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Oxamyl 10SL

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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 10SL 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;

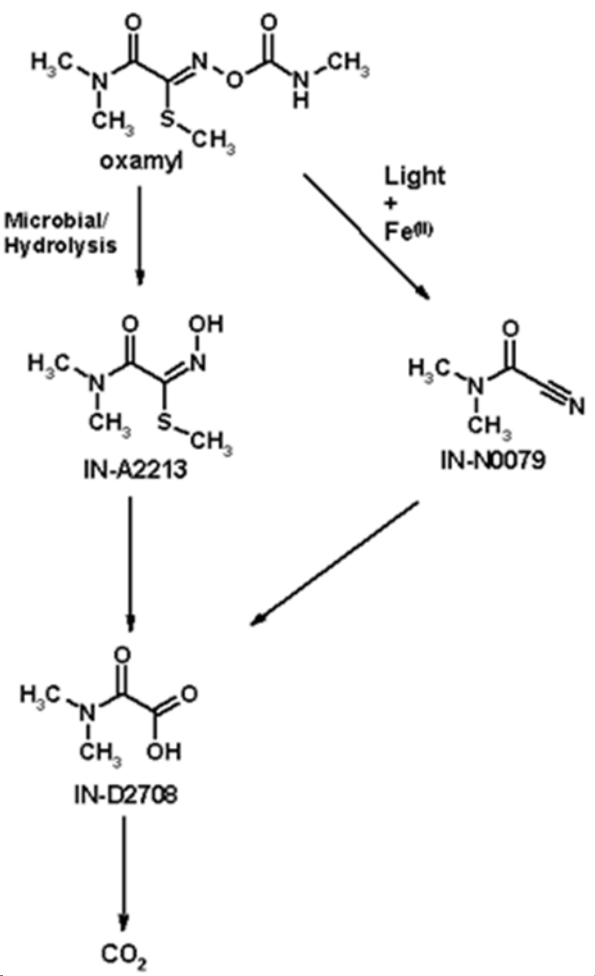
- Oxamyl → IN-N0079 → IN-D2708 under submerged conditions at presence of Fe^{II} ions or as a result of indirect photolysis.

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.

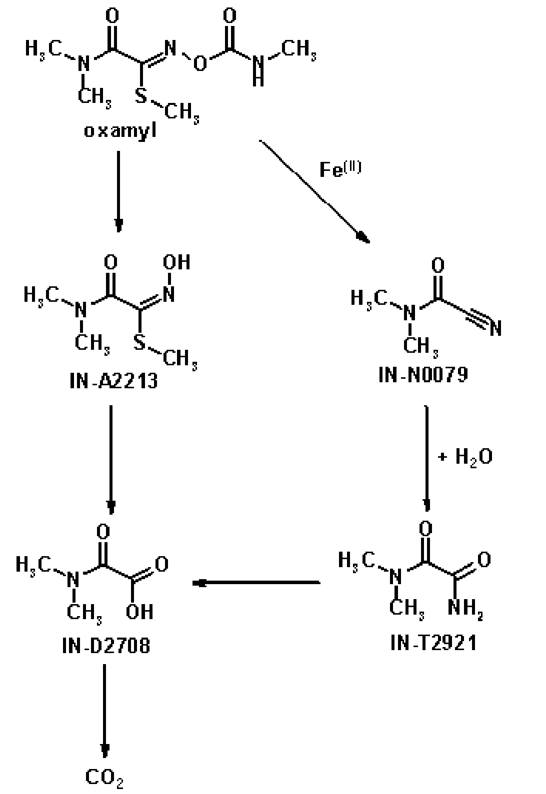
Based on these studies, a schematic degradation pathway was proposed, as depicted in Figure 1.

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.8.2, B.8.3, and B.8.5 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. Oxamyl 10SL is a water soluble liquid concentrate. Major application is made *via* drip irrigation in greenhouses. The intended uses for the liquid formulation Oxamyl 10SL include application to tomatoes and solarisation use in greenhouses and are outlined in Table 2.

Table 2 Representative uses of Oxamyl 10SL formulation (greenhouse uses)

Application to tomatoes at 2000 + 1000 + 1000 +1000 g a.s./ha *via* drip irrigation
• In the permanent closed greenhouses; • Drip tape emitters are positioned right next to the root system of the transplanted plants, typically as a single drip line per one crop row; • Drift is considered to be negligible.
Solarisation use at 1 × 5500 g a.s./ha
• In the permanent closed greenhouses; • Mainly during July-August for a period of 6 to 8 weeks; • Soil is brought to field capacity (~50000 L/ha). Oxamyl is applied at approximately 50% of the irrigation cycle. No further irrigation is typically needed. • Soil is covered with a plastic sheet for several weeks. During this period, soil temperatures increase dramatically and exceed 40°C.

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 tomato and solarisation use.

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

Executive Summary:

Four aerobic soil degradation studies in nine soils for oxamyl under laboratory conditions (DuPont-2957, AMR 1851-90, 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 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 together with modelling endpoints 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 studies and chosen according to FOCUS (2006, 2011) guidelines, are summarised in Table 3 through Table 18.

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

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.

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-2675b	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-2674b	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-40934 EU

Table 9 Summary of degradation parameters as modelling endpoints for oxamyl

Study[a]	Soil/Condition	DegT50 at 20°C (days)	Moisture content (w/w %)			DegT50 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[a]	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 DegT90/ 3.32
	Speyer 582 20°C	7.2	-	pF2	-	7.2	SFO
	Tama 583 20°C	14.3	-	pF2	-	14.3	FOMC DegT90/ 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	DT50 at 20°C (days)	Moisture content (w/w %)			DT50 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	DegT50 at 20°C (days)	Moisture content (w/w %)			DegT50 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 %)			$DegT_{50}$ at 20°C & 10 kPa[b] (days)	Model
			At MWHC	During study	At 10 kPa		
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 %)			$DegT_{50}$ at 20°C & 10 kPa[b] (minutes)	Model
			At MWHC	During study	At 10 kPa		
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 %)			DT_{50} at 20°C & 10 kPa[b] (days)	Model
			At MWHC	During study	At 10 kPa		
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, 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.

Greenhouse dissipation studies with application of Oxamyl 10SL (soluble concentrate) have been presented as confirmatory data in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont–40934 EU, to expand the pool of field dissipation data for oxamyl. The studies have been included because the greenhouse results are consistent with those from the traditional bare field studies in rate and metabolite profile, and thus increase the confidence in the understanding of oxamyl dissipation under actual use conditions.

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

Executive Summary

Residue data from soil dissipation studies (DuPont-2815, DuPont-3026) were reevaluated to meet the requirements of the current FOCUS (2006, 2011, 2014a[3]) and EFSA (2014a)[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

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 (2014a) 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.

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.

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 (2014a) 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.

Table 19 Summary of persistence endpoints for oxamyl

Study[a]	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

[a] 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[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

[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 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 [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 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 [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

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 DT_{50} 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–40934 EU).

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 10SL 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 10SL 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 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 10SL.

B.8.1.2.3 Field leaching studies

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

B.8.2 Predicted environmental concentrations in soil (PEC_s)

For indoor uses, no assessment on PEC_s is required (EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014; 12 (3): 3615, 43 pp., doi:10.2903/j.efsa.2014.3615).

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

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

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

Active substance

Not applicable for permanent glasshouses. Metabolites

Not applicable for permanent glasshouses.

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

Active substance

Not applicable for permanent glasshouses.

Metabolites

Not applicable for permanent glasshouses.

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

Executive Summary

The predicted groundwater concentrations (PEC_{gw}) of oxamyl and its soil metabolites IN-A2213, IN-D2708, and IN-N0079 were determined following recommendations of the FOCUS workgroup (FOCUS, 2000[6], 2009[7], European Commission, 2014[8]). The most current versions of FOCUS models, FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3, were used to generate PEC_{gw} 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 application to tomatoes in greenhouses at 2000 + 1000 + 1000 + 1000 g a.s./ha and a greenhouse solarisation use at 1 × 5500 g.a.s./ha both by drip irrigation.

Key input parameters for oxamyl and metabolites are summarised in Table 25.

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 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 tomato and solarisation uses in greenhouse, a tiered approach was used to calculate PEC_{gw}. At Tier 1, the same climatic conditions (temperature, rainfall, humidity, *etc.*) in the protected structures as in the open field were assumed, based on recommendations of EFSA (2014b)[9]. Since in closed greenhouses temperatures are higher than those in the open field, simulations at Tier 2 were performed using an increased daily temperature of

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

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

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

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

2°C for the scenarios Châteaudun, Piacenza, and Porto to evaluate the effect of increased temperatures on PEC_{gw} for oxamyl and its metabolites. Water input was not changed at Tier 2 calculations.

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 26 and Table 27.

Table 25 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 $DegT_{50}$ 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; Single values are reported 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; Single values are reported in the Oxamyl EU 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	 -	 default
Q_{10} Oxamyl and all metabolites	 2.58	 -	 default

[a] Geometric mean values.

[b] Arithmetic mean values.

[c] Conservative worst case.

Table 26 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]
Tomatoes	Tomatoes	2000 + 1000 + 1000 + 1000	10	0	5000	0	At planting
Solarisation	Tomatoes[b]	5500	-	0	5500	0	July-August

[a] Greenhouse use on tomato and the solarisation use are associated with drip irrigation; therefore, "application to soil surface" mode was taken forward in simulations.

[b] Oxamyl is applied to bare soil. However, to run groundwater simulations, FOCUS models require FOCUS crop to be specified. FOCUS crop tomatoes was chosen for this purpose.

Table 27 Application dates of oxamyl used in the modelling study

Tomatoes 2000 + 1000 + 1000 + 1000 g a.s./ha				
FOCUS scenario	**1st application**	**2nd application**	**3rd application**	**4th application**
Châteaudun	10-May	20-May	30-May	09-Jun
Piacenza	10-May	20-May	30-May	09-Jun
Porto	15-Mar	25-Mar	04-Apr	14-Apr
Sevilla	15-Apr	25-Apr	05-May	15-May
Thiva	10-Apr	20-Apr	30-Apr	10-May
Solarisation 1 × 5500 g a.s./ha				
Châteaudun	1-Jul/1-Aug[a]	-	-	-
Piacenza	1-Jul/1-Aug[a]	-	-	-
Porto	1-Jul/1-Aug[a]	-	-	-
Sevilla		-	-	-
Thiva	1-Jul/1-Aug[a]	-	-	-

[a] Two application dates were used, 1 July and 1 August, representing the most typical application timing for the use in combination with solarisation.

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. Results obtained by FOCUS PEARL and FOCUS PELMO are summarised for greenhouse and solarisation uses in Table 28 to Table 30 (Tier 1) and in Table 31 to Table 33 (Tier 2).

Table 28 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following applications to tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha, Tier 1

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708[a]	IN-N0079
FOCUS PEARL 4.4.4				
Châteaudun	0.103	0.047	0.285	0.004
Piacenza	0.023	0.010	0.047	0.001
Porto	0.023	0.028	0.010	0.001
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001	<0.001
FOCUS PELMO 5.5.3				
Châteaudun	0.033	0.018	0.050	0.001
Piacenza	0.156	0.127	0.136	0.007
Porto	0.373	0.371	0.071	0.020
Sevilla	0.001	0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001	<0.001

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

Table 29 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following application with solarisation at 1 × 5500 g a.s./ha, application on 1 July, Tier 1

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708[a]	IN-N0079
FOCUS PEARL 4.4.4				
Châteaudun	0.123	0.054	0.317	0.005
Piacenza	0.021	0.010	0.024	<0.001
Porto	0.003	0.003	<0.001	<0.001
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	0.002	<0.001	<0.001	<0.001
FOCUS PELMO 5.5.3				
Châteaudun	0.084	0.043	0.190	0.003
Piacenza	0.089	0.058	0.152	0.004
Porto	0.003	0.003	0.001	<0.001
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	0.002	0.001	<0.001	<0.001

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

Table 30 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following application with solarisation at 1 × 5500 g a.s./ha, application on 1 August, Tier 1

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708[a]	IN-N0079
FOCUS PEARL 4.4.4				
Châteaudun	0.099	0.049	0.077	0.004
Piacenza	0.284	0.142	0.979	0.011
Porto	0.055	0.043	0.116	0.002
Sevilla	0.001	<0.001	<0.001	<0.001
Thiva	0.017	0.008	0.003	<0.001
FOCUS PELMO 5.5.3				
Châteaudun	0.038	0.021	0.007	0.002
Piacenza	0.261	0.163	0.804	0.011
Porto	0.051	0.049	0.042	0.002
Sevilla	0.001	0.001	<0.001	<0.001
Thiva	0.007	0.004	0.001	<0.001

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

Table 31 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following applications to tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha, Tier 2

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708[a]	IN-N0079
FOCUS PEARL 4.4.4				
Châteaudun	0.024	0.011	0.035	0.001
Piacenza	0.005	0.002	0.007	<0.001
Porto	0.011	0.014	0.001	0.001
FOCUS PELMO 5.5.3				
Châteaudun	0.007	0.004	0.003	<0.001
Piacenza	0.081	0.071	0.039	0.004
Porto	0.232	0.244	0.032	0.012

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

Table 32 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following application with solarisation at 1 × 5500 g a.s./ha, application on 1 July, Tier 2

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708[a]	IN-N0079
FOCUS PEARL 4.4.4				
Châteaudun	0.029	0.013	0.045	0.001
Piacenza	0.004	0.002	0.003	<0.001
Porto	<0.001	<0.001	<0.001	<0.001
FOCUS PELMO 5.5.3				
Châteaudun	0.019	0.010	0.023	0.001
Piacenza	0.029	0.018	0.027	0.001
Porto	<0.001	0.001	<0.001	<0.001

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

Table 33 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following application with solarisation at 1 × 5500 g a.s./ha, application on 1 August, Tier 2

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	IN-A2213	IN-D2708[a]	IN-N0079
FOCUS PEARL 4.4.4				
Châteaudun	0.024	0.011	0.008	0.001
Piacenza	0.077	0.043	0.218	0.003
Porto	0.009	0.008	0.005	<0.001
FOCUS PELMO 5.5.3				
Châteaudun	0.009	0.005	<0.001	<0.001
Piacenza	0.077	0.058	0.198	0.003
Porto	0.009	0.012	0.002	<0.001

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

It should be noted that results of Tier 2 simulations for Porto scenario with FOCUS PELMO 5.5.3 still showed oxamyl exceedance of 0.1 µg/L, while no exceedance was predicted with FOCUS PEARL 4.4.4. To show that the former was a result of water input untypical for greenhouses, water input data were adjusted in Porto scenario. For two months following first application (15 March-15 May), daily irrigation volumes were set to conservative 4 mm/day and simulations with FOCUS PELMO 5.5.3 were performed. The 80th percentile PEC_{gw} for oxamyl decreased dramatically: from 0.232 µg/L (Tier 1, Porto scenario) to 0.003 µg/L (Tier 1 with adjusted water input as alternative refinement).

The predicted concentrations of oxamyl in groundwater were estimated using FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3. Simulations were based on proposed usage regimes in greenhouse uses on tomatoes and solarisation.

The simulation runs resulted in concentrations below 0.1 µg/L for oxamyl when using parameterisation drawn upon the laboratory degradation studies and more realistic conditions. Predicted concentrations for the metabolites IN-A2213 and IN–D2708 exceeded the threshold value of 0.1 µg/L in some of the scenarios at Tier 1 and 2, whereas PEC_{gw} for IN–N0079 were always lower than 0.1 µg/L. It should be noted that Tier 2 is still very conservative for solarisation use, as it considers increase of temperatures by 2°C together with the outdoor rainfall input. In reality, soil temperatures rise >40°C and there is rarely any irrigation following oxamyl application, as it might cool down soils and thus reduce solarisation efficacy.

Additional PEC_{gw} calculations for scenario Châteaudun:

The potential of oxamyl and its metabolites to reach groundwater by macropore/preferential flow was simulated for the standard FOCUS scenario Châteaudun, using the leaching model FOCUS MACRO 5.5.4. According to FOCUS groundwater guidance (FOCUS, 2014) such simulations are required for crops that are parameterised for the Châteaudun scenario. Since this is true for fruiting vegetables (used as surrogate crop for tomatoes in the present study), additional simulations were conducted for this use in greenhouse (Tier 1 only, Table 34).

Input parameters and application scenario were identical to the simulations with FOCUS PEARL and PELMO. 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.

Results of the FOCUS MACRO 5.5.4 simulations are summarised in Table 34. The calculated 80th percentile PEC_{gw} values (at 1 m soil depth) for oxamyl 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 greenhouse applications.

Table 34 The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites for proposed greenhouse uses

Scenario	80th percentile annual average PEC_{gw} (µg/L)			
	Oxamyl	**IN-A2213**	**IN-D2708[a]**	**IN-N0079**
FOCUS MACRO 5.5.4 to tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha				
Châteaudun	0.019	0.012	0.018	0.002
FOCUS MACRO 5.5.4 solarisation at 1 × 5500 g a.s./ha, application on 1 July				
Châteaudun	0.031	0.021	0.032	0.003
FOCUS MACRO 5.5.4, solarisation at 1 × 5500 g a.s./ha, application on 1 August, Tier 1				
Châteaudun	0.038	0.030	0.014	0.004

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

Additional field testing

As the results from the modeling 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

The predicted concentrations of oxamyl in groundwater were estimated using FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3. Simulations were based on proposed usage regimes in greenhouse uses on tomatoes and solarisation. Predicted concentrations for oxamyl and the metabolites IN-A2213 and IN–D2708 exceeded the threshold value of 0.1 µg/L in some of the scenarios at Tier 1 and 2, whereas PEC_{gw} for IN–N0079 were always lower than 0.1 µg/L
The calculated PEC_{gw} values (using FOCUS MACRO 5.5.4 simulations) for oxamyl 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 greenhouse applications.
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

Executive Summary

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 35 through Table 42.

Table 35 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 36 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 37 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 38 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 39 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 40 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 41 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 42 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 43 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 44 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 enviromental 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.:** **GLP:** No **Certifying Authority:** Not applicable

Executive Summary

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 tomatoes in greenhouses and a greenhouse solarisation use. Step 1 and 2 calculations were performed for oxamyl and its metabolites, while Step 3 calculations were performed for the parent substance oxamyl alone. All simulations at Steps 1-3 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, and FOCUS TOXSWA 3.3.1 and recommendations of EFSA and the FOCUS surface water workgroup.

The application of Oxamyl 10SL was assumed to be made through drip irrigation in permanently closed greenhouses using drip tape emitters right next to the root system of the plants (tomatoes) or onto bare soil (solarisation) covered by transparent plastic film. The application framework included application to tomatoes in greenhouses at 2000 + 1000 + 1000 + 1000 g a.s./ha and a greenhouse solarisation use at 1 × 5500 g.a.s./ha (Table 45). It is noted that this assessment is based on open field assumptions and provides therefore worst-case conditions for the proposed application regime. Oxamyl 10SL is proposed for closed greenhouse structures. The green houses are typically kept closed to increase the temperature and soil is covered with a plastic film for the solarisation use.

Table 45 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
Tomatoes	No drift/ Fruiting vegetables[a]	2000 + 1000 + 1000 + 1000	10	0	2000 + 1000 + 1000 + 1000	At planting
Solarisation	No drift/ Fruiting vegetables[a]	5500	-	0	5500	July-August

[a] Depending on FOCUS Step: "no drift" technique at Steps 1-2 and "Fruiting vegetables" at Step 3.

Substance parameters

For all substances, geometric mean $DegT_{50}$ values derived from laboratory aerobic degradation studies and geometric means of OC-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 46.

Table 46 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, Part3, 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 $DegT_{50}$ normalised Oxamyl IN-A2213 IN-D2708 IN-N0079	 5.3[a] 1.7[a] 5.7[a] 1.0[c]	 days	 DuPont-40858 EU and 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

Table 46 Key input parameters used in simulation of PECsw and PECsed for oxamyl and its soil and aquatic metabolites (continued)

Parameter	Value	Units	Reference
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
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 tomatoes in greenhouse and a solarisation use using zero drift and zero interception settings. 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; Table 47). PEC_{sw} values 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.

Applications of oxamyl to tomatoes and solarisation are performed in greenhouses. The relevant emission routes to surface water are drainage, condensation, and discharge of recirculation water (EFSA, 2014[9]). Therefore, only drainage scenarios were addressed in Step 3 calculations. Since oxamyl is applied *via* drip irrigation in both intended uses, application method "granular application" was chosen for drainage scenarios. Chemical Application Method (CAM) = 1 was used in calculations, to account for zero interception by plants. Drift was also not accounted for since only negligible amounts of oxamyl were assumed to enter air following drip irrigation in greenhouses and due to the low vapour pressure of oxamyl (Table 46).

For application to tomatoes, multiple applications are proposed. FOCUS recommends additional simulations of single application to cover worst case drift value. However, only multiple applications were calculated for tomatoes because losses by drift following drip application were considered negligible.

Oxamyl use in combination with solarisation is applied to bare soil in greenhouses. However, the surrogate FOCUS crop "fruiting vegetables" was chosen in simulations as FOCUS crop is required to perform FOCUS Step 3 simulations.

At Step 3a, simulations for all greenhouse uses were conducted with the parameterisation presented in Table 48. The simulations were performed following an open field approach.

At Step 3d[10], greenhouse specific conditions were taken into account. Temperature and irrigation in protected structures differ to those under open field conditions. As a conservative approach, simulations using increased daily temperatures by 2°C and a daily irrigation of tomatoes at 4 mm/day (10 April to 10 August) were performed for oxamyl use on tomatoes.

Based on the above discussions, detailed parameterisation of the application scenarios and application dates at FOCUS Steps 1-3 are provided in Table 47 to Table 49.

Table 47 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
Tomatoes (SEU)	No drift	2000+1000+ 1000+1000[c]	0	No	SEU: Mar – May[b]
Solarisation use (SEU)	No drift	1 × 5500	0	No	SEU: Mar – May[b]

[a] FOCUS crops were chosen following FOCUS (2001, 2014). In greenhouses, drip irrigation is employed for use on tomatoes and solarisation use. Hence, "no drift" technique was chosen in Steps 1-2.

[b] This combination was defined to be characterised by the highest run-off, drainage, and erosion loadings in SEU.

[c] A single application of 5000 g a.s/ha was employed in Step 1-2 calculations.

10 DuPont-40859 reports PEC_{sw} and PEC_{sed} simulations for different products containing the active substance oxamyl. For an easier understanding when referring back to the modelling paper, the original naming of Step 3 approaches was kept within the current product dossier.

Table 48 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 (%)
Tomatoes drip irrigation	Fruiting vegetables	2000+1000+ 1000+1000[a]	Granular	1	nr[b]	nr[c]
Solarisation drip irrigation	Fruiting vegetables[d]	1 × 5500	Granular	1	nr[b]	nr[c]

[a] With a 10-days interval. No single application was considered, due to the fact that no drift entry into surface water occurs.

[b] For applications in greenhouses, drainage, condensation, and discharge of the recirculation water are the only relevant entry route to surface water.

[c] Applications in greenhouses are made *via* drip irrigation; therefore, no drift entries to air were accounted for.

[d] Oxamyl is applied to bare soil. However, to run surface water simulations at Step 3, FOCUS models require FOCUS crop to be specified. FOCUS crop "fruiting vegetables" was chosen for this purpose

Table 49 Application dates for oxamyl in the FOCUS Step 3 scenarios

Crop (use)	Location[a]	Application window	Julian days	Application dates found by PAT[b]
Fruiting vegetables (2000 + 1000 + 1000 + 1000 g/ha)	D6	10-Apr - 9-Jun	100-160	10-Apr, 23-Apr, 7-May, 19-May
	R2	15-Mar - 14-May	74-134	15-Mar, 26-Mar, 22-Apr, 5-May
	R3	10-May - 9-Jul	130-190	18-May, 1-Jun, 11-Jun, 29-Jun
	R4	20-Apr - 19-Jun	110-170	21-Apr, 4-May, 27-May, 6-Jun
Fruiting vegetables (combination with solarisation at 1 × 5500 g/ha)	**Application on 1 July**			
	D6	1-Jul - 31-Jul	182-212	6-Jul
	R2	1-Jul - 31-Jul	182-212	31-Jul
	R3	1-Jul - 31-Jul	182-212	11-Jul
	R4	1-Jul - 31-Jul	182-212	1-Jul
	Application on 1 August			
	D6	1-Aug - 31-Aug	213-243	1-Aug
	R2	1-Aug - 31-Aug	213-243	5-Aug
	R3	1-Aug - 31-Aug	213-243	1-Aug
	R4	1-Aug - 31-Aug	213-243	1-Aug

[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[11], 2014b[12]).

Results

Predicted concentrations of oxamyl in surface water (PEC_{sw}) and sediment (PEC_{sed}) after application *via* drip irrigation to tomatoes in greenhouses at 2000 + 1000 + 1000 + 1000 g a.s./ha and a greenhouse solarisation use at 1 × 5500 g.a.s./ha are presented in Table 50 to Table 53 for all simulated Steps.

Predicted concentrations of oxamyl metabolites in surface water (PEC_{sw}) and sediment (PEC_{sed}) are presented in Table 50 for Step 1-2 simulations. Based on these results, Step 3 simulations were not triggered for any of the metabolites in any of the application scenarios.

11 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.

12 FOCUS (2014b): Generic guidance for FOCUS surface water Scenarios, version 1.3.

Initial PEC_{sw} values for static water bodies

Active substance and metabolites

Table 50 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)
	Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha[b]			
Oxamyl	1640.000	182.626	389.336	43.294
IN-A2213	635.611	40.488	49.768	3.170
IN-D2708	691.969	63.177	170.176	15.537
IN-N0079	75.525	3.912	1.888	0.098
IN-T2921[a]	98.979	-	23.498	-
	Solarisation 1 × 5500 g a.s./ha			
Oxamyl	1810.000	200.888	428.270	47.624
IN-A2213	699.172	44.537	54.744	3.487
IN-D2708	761.166	69.495	187.193	17.091
IN-N0079	83.077	4.303	2.077	0.108
IN-T2921[a]	109.239	-	25.847	-

[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, a single application of 5000 g a.s./ha was employed in Steps 1-2 calculations.

Table 51 Summary of maximum Step 3a PEC_{sw} and PEC_{sed} values for oxamyl following applications to tomatoes at 2000 + 1000 + 1000 + 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)
D6, ditch	11.386	4.000	2.295	Drainage	1.579

Application parameterisation: application mode “granular”, no drift, CAM 1, and DEPI 4.

Table 52 Summary of maximum Step 3a PEC_{sw} and PEC_{sed} values for oxamyl following application at 1 × 5500 g a.s./ha in combination with solarisation

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)
	Application window starts on 1 July				
D6, ditch	0.002	0.001	<0.001	Drainage	0.001
	Application window starts on 1 August				
D6, ditch	0.014	0.013	0.013	Drainage	0.011

Application parameterisation: application mode “granular”, no drift, CAM 1, and DEPI 4.

For applications in greenhouses, the simulations for the D6 scenario were performed using an open field approach in Step 3a. Maximum PEC_{sw} concentrations for oxamyl applications on tomatoes were predicted to be significant higher compared to maximum PEC_{sw} concentrations predicted for the solarisation use (Table 51 and Table 52). Figure 2 shows peak concentrations of oxamyl in surface water and rainfall amount following oxamyl application to tomatoes (referring to Table 51). Maximum PEC_{sw} was predicted to occur following two days with rainfall exceeding 15 mm/d. Such rainfall pattern is not realistic for tomatoes growing in greenhouses, as typical irrigation to tomatoes vary within ~1.5 to 5 mm/d, depending on the seasonal evapotranspiration rates (http://www.infoagro.com/hortalizas/tomate.htm). Considering more realistic conditions for uses on tomatoes in greenhouses the maximum PEC_{sw} concentration decrease from 11.386 µg/L (Step 3a, Table 51) to 0.002 µg/L (Step 3d, Table 53).

Figure 2 Peak concentration of oxamyl in the D6 ditch in relation to the rainfall pattern

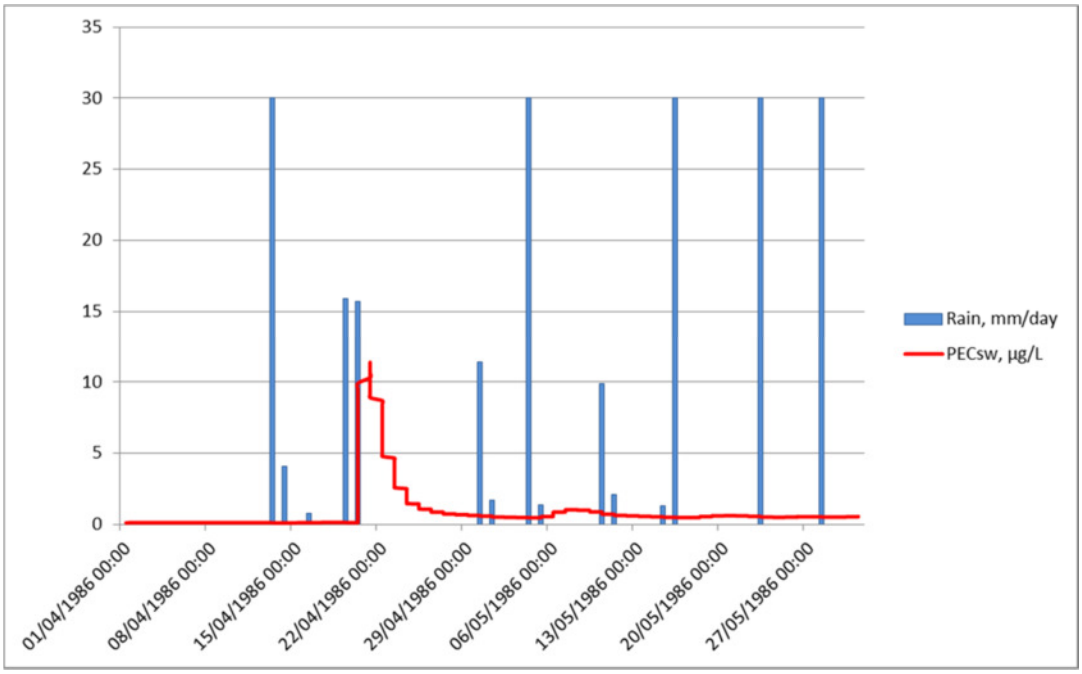

Table 53 Summary of maximum Step 3d PEC_{sw} and PEC_{sed} values for oxamyl following applications to tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha

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)
D6, ditch	0.002	0.002	0.002	Drainage	0.002

Application parameterisation: application mode "granular", no drift, CAM 1, and DEPI 4. Yearly minimum and maximum temperatures were increased by 2°C and daily water irrigation to mm/day for a period from 10 April to 10 August.

Initial PEC_{sw} value for slow moving water bodies

FOCUS stream scenarios represent slow moving water bodies. For application to FOCUS crop tomatoes no stream scenarios are defined in FOCUS guidances.

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

See Table 51 to Table 53 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 tomatoes in greenhouses and a greenhouse solarisation 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 50.
FOCUS Step 3 were performed for the parent substance only. For applications in greenhouses, the simulations for the D6 scenario were performed using an open field approach in Step 3a (Table 51 and 52) and considering more realistic conditions for uses on tomatoes in greenhouses in Step 3d (Table 53).

B.8.6 Fate and behaviour in air

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

Oxamyl is applied to the soil surface. For solarisation use the soil surface is covered with plastic directly after the application. 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 (see also the Oxamyl EU Renewal Dossier, Document M-CA, Section 2, DuPont-40929 EU and Section 7, DuPont–40934 EU).

B.8.6.2 Predicted environmental concentrations from airborne transport

No EU agreed guideline is available for the estimation of the predicted environmental concentrations of chemicals in air.

B.8.6.3 Predicted environmental concentrations from other routes of exposure

No other studies are required or conducted.

B.8.7 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.8.3/01	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 DuPont Report No.: DuPont-40858 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.8.5/01	Anyusheva, M., Zillgens, B.	2015	Predicted enviromental 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 DuPont Report No.: DuPont-40858 EU GLP: No Published: No	N	N	DuPont
B.8.5/01	Anyusheva, M., Zillgens, B.	2015	Predicted enviromental 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

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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.8.1.1.2.1/01	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