N	DuPont
B.8.3/01	Anyusheva, M., Zillgens, B.	2015	Predicted environmental concentrations of oxamyl and its metabolites in groundwater following applications to various crops - a modelling assessment for Europe using the FOCUS groundwater scenarios Dr. Knoell Consult GmbH DuPont-40858 EU GLP: No Published: No	N	N	DuPont
B.8.5/01	Anyusheva, M., Zillgens, B.	2015	Predicted evniromental concentrations of oxamyl and its metabolites in surface water following applications to various crops -- a modelling assessment for Europe using the FOCUS surface water scenarios Dr. Knoell Consult GmbH DuPont-40859 EU GLP: No Published: No	N	N	DuPont

Sorted by Author

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Owner
B.8.3/01	Anyusheva, M., Zillgens, B.	2015	Predicted environmental concentrations of oxamyl and its metabolites in groundwater following applications to various crops - a modelling assessment for Europe using the FOCUS groundwater scenarios Dr. Knoell Consult GmbH DuPont-40858 EU GLP: No Published: No	N	N	DuPont
B.8.5/01	Anyusheva, M., Zillgens, B.	2015	Predicted evniromental concentrations of oxamyl and its metabolites in surface water following applications to various crops -- a modelling assessment for Europe using the FOCUS surface water scenarios Dr. Knoell Consult GmbH DuPont-40859 EU GLP: No Published: No	N	N	DuPont
B.8.1.1.1/01	Ghafoor, A., Zillgens, B.	2015	Estimation of kinetic endpoints for oxamyl and its metabolites oxamyl oxime (IN-A2213), DMOA (IN-D2708), DMCF (IN-N0079) from laboratory soil degradation studies Dr. Knoell Consult GmbH DuPont-41859 EU GLP: No Published: No	N	N	DuPont

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Owner
B.8.4/01	Ghafoor, A., Zillgens, B.	2015	Estimation of kinetic endpoints of oxamyl and its metabolites oxamyl oxime (IN-A2213), DMOA (IN-D2708), DMCF (IN-N0079) and IN-T2921 in water/sediment systems - kinetic calculations following FOCUS kinetics guidelines Dr. Knoell Consult GmbH DuPont-44046 EU GLP: No Published: No	N	N	DuPont
B.8.2/01	Juraske, R., Zillgens, B.	2015	Predicted enviromental concentrations of oxamyl and its major metabolites in soil after the application to various crops - a modelling assessment for Europe Dr. Knoell Consult GmbH DuPont-40857 EU GLP: No Published: No	N	N	DuPont
B.8.1.1.2.1/01	Partsch, S., Zillgens, B.	2015	Estimation of kinetic endpoints for oxamyl and its metabolites oxamyl oxime (IN-A2213) and DMOA (IN-D2708) from field soil dissipation studies Dr. Knoell Consult GmbH DuPont-41859 EU, Supplement No. 1 GLP: No Published: No	N	N	DuPont