European Commission

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

Oxamyl 10SL

Volume 3

B.9 (CP) Ecotoxicology data and assessment of risks for non-target species

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

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VERSION HISTORY

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

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B.9 ECOTOXICOLOGY DATA AND ASSESSMENT OF RISKS FOR NON-TARGET SPECIES

Ecotoxicological studies described in this document address data requirements specified in Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Experimental details of ecotoxicological studies done with the formulated product Oxamyl 10SL that also satisfy data requirements specified in Point CA 8 were included in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU; only the conclusions will be reported here in summary form.

Details of parameters, assumptions, and calculations used in the estimation of environmental exposure used for TER calculations are discussed in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10SL, DuPont-42129 EU.

This document includes summaries of studies and/or risk assessments conducted with Oxamyl 10SL, and all significant metabolites.

The test substance specification can be determined from the test substance code, which is a research and development code number given to a specific batch of produced material (either technical or formulated). The test substances/materials used in ecotoxicology tests are listed in Table 1. The name of the 10% liquid formulation changed between the Annex 1 listing in 2005 and the current Annex 1 Renewal from Oxamyl 10L to Oxamyl 10SL to meet current naming conventions for formulations. Study summaries and references that use the name Oxamyl 10L were conducted with test material that is the same as Oxamyl 10SL.

Table 1 Test substance/material specifications

Test substance code	Type	Composition	Detailed specifications
Annex I inclusion EU approval review			
D1410-381	Formulated Oxamyl 10SL	100 g a.s./L	RAR Volume 4
D1410-424	Formulated Oxamyl 10SL	100 g a.s./L	RAR Volume 4
D1410-393	Formulated Oxamyl 10SL	100 g a.s./L	RAR Volume 4
D1410-460	Formulated Oxamyl 10SL	100 g a.s./L	RAR Volume 4

Consideration of metabolites

The occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered; detailed discussion was provided in the EU review of oxamyl and in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10SL, DuPont-42129 EU. The metabolites to which non-target organisms could be exposed are presented in Table 2.

Table 2 Oxamyl metabolites

Parent compound	Metabolite name[a]	Compound found in	Maximal percentage of formation %
Oxamyl	IN-A2213	Soil	52.0
		Water	42.8
		Sediment	4.4
	IN-D2708	Soil	78.7
		Water	66.8
		Sediment	12.1
	IN-N0079	Soil	10.2
		Water	52.9
		Sediment	3.7
	IN-T2921	Soil	NA
		Water	11.4
		Sediment	0.4

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

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

Unless specifically indicated, all tests submitted in this section, which involve vertebrate animals, address mandatory data requirements which could not be met with alternative methods. Studies were conducted according to prescribed guidelines.

Unless specifically indicated, this section does not contain reports of studies duplicating previous tests on vertebrate animals.

Relevant EU Guidance on specific data requirements, purposes of required studies, circumstances in which they are required, test conditions, and test guidelines may be obtained in the following documents (current as of September 2013)

- Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
- Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
- Scientific opinion “Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters” EFSA Journal 2013;11(7):3290
- European Commission SANCO/10329/2002 rev 2 Final 17 October 2002 Draft Working Document,
- Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC
- Risk Assessment for Birds and Mammals on request from EFSA, Question No EFSA-Q-2009-00223 EFSA Journal 2009; 7(12):1438 3/139
- Scientific Opinion “On the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations of plant protection products in soil” EFSA Journal 2012;10(2):2562.

- 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

- EPPO 2010. Environmental risk assessment scheme for plant protection products. European Plant Protection Organization (EPPO) Bulletin http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2338.2010.02419.x/epdf

- ESCORT 3: Linking Non-Target Arthropod Testing and Risk Assessment with Protection Goals. Hotel Auiderduin, Egmond aan Zee, the Netherlands: 8-11 March 2010/editors, Anne Alix, *et al.* 136 pages.

Oxamyl 10SL is used in drip irrigation to vegetables together with solarisation in glasshouses in Southern Europe.

Drip-Irrigation: For use in tomatoes, Oxamyl 10SL may be applied up to four times per season by drip irrigation under the soil to the roots at rates of 2 + 1 + 1 + 1 kg a.s./ha with intervals of 10 to 14 days.

All applications are made by drip irrigation to soil or incorporation in soil followed by immediate coverage by plastic foil within enclosed spaces (glasshouses); generally, non-target organisms are considered not exposed to residues of the formulated product, the active substance oxamyl, or its metabolites.

Solarisation: For use in solarisation, Oxamyl 10SL may be applied through drip irrigation directly to the bare soil followed by immediate coverage by plastic foil. Soil is then left heating by natural sunlight at up to 50°C under the July/August sun for several weeks to kill pathogens, fungi, and weeds (solarisation). Soil disinfection is usually done between July and August and workers do not enter the glasshouses during the day because of excessive heat. After solarisation, glasshouse crops are grown and treated according to normal glasshouse practices.

All applications are made by incorporation in soil followed by immediate coverage by plastic foil within enclosed spaces (glasshouse); therefore, birds and mammals are considered not exposed to residues of the formulated product, the active substance oxamyl, or its metabolites.

The proposed use patterns that will be assessed are shown in the Oxamyl EU Renewal Dossier, Document D, Part 1, DuPont-40925 EU.

According to Regulation (EC) No. 1107/2009, Article 3 (27) a glasshouse means a walk-in, static, closed space of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment.

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 are not warranted in these protected environments. Nevertheless, standard exposure assessments are provided assuming that the ‘soil’ is to be considered a ‘natural soil’.

B.9.1 Effects on birds and other terrestrial vertebrates

B.9.1.1 Effects on birds

B.9.1.1.1 Acute oral toxicity

An avian toxicity test with the formulation was performed for another country and is included in the summary below for completeness.

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

B.9.1.1.1/01

Reference: **CP 10.1.1.1/01**	**Report:**	[redacted] (1999); Oxamyl 10L: An acute oral toxicity study with the northern bobwhite **DuPont Report No.:** DuPont-2956 **Guidelines:** U.S. EPA 850.2100 (1996) **Deviations:** None that affect the validity of the study. **Testing Facility:** [redacted] **Testing Facility Report No.:** 112-499 **GLP:** Yes **Certifying Authority:** Laboratories in the USA are not certified by any governmental agency, but are subject to regular inspections by the U.S. EPA.

Executive summary:

Oxamyl 10SL was administered to fasted northern bobwhite quail (*Colinus virginianus*) in an acute oral toxicity study. The study was conducted according to U.S. EPA, Series 850-Ecological Effects Test Guidelines OPPTS 850.2100 and FIFRA Subdivision E, Section 7.1. Five quail/sex/dose received single oral doses of 0, 0.5, 1, 2, 4, 8, 16, and 32 mg a.s./kg bw at a dose volume of 4 mL/kg in reverse osmosis water. Birds were observed for clinical signs of toxicity, body weight effects and mortality for 14 days after dosing. All birds were examined for gross pathological changes. A single incidental mortality occurred in the control group. At the 4 mg a.s./kg one bird was euthanised due to a leg fracture sustained during body weight procedures. Otherwise, all birds at the 4 mg a.s./kg dosage level were normal in appearance and behavior throughout the duration of the study. There was 30% (3 of 10) mortality in the 8 mg a.s./kg treatment group, 70% (7 of 10) mortality in the 16 mg a.s./kg treatment group and 100% (10 of 10) mortality in the 32 mg a.s./kg treatment group. Clinical signs of toxicity most often observed in males and females included loss of coordination, lower limb weakness, prostrate posture, loss of righting reflex, gaping, ruffled appearance, reduced reaction to stimuli (sound and motion), and lethargy. Other clinical signs of toxicity observed in male and/or females included lacrimation, convulsions, salivation, and shallow and rapid respiration. With the exception of treatment group 32 mg a.s./kg bw Oxamyl 10SL, all surviving quail appeared normal by Day 3 or earlier and throughout the remainder of the study. There were no test substance-related body weight or food intake effects noted. Necropsy of those birds found dead on the day of actual dosing revealed that all birds, with one exception, had a clear to green colored fluid and/or material in the crop, assumed to be the dosing solution. One bird in the 16 mg a.s./kg treatment group had slightly pale and mottled kidneys and another bird at this dosage was noted with bruising on the cranium, autolysis throughout the abdominal cavity, and slightly pale kidneys. In addition, three birds in the 32 mg a.s./kg treatment group had pale spleens. The acute oral LD_{50} value for northern bobwhite quail exposed to Oxamyl 10SL by single oral dose was 11 mg a.s./kg bw (or 110 mg product/kg bw), with a 95% confidence interval of 8 to 15 mg a.s./kg bw. The no

mortality dosage was 2 mg a.s./kg bw (20 mg product/kg bw). Based on signs of toxicity at the 2 mg a.s./kg dose, the NOEL was 1 mg a.s./kg bw (10 mg product/kg bw).

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-381
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
2.	Vehicle and/or positive control:	Dilution (reverse osmosis water) water control
3.	Test organism:	Bobwhite
	Species:	*Colinus virginianus*
	Age at dosing:	19 weeks
	Weight at dosing:	166–219 g
	Source:	[redacted]
	Acclimation period:	4 weeks
	Diet:	[redacted] Game bird ration.
	Water:	Tap water, *ad libitum*
	Housing:	Indoors, one pen/dosage group/sex
4.	Environmental conditions	
	Temperature:	22.2–24.6°C
	Relative humidity:	49–51%
	Photoperiod:	8 hour photoperiod (approximately 134 lux)

B. STUDY DESIGN AND METHODS:

1. In-life initiated/completed

   31-August-1999 to 14-September-1999

2. Experimental treatments

   In an acute toxicity study, northern bobwhite quail (*Colinus virginianus*) were exposed to Oxamyl 10SL. Oxamyl 10SL was administered in reverse osmosis water by single oral dose to fasted northern bobwhite quail. Five quail/sex/dose received single oral doses of 0, 0.5, 1, 2, 4, 8, 16, and 32 mg a.s./kg bw at a dose volume of 4 mL/kg.

3. Observations

   Birds were observed for clinical signs of toxicity, body weight effects, and mortality for 14 days after dosing. All birds were examined for gross pathological changes.

4. Statistics

   In this study the LD_{50} value was determined by the probit analyses. No statistical analyses were applied to separate mean responses among treatment groups for the endpoints of food consumption or body weight.

II. RESULTS AND DISCUSSION

A. FINDINGS

Treatment related mortalities occurred at 8, 16, and 32 mg a.s./kg bw. Clinical signs of toxicity most often observed in males and females included loss of coordination, lower limb weakness, prostrate posture, loss of righting reflex, gaping, ruffled appearance, reduced reaction to stimuli (sound and motion), and lethargy. Other clinical signs of toxicity observed in male and/or females included lacrimation, convulsions, salivation, and shallow and rapid respiration. With the exception of treatment group 32 mg a.s./kg bw

Oxamyl 10SL, all surviving quail appeared normal by Day 3 or earlier and throughout the remainder of the study. There were no test substance-related body weight or food intake effects noted. Necropsy of those birds found dead on the day of actual dosing revealed that all birds, with one exception, had a clear to green colored fluid and/or material in the crop, assumed to be the dosing solution. One bird in the 16 mg a.s./kg treatment group had slightly pale and mottled kidneys and another bird at this dosage was noted with bruising on the cranium, autolysis throughout the abdominal cavity, and slightly pale kidneys. In addition, three birds in the 32 mg a.s./kg treatment group had pale spleens.

Results are summarised in the tables that follow.

Table 3 Summary of toxicological responses of northern bobwhite quail following a single oral dose of Oxamyl 10SL

Dose (mg a.s./kg body wt.)	Sex	Toxicological results[a]	Duration of clinical signs	Time of death
Control	M	1[b]/0/5	--	Day 7
	F	0/05	--	--
0.5	M	0/0/5	--	--
	F	0/0/5	--	--
1	M	0/0/5	--	--
	F	0/0/5	--	--
2	M	0/NR[c]/5	1 day	--
	F	0/NR/5	1 day	--
4	M	0/NR/5	2 days	--
	F	1/NR5	3 days	Day 0
8	M	1/NR/5	2 days	Day 0
	F	3/NR/5	2 days	Day 0
16	M	3/NR/5	3 days	Day 0
	F	4/NR/5	3 days	Day 0
32	M	5/0/5	3 hours	Day 0
	F	5/0/5	3 hours	Day 0

[a] number of animals which died/number of animals with clinical signs/number of animals used

[b] animal was euthanised due to a broken leg which occurred during handling

[c] NR means not reported

Table 4 Acute oral toxicity to northern bobwhite quail - Summary of endpoints

Test substance	Oxamyl 10SL
Test object	Northern bobwhite quail, male and female
LD_{50}	110 mg product/kg bw
Lowest observed effect level (LOEL)	20 mg product/kg bw
Highest tested dose without toxic effect (NOEL)	10 mg product/kg bw

III. CONCLUSIONS

The acute oral LD_{50} value for northern bobwhite quail exposed to Oxamyl 10SL by single oral dose was calculated to be 11 mg a.s./kg bw (or 110 mg product/kg bw), with a 95% confidence interval of 8 to 15 mg a.s./kg bw. The no mortality dosage was 2 mg a.s./kg bw (20 mg product/kg bw). Based on signs of toxicity at the 2 mg a.s./kg dose, the NOEL was 1 mg a.s./kg bw (10 mg product/kg bw).

([redacted] 1999)

RMS summary and conclusion

The study was conducted according to U.S. EPA 850.2100 (1996). A review of this study indicates that it is in line with the current guideline OECD 223 [2012]). A higher number of birds/dose was used, which increase the statistical power. The test is valid because one single incidental mortality was observed in the control animals.

The study is acceptable.

B.9.1.1.2 Higher tier data on birds

Supervised cage or field trials are not required because safe uses in glasshouses can be concluded because there will be no exposure to wild birds after use in glasshouses in drip irrigation or as a soil sterilant.

The concentration of the active substance in bait (mg/kg)

Not relevant because the plant protection product Oxamyl 10SL is not intended for use as bait, granules, or seed treatments and safe uses in glasshouses can be concluded because there will be no exposure to wild birds after use in glasshouses in drip irrigation or as a soil sterilant.

Pellets, granules, prills, or treated seed

The amount of the active substance(s) in or on each pellet, granule, prill, or treated seed

Not relevant because the plant protection product Oxamyl 10SL is not intended for use as bait, granules, or seed treatments.

Proportion of the LD_{50} for the active substance in 100 particles and per gram of particles

Not relevant because the plant protection product Oxamyl 10SL is not intended for use as bait, granules, or seed treatments.

The size and shape of pellets, granules, and prills

Not relevant because the plant protection product Oxamyl 10SL is not intended for use as bait, granules, or seed treatments.

Acceptance of bait, granules, or treated seed by birds (palatability test)

This test is not required because the plant protection product Oxamyl 10SL is not intended for use as bait, granules, or seed treatments.

B.9.1.2 Effects on terrestrial vertebrates other than birds

Overview and summary

Effects on terrestrial vertebrates other than birds

Study	Test species	Endpoints	Reference[a]
Acute toxicity	Rat	LD_{50} (oral): 2.5 mg/kg bw	DuPont-26931
Reproductive toxicity (2 generation)	Rat	NOAEL: 1.43 mg/kg/day	HLR 423-90

[a] Reports reviewed and summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

Details of mammalian toxicity studies are provided in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU.

B.9.1.2.1 Acute oral toxicity to mammals

No risk assessment is required, because there will be no exposure to wild mammals, indicating safe uses.

Exposure *via* drinking water

Acute drinking water risk assessment

No risk assessment is required because there will be no exposure to wild mammals, indicating Oxamyl 10SL presents no unacceptable acute risk to mammals when used according to the proposed GAP.

B.9.1.2.2 Higher tier data on mammals

No risk assessment is required because there will be no exposure to wild mammals, indicating Oxamyl 10SL presents no unacceptable acute risk to mammals when used according to the proposed GAP.

Reproductive drinking water risk assessment

No risk assessment is required because there will be no exposure to wild mammals, indicating Oxamyl 10SL presents no unacceptable acute risk to mammals when used according to the proposed GAP.

Acceptance of bait, granules or treated seeds by terrestrial vertebrates (palatability test)

Oxamyl 10SL is not intended for use as bait, granules, or seed.

Effects of secondary poisoning

The log K_{ow} of oxamyl is less than 3, and log K_{ow} of soil metabolites (IN-A2213, IN-D2708, IN-N0079) <3. Therefore, estimation of potential risks from exposure through consumption of earthworms, fish, and terrestrial vertebrate prey are not warranted.

Exposure from earthworm to earthworm-eating mammals

No risk assessment is required.

Exposure from fish to fish-eating mammals

No risk assessment is required.

Biomagnification in terrestrial food chains

The list of endpoints on ADME studies in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU and on metabolism studies with livestock in the Oxamyl EU Renewal Dossier, Document M-CA, Section 6, DuPont-40933 EU reports a low risk of bioaccumulation for oxamyl. Therefore, no further assessment is required.

Supervised cage or field trials or other appropriate studies

Supervised cage/field trials with the formulation were not performed, since low risk to mammals indicates that further studies are not required.

Mammal risk assessment conclusion

There will be no exposure to wild mammals, indicating Oxamyl 10SL presents no unacceptable acute risk to mammals when used according to the proposed GAP.

B.9.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

There will be no exposure to terrestrial wildlife, indicating Oxamyl 10SL presents no unacceptable acute risk when used according to the proposed GAP. Therefore, no additional testing is necessary.

B.9.2 Risk assessment for birds and other terrestrial vertebrates

B.9.2.1 Risk assessment for birds

Toxicity of oxamyl to birds

Study	Test species	Endpoints used in risk assessment
Acute toxicity	Mallard duck	LD_{50} = 3.16 mg a.s./kg bw/d
Acute toxicity	Northern bobwhite	LD_{50} = 9.5 mg a.s./kg bw/d
Acute toxicity 10SL	Northern bobwhite	LD_{50} = 11.0 mg a.s./kg bw/d
Dietary toxicity (short-term)	Northern bobwhite	LDD_{50} = 85 mg a.s./kg bw/d
Dietary toxicity (short-term)	Mallard duck	LDD_{50} = 96.6 mg a.s./kg bw/d
Reproductive toxicity (long-term)	Mallard duck	NOEC = 1.5 mg a.s./kg bw/d
Reproductive toxicity (long-term)	Northern bobwhite	NOEC = 4.36 mg a.s./kg bw/d

Details of avian studies are provided in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

Application conditions

Good Agricultural Practices are summarised in the Oxamyl EU Renewal Dossier, Document D, Part 1, DuPont-40925 EU.

Exposure scenario

The product will be used within enclosed spaces (glasshouses); therefore, birds are considered to be not exposed to residues of the formulated product, the active substance oxamyl, or its metabolites.

Risk Assessment assumptions

Avian toxicity endpoints

A summary of the acute, short-term, and sub-chronic toxicity endpoints of oxamyl to birds is provided in Table 5. Details of avian studies are provided in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

Table 5 Summary of avian toxicity endpoints for oxamyl and Oxamyl 10SL

Toxicity study (species)	Test substance	LD_{50} or LC_{50}	Lowest lethal dose	NOEL or NOEC	Reference[a]
Acute oral (mallard)	Oxamyl	3.16 mg a.s./kg bw	3.16 mg a.s./kg bw	1.0 mg a.s./kg bw	HLO 89-81
Acute oral (northern bobwhite)	Oxamyl	9.5 mg a.s./kg bw	2.2 mg a.s./kg bw	0.8 mg a.s./kg bw	DuPont-2954
Acute oral (northern bobwhite)	Oxamyl 10SL	11.0 mg a.s./kg bw	8.0 mg a.s./kg bw	1.0 mg a.s./kg bw	DuPont-2956[b]
Short-term dietary (mallard)	Oxamyl	96.6 mg a.s./kg bw (766 mg a.s./kg feed)	313 mg a.s./kg feed	<78 mg a.s./kg feed	HLO 48-88
Short-term dietary (northern bobwhite)	Oxamyl	85 mg a.s./kg bw (340 mg a.s./kg feed)	156 mg a.s./kg feed	39 mg a.s./kg feed	HLO 47-88
Subchronic and reproductive (mallard)	Oxamyl	Not calculated	10 mg a.s./kg feed	1.5 mg a.s./kg bw/day (10 mg a.s./kg feed)	HLO 337-82
Subchronic and reproductive (northern bobwhite)	Oxamyl	Not calculated	50 mg a.s./kg feed	4.36 mg a.s./kg bw/day (50 mg a.s./kg feed)	HLO 453-82

[a] Reports reviewed and summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

b Report summarised in Point B.9.1.1 in this document.

Oxamyl metabolites

The product will be used within enclosed spaces (glasshouses); therefore, birds are not considered to be exposed to residues of the formulated product, the active substance oxamyl, or its metabolites.

Exposure scenario

No risk assessment is required because there will be no exposure to wild birds.

Guidelines

The avian risk assessment is based on the Guidance of EFSA. Risk Assessment for Birds and Mammals, European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal 2009: 7(12):1438.

Exposure *via* Drinking Water

Acute drinking water risk assessment

No risk assessment is required because there will be no exposure to wild birds.

Reproductive drinking water risk assessment – puddle scenario

No risk assessment is required because there will be no exposure to wild birds.

Avian risk assessment conclusion

Safe uses in glasshouses can be concluded because there will be no exposure to wild birds after use in glasshouses in drip irrigation or as a soil sterilant.

Effects of secondary poisoning

Bioaccumulation and food chain behaviour

The log K_{ow} of oxamyl is less than 3, and log K_{ow} of soil metabolites (IN-A2213, IN-D2708, IN-N0079) <3. Therefore, estimation of potential risks from exposure through consumption of earthworms, fish, and terrestrial vertebrate prey are not warranted.

Exposure from earthworm to earthworm-eating birds

No risk assessment is required.

Biomagnification in terrestrial food chains

The list of endpoints on ADME studies in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU and on metabolism studies with livestock in the Oxamyl EU Renewal Dossier, Document M-CA, Section 6, DuPont-40933 EU reports a low risk of bioaccumulation for oxamyl. Therefore, no further assessment is required.

RMS comment: In open glasshouse, birds can have access. The conclusion of no exposure of birds to oxamyl residues after drip irrigation is guaranteed only if the glasshouse is closed. Hence, the conclusion of no risk is acceptable only if application of the product is made in closed glasshouse.

B.9.2.2 Risk assessment for terrestrial vertebrates other than bird

Mammalian toxicity endpoints

The mammalian toxicity endpoints for oxamyl that are most appropriate for acute and long-term ecological risk assessment are summarised above. Further details can be found in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU.

A summary of all mammal toxicology endpoints used in the risk assessment is provided in Table 6.

Table 6 Summary of mammal toxicity endpoints for oxamyl and oxamyl 10SL

Toxicity study (species)	Test substance	LD_{50} or LC_{50} (mg a.s. or metabolite/kg bw/day)	Lowest lethal dose (mg oxamyl/kg bw/day)	NOEL or NOEC (mg oxamyl/kg bw/day)	Reference[a]
Acute oral (rat)	oxamyl	3.1 (males) 2.5 (females)	2.5	<1.0	DuPont-26931
Acute oral (rat)	Oxamyl 10SL	3.9 (males + females)	3.9	<2.2	DuPont-2140[b]
Acute oral (rat)	IN-A2213	ALD = 11000	11000	90	HLR 300-68
Acute oral (rat)	IN-D2708	LD_{50} = 3540	5000	Not given	HLR 399-72
Acute oral (rat)	IN-L2953	LD_{50} = 6675	4000	<4000	HLR 126-73
Acute oral (rat)	IN-N0079	ALD = 450	450	Not given	HLR 585-74
Subchronic and reproductive (rat)	oxamyl	Not applicable	5.43 (150 mg a.s./kg feed)	1.43 (25 mg a.s./kg feed)	HLR 423-90

[a] Studies are cited in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932 EU unless otherwise noted.

[b] Study cited in the Oxamyl EU Renewal Dossier, Document M-CP, Section 7 for Oxamyl 10SL, DuPont-42127 EU.

Guidelines

The mammalian risk assessment is based on Guidance of EFSA. Risk Assessment for Birds and Mammals, European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal 2009: 7(12):1438.

Application conditions

Refer the Oxamyl EU Renewal Dossier, Document D, Part 1, DuPont-40925 EU for application conditions.

Exposure

The product will be used within enclosed spaces (glasshouses); therefore, wild mammals are considered to be not exposed to residues of the formulated product, the active substance oxamyl, or its metabolites.

Risk assessment assumptions

No risk assessment is required because there will be no exposure to wild mammals.

RMS comment: In open glasshouse, mammals can have access. The conclusion of no exposure of birds to oxamyl residues after drip irrigation is guaranteed only if the glasshouse is closed. Hence, the conclusion of no risk is acceptable only if application of the product is made in closed glasshouse.

B.9.3 Effects on aquatic organisms

B.9.3.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Fish acute toxicity

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

B.9.3.1/01

Reference: CP 10.2.1/02	**Report:**	[redacted] (2000b); Oxamyl 10L: Static, acute, 96-hour, ($LC5_0$) test to rainbow trout, *Oncorhynchus mykiss* **DuPont Report No.:** DuPont-2910 **Guidelines:** U.S, EPA 72-1 (1988), EEC Method C.1. (1992), OECD 203 (1992) **Deviations:** None that affect the validity of the study. **Testing Facility:** [redacted] **Testing Facility Report No.:** 1817-DU **GLP:** Yes **Certifying Authority:** Laboratories in the USA are not certified by any governmental agency, but are subject to regular inspections by the U.S. EPA.

Executive summary:

The acute toxicity of Oxamyl 10SL to unfed fingerling rainbow trout, *Oncorhynchus mykiss*, a coldwater fish was determined in an unaerated, static, 96-hour dose response test. The test was conducted in accordance with U.S. EPA 72-1 (1988), EEC Method C.1. (1992) and OECD 203 (1992). Treatments consisted of a dilution water control and five nominal concentrations of 13, 22, 36, 60, and 100 mg Oxamyl 10SL/L. The corresponding mean, measured concentrations of oxamyl were 1.28, 2.16, 3.60, 6.18, and 10.4 mg oxamyl/L. The 96-hour LC_{50} for *Oncorhynchus mykiss* based on nominal concentrations and mortality was 27 mg Oxamyl 10SL/L.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-381
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Shown to be stable in the test system by analysis
2.	Control:	[redacted] dilution water
	Test vehicle:	[redacted] dilution water
	Toxic reference:	None

3.	Test organism:	Rainbow trout
	Species:	*Oncorhynchus mykiss*
	Age at dosing:	Life stage: fingerling
	Initial population:	5 fish per test chamber (2 reps/concentration)
	Source:	[redacted]
	Acclimation period:	16 days
	Diet:	Pre-test (approx. 48 hr): unfed Test period: unfed
	Test chamber:	Glass aquaria (40 l × 20 w × 25 h cm) holding approx 10 L of test solution (13 cm liquid depth)
	Test medium:	[redacted] dilution water
4.	Environmental conditions (in-life period)	
	Temperature:	12.1 to 12.7°C (of test solution)
	Water control Hardness	40 mg/L as CaCO3
	Oxygen concentration	9.0 - 9.6 mg/L (mean = 9.4 mg/L)
	pH	7.4 -7.8
	Photoperiod:	16 hr light (approx 170 lux) and 8 hr dark including 15 min transitional light preceding and following the 16-hr light interval

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

23-July-1999 to 01-November-1999

2. Experimental treatments

The acute toxicity of Oxamyl 10SL to unfed fingerling rainbow trout, *Oncorhynchus mykiss*, a coldwater freshwater fish, was determined in an unaerated, static, 96-hour dose-response test. Treatments consisted of a dilution water control and five nominal concentrations of 13, 22, 36, 60, and 100 mg Oxamyl 10SL/L. Two replicate control test chambers and two replicate test concentration chambers containing 5 fish each were exposed to each treatment concentration and control (total of 10 fish in the dilution water control and 10 fish in the test concentration). Samples were analyzed using a Hewlett Packard Series 1100 HPLC equipped with a UV detector at the beginning and at test end (or on the day of total mortality).

3. Observations

Mortality and behavioural observations were made every 24 hours. Dead fish were removed from the test chambers when observed.

4. Statistics

The 24-, 48-, 72-, and 96-hour LC_{50}s and their 95% confidence intervals were calculated using the number of dead fish and nominal Oxamyl 10SL concentration. The binomial method was used to calculate 24-, 48-, and 72-hr LC_{50}s and 95% confidence limits and the probit method was used to calculate the 96-hr LC_{50} and 95% confidence limits. The probit method was also used for determination of the slope of the concentration-response curve.

II. RESULTS AND DISCUSSION

A. FINDINGS

At test conclusion, fish from the water control ranged from 2.72 to 3.30 cm in total length (mean 3.08 cm), and 0.20 to 0.31 g in wet weight, blotted dry (mean 0.24 g). Total length of the longest fish was not more than twice the length of the shortest fish in the control. Loading in the water control was 0.12 g/L at test conclusion.

During the 96h, the test solution concentrations were maintained within 20% of nominal. Mean, measured concentrations of oxamyl were 1.28, 2.16, 3.60, 6.18, and 10.4 mg oxamyl/L and ranged from 98 to 104% of nominal concentrations. .All validation criteria were met for the study. No mortality was observed in the dilution water control and none of the surviving control fish were affected. A summary of cumulative mortality and sublethal effects is presented in Table 7 and Table 8, respectively.

Table 7 Observed mortality of rainbow trout, *Oncorhynchus mykiss*, exposed to Oxamyl 10SL for 96 hours in an unaerated, static, acute test

Nominal Oxamyl 10SL concentration (mg/L)	Cumulative mortality (No. dead/No. at test start)[a]							
	24 hour		48 hour		72 hour		96 hour	
	A	B	A	B	A	B	A	B
Water Control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
13	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
22	0/5	0/5	0/5	0/5	0/5	0/5	2/5	1/5
36	5/5	2/5	5/5	3/5	5/5	3/5	5/5	3/5
60	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5
100	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5

[a] A and B represent replicates; each replicate contained 5 fish (total 10 fish per test concentration) at test start.

Table 8 Observed sublethal effects of rainbow trout, *Oncorhynchus mykiss*, exposed to Oxamyl 10SL for 96 hours in an unaerated, static, acute test

Nominal Oxamyl 10SL concentration (mg/L)	Sublethal effects (Number affected/Number alive)[a]							
	24 hour		48 hour		72 hour		96 hour	
	A	B	A	B	A	B	A	B
Water Control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
13	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
22	0/5	0/5	2[b]/5	0/5	1[b]/5	0/5	0/3	0/4
36	L	0/3	L	0/2	L	1[b]/2	L	1[b]/2
60	L	L	L	L	L	L	L	L
100	L	L	L	L	L	L	L	L

[a] A and B represent replicates; each replicate contained 10 fish (total 20 fish per test concentration) at test start.

[b] Loss of equilibrium

L Total mortality

III. CONCLUSION

The 96-hour LC_{50} for *Oncorhynchus mykiss* based on mortality and nominal concentrations and mortality was 27 mg Oxamyl 10SL/L (c.i., 22-33 mg Oxamyl 10SL/L.

([redacted] 2000b)

RMS comments and conclusion

The RMS added additional details to the study summary.
The study fulfils the validity criteria according to current OECD 203 (1992). Nevertheless, it is noted that:
- Fish were starved for 2 d prior the test instead of 1d.
- Control fish were smaller (from 2.72 to 3.30 cm in total length, with mean of 3.08 cm) than the recommended length for rainbow trout of 5.0 ±1.0 cm.

Conclusion: the noted deviations are not considered severe, hence also taking into account issues of animal welfare, the study is judged acceptable.

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

B.9.3.1/02

Reference: CP 10.2.1/03	**Report:**	[redacted] (2000c); Oxamyl 10L: Static-renewal, acute, 96-hour, (LC_{50}) test to bluegill sunfish, *Lepomis macrochirus* **DuPont Report No.:** DuPont-2911 **Guidelines:** U.S. EPA 72-1 (1988),OECD 203 (1992),EEC Method C.1. (1992) **Deviations:** None that affect the validity of the study. **Testing Facility:** [redacted] **Testing Facility Report No.:** 1818-DU **GLP:** Yes **Certifying Authority:** Laboratories in the USA are not certified by any governmental agency, but are subject to regular inspections by the U.S. EPA.

Executive summary:

The acute toxicity of Oxamyl 10SL to unfed juvenile bluegill sunfish, *Lepomis macrochirus*, a coldwater fish was determined in an unaerated, static-renewal, 96-hour dose response test.The test was conducted in accordance with U.S. EPA 72-1 (1988),OECD 203 (1992), and EEC Method C.1. (1992). Treatments consisted of a dilution water control and five nominal concentrations of 13, 22, 36, 60, and 100 mg Oxamyl 10SL/L. The corresponding mean, measured concentrations of oxamyl were 1.27, 2.05, 3.40, 5.73, and 9.52 mg oxamyl/L. The 96-hour LC_{50} for *Lepomis macrochirus* based on nominal concentrations and mortality was 51 mg Oxamyl 10SL/L.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-381
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Shown to be stable in the test system by analysis
2.	Control:	[redacted] dilution water
	Test vehicle:	[redacted] dilution water
	Toxic reference:	None

3.	Test organism:	Bluegill sunfish
	Species:	*Lepomis macrochirus*
	Age at dosing:	Life stage: juvenile
	Initial population:	5 fish per test chamber (two replicates/concentration)
	Source:	[redacted]
	Acclimation period:	82 days at 22 ±2°C
	Diet:	Pre-test (approx. 48 hr): unfed Test period: unfed
	Test chamber:	Glass aquaria (40 l × 20 w × 25 h cm) holding approx 10 L of test solution (13 cm liquid depth)
	Test medium:	[redacted] dilution water
4.	Environmental conditions (in-life period)	
	Temperature:	21.5 to 22.3°C (of test solution)
	Water control EDTA Hardness	48 mg/L as CaCO3
	Conductivity	140-180 µmhos/cm
	Oxygen concentration	7.7 – 8.9 mg/L (mean = 9.4 mg/L)
	pH	7.2 -7.9
	Photoperiod:	16 hr light (approx 550 lux) and 8 hr dark including 15 min transitional light preceding and following the 16-hr light interval

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

10-August-1999 to 30-October-1999

2. Experimental treatments

The acute toxicity of Oxamyl 10SL to unfed fingerling juvenile bluegill sunfish, *Lepomis macrochirus*, a coldwater freshwater fish, was determined in an unaerated, static-renewal, 96-hour dose-response test. Solutions were renewed daily. Treatments consisted of a dilution water control and five nominal concentrations of 13, 22, 36, 60, and 100 mg Oxamyl 10SL/L. Two replicate control test chambers and two replicate test concentration chambers containing 5 fish each were exposed to each treatment concentration and control (total of 10 fish in the dilution water control and 10 fish in the test concentration). Samples were analyzed using a Hewlett Packard Series 1100 HPLC equipped with a UV detector at the beginning and at test end (or on the day of total mortality).

3. Observations

Mortality and behavioural observations were made every 24 hours. Dead fish were removed from the test chambers when observed.

4. Statistics

The 24-, 48-, 72-, and 96-hour LC_{50}s and their 95% confidence intervals were calculated using the number of dead fish and nominal Oxamyl 10SL concentration. The probit method was used to calculate LC_{50}s and 95% fiducial limits. The probit method was also used for determination of the slope of the concentration-response curve.

II. RESULTS AND DISCUSSION

A. FINDINGS

At test conclusion, fish from the water control ranged from 2.73 to 3.73 cm in total length (mean 3.05 cm), and 0.19 to 0.48 g in wet weight, blotted dry (mean 0.30 g). Total length of the longest fish was not more than twice the length of the shortest fish in the control. Loading in the water control was 0.15 g/L at test conclusion.

During the 96h test, the test solution concentrations were maintained within 20% of nominals. Mean, measured concentrations of oxamyl were 1.27, 2.05, 3.40, 5.73, and 9.52 mg oxamyl/L and ranged from 93 to 98% of nominal concentrations. All validation criteria were met for the study. No mortality was observed in the dilution water control and none of the surviving control fish were affected. A summary of cumulative mortality and sublethal effects is presented in Table 9 and Table 10, respectively.

Table 9 Observed mortality of bluegill sunfish, *Lepomis macrochirus*, exposed to Oxamyl 10SL for 96 hours in an unaerated, static, acute test

Nominal Oxamyl 10SL concentration (mg/L)	Cumulative mortality (No. dead/No. at test start)[a]							
	24 hour		48 hour		72 hour		96 hour	
	A	B	A	B	A	B	A	B
Water Control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
13	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
22	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
36	0/5	0/5	0/5	1/5	1/5	1/5	1/5	1/5
60	1/5	0/5	1/5	2/5	2/5	2/5	2/5	4/5
100	3/5	4/5	5/5	5/5	5/5	5/5	5/5	5/5

[a] A and B represent replicates; each replicate contained 10 fish (total 20 fish per test concentration) at test start.

Table 10 Observed sublethal effects of bluegill sunfish, *Lepomis macrochirus*, exposed to Oxamyl 10SL for 96 hours in an unaerated, static, acute test

Nominal Oxamyl 10SL concentration (mg/L)	Sublethal effects (Number affected/Number alive)[a]							
	24 hour		48 hour		72 hour		96 hour	
	A	B	A	B	A	B	A	B
Water Control (0.0)	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
13	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
22	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
36	0/5	0/5	0/5	0/4	0/4	0/4	0/4	0/4
60	0/4	0/5	$2^{b,c}$/5	0/3	$3^{b,c}$/3	$3^{b,c}$/3	$3^{b,c}$/3	$1^{b,c}$/1
100	$2^{b,c}$/2	$1^{b,c}$/1	L	L	L	L	L	L

[a] A and B represent replicates; each replicate contained 10 fish (total 20 fish per test concentration) at test start.

[b] Lethargic

[c] Discolored

L Total mortality

III. CONCLUSION

The 96-hour LC_{50} for *Lepomis macrochirus* based on mortality and nominal concentrations was 51 mg (c.i., 41-64) Oxamyl 10SL/L.

([redacted] 2000c)

RMS comments and conclusion

The RMS added additional details to the study summary.

The study fulfils the validity criteria according to current OECD 203 (1992). Nevertheless, it is noted that:
-Fish were starved for 2 d prior the test instead of 1d.

-The fish total length was 2.73 to 3.73 cm, i.e. somewhat longer than the recommended 2.0 ±1.0 cm, anyhow the total length of the longest fish was not more than twice the length of the shortest fish in the control.

Conclusion: the noted deviations are not considered severe, The test is valid and the results acceptable.

***Daphnia* acute toxicity**

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

B.9.3.1/03

Reference: CP 10.2.1/04	**Report:**	Ward, T.J., Magazu, J.P., Boeri, R.L. (2000a); Oxamyl 10L: Acute, static-renewal, 48-hour EC_{50} to *Daphnia magna* **DuPont Report No.:** DuPont-2556 **Guidelines:** U.S. EPA 72-2 (1988), EEC Method C.2. (1992), OECD 202 (1984) **Deviations:** None that affect the validity of the study. **Testing Facility:** T.R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA **Testing Facility Report No.:** 1767-DU **GLP:** Yes **Certifying Authority:** Laboratories in the USA are not certified by any governmental agency, but are subject to regular inspections by the U.S. EPA.

Executive summary:

The acute toxicity of Oxamyl 10SL to unfed *Daphnia magna* was determined in an unaerated, static-renewal, 48-hour test. The test was conducted in accordance with U.S. EPA 72-2 (1988), EEC Method C.2. (1992), OECD 202 (1984). Treatments consisted of a dilution water control and five nominal concentrations of 1.3, 2.2, 3.6, 6.0, and 10 mg Oxamyl 10SL/L. The corresponding mean, measured concentrations of oxamyl were 0.132, 0.224, 0.366, 0.618, and 0.970 mg oxamyl/L. The 48-hour EC_{50} for *Daphnia magna* based on immobility and nominal concentrations was 3.0 mg Oxamyl 10SL/L.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-381
	Purity:	100 g a.s./L (10.02% by analysis)
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Shown to be stable in the test system by analysis
2.	Control:	T.R. Wilbury Laboratory dilution water
	Test vehicle:	T.R. Wilbury Laboratory dilution water
	Toxic reference:	None
3.	Test organism:	
	Species:	*Daphnia magna*
	Age at dosing:	<24 hours
	Initial population:	10 daphnids per test chamber
	Source:	Aquatic Biosystems, Inc., Fort Collins, Colorado, USA
	Diet:	Unfed during test
	Test chamber:	250-mL Pyrex beaker containing 200 mL of test solution (6.5-cm test solution depth), loosely covered with clear plastic sheets
4.	Environmental conditions (in-life period)	
	Temperature:	20.3 to 20.8°C (of recirculating waterbath used to maintain test chamber temperature)
	Conductivity	560 - 590 µmhos/cm (mean = 580 µmhos/cm)
	Alkalinity	90-95 mg/L as CaCO3
	Hardness	176- 180 mg/L as CaCO3
	pH	7.5 - 7.9,
	Dissolved oxygen	8.6 to 9.1 mg/L (mean = 8.9 mg/L),
	Photoperiod:	16 hr photoperiod (500 lux) and 8 hr darkness which included 15 min transitional light preceding and following the 16-hr light interval

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

22-July-1999 to 29-October-1999

2. Experimental treatments

The acute toxicity of Oxamyl 10SL to unfed *Daphnia magna* (<24-hour old and collected 22 days after the first appearance of neonates in the parent culture)) was determined in an unaerated, static-renewal, 48-hour test. The test solutions were renewed at 24 hours. Daphnids were transferred to freshly prepared test solutions.Treatments consisted of a dilution water control and five nominal concentrations of 1.3, 2.2, 3.6, 6.0, and 10 mg Oxamyl 10SL/L. The dilution water control met OECD and ASTM dilution water criteria and specifications and contained no solvent. The pH of the dilution water was adjusted to approximately 7.5 with phosphoric acid. Ten daphnids were used per replicate with two replicates per test concentration and control. Actual concentrations of oxamyl to which the Daphnia were exposed were determined by chemical analysis at 0 and 48 hours using a Hewlett Packard Series 1100 HPLC equipped with a UV detector. Chemico-physical parameters were measured in fresh and old solutions at 0, 24 and 48h as appropriate.

3. Observations

Immobility and behavioural observations were made every 24 hours.

4. Statistics

The 24- and 48-hour EC_{50}s and their 95% confidence intervals their 95% confidence intervals were calculated using the number of immobilised daphnids and nominal Oxamyl 10SL concentrations. The binomial method was used to calculate the 24 and 48 hour EC_{50} values and 95% confidence limits. The slope of the 48-hour concentration-response curve was calculated by the probit method.

II. RESULTS AND DISCUSSION

A. FINDINGS

During the 48h test, the test solution concentrations were maintained within 20% of nominals. Mean, measured concentrations of oxamyl were 0.132, 0.224, 0.366, 0.618, and 0.970 mg oxamyl/L and ranged from 97 to 103% of nominal concentrations. All validation criteria were met for the study. There were no sublethal effects other than immobility observed at any time. A summary of observed immobility and sublethal effects is presented in the tables below.

Table 11 Summary of observed immobility of unfed *Daphnia magna* exposed to Oxamyl 10SL for 48 hours in an unaerated, static-renewal, acute test

Nominal Oxamyl 10SL concentration (mg/L)	Immobility (No. immobile/No. at test start) [a]			
	24 hours		48 hours	
	A	B	A	B
Dilution water control (0.0)	0/10	0/10	1/10	0/10
1.3	1/10	0/10	1/10	0/10
2.2	0/10	0/10	0/10	0/10
3.6	3/10	3/10	10/10	8/10
6.0	10/10	10/10	10/10	10/10
10	10/10	10/10	10/10	10/10

[a] A and B represent replicate test chambers containing 10 daphnids each at test start.

Table 12 Summary of sublethal effects of unfed *Daphnia magna* exposed to Oxamyl 10SL for 48 hours in an unaerated, static-renewal, acute test

Nominal Oxamyl 10SL concentration (mg/L)	Number affected/Number alive[a]			
	24 hours		48 hours	
	A	B	A	B
Dilution water control (0.0)	0/10	0/10	0/9	0/10
1.3	0/9	0/10	0/9	0/10
2.2	0/10	0/10	0/10	0/10
3.6	0/7	0/7	I	0/2
6.0	I	I	I	I
10	I	I	I	I

[a] A–D represent replicate test chambers containing 10 daphnids each at test start.

I Total immobility in test replicate

III. CONCLUSION

The 48-hour EC_{50} for *Daphnia magna* based immobility and on nominal concentrations was 3.0 mg Oxamyl 10SL/L (c.i., 2.2-3.6).

(Ward, T.J., Magazu, J.P., Boeri, R.L., 2000a)

RMS comments and conclusion

The acute toxicity to *Daphnia magna* study DuPont-2556 was conducted under guidelines OECD 202 (1984), EEC Method C.2. (1992), and U.S. EPA 72-2 (1988). A review of this study indicates that it fully meets the current guideline OECD 202 (2004). The validity criteria are fulfilled:

- No more than 10% immobilisation or other sign of disease/stress in the control (actual 5%);

DO at the end of test ≥ 3 mg/L in the control and test vessels (actual 8.6 mg/L

Conclusion: The study is acceptable study is relied upon.

Algal growth and growth rate

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

B.9.3.1/04

Reference: **CP 10.2.1/01**	**Report:**	Boeri, R.L., Ward, T.J. (2000); Oxamyl 10L: Influence on growth and growth rate of the alga, *Selenastrum capricornutum* **DuPont Report No.:** DuPont-3913 **Guidelines:** OECD 201 (1984) **Deviations:** None that affect the validity of the study. **Testing Facility:** T.R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA **Testing Facility Report No.:** 1982-DU **GLP:** Yes **Certifying Authority:** Laboratories in the USA are not certified by any governmental agency, but are subject to regular inspections by the U.S. EPA.

Executive summary:

The effect of Oxamyl 10SL on the growth and growth rate of the green alga *Pseudokirchneriella subcapitata* (formerly known as *Selenastrum capricornumtum*) was determined in a 72-hour test without test medium renewal. The test was conducted according to OECD 201 (1984). Treatments consisted of five nominal concentrations of 4.0, 8.0, 15, 30, and 60 mg Oxamyl 10SL/L and an untreated control. The EC_{50} and NOEC for *Pseudokirchneriella subcapitata* were based on nominal concentrations and cell count (density), area under the curve, and growth rate. The 72-hr E_bC_{50} based on cell count was 16 mg Oxamyl 10SL/L and the NOEC was <4.0 mg Oxamyl 10SL/L. The 72-hr E_bC_{50} based on area under the curve was 16 mg Oxamyl 10SL/L and the NOEC was <4.0 mg Oxamyl 10SL/L. The 72-hr E_rC_{50} based on growth rate was 34 mg Oxamyl 10SL/L and the NOEC was <4.0 mg Oxamyl 10SL/L. After 96 hours of the recovery period, the number of healthy cells increased at least 16X indicating that the effect of Oxamyl 10SL at concentrations equal to or below 60 mg/L are algistatic rather than algicidal.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-381
	Purity:	10.02% (100 g a.s./L)
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Shown to be stable for less than 72h in the test system by analysis
2.	Control:	AAP nutrient medium
	Test vehicle:	AAP nutrient medium
	Toxic reference:	None
3.	Test organism:	Green alga
	Species:	*Pseudokirchneriella subcapitata* (formerly known as *Selenastrum capricornutum)*
	Initial population:	Approximately 10000/mL
	Source:	Origin: Department of Botany - Culture Collection of Algae - The University of Texas at Austin - Austin, Texas
	Growth medium:	AAP nutrient medium
	Test chamber:	250-mL Erlenmeyer flask containing 100 mL of test solution and loosely capped with inverted glass beakers, randomly arranged on a rotary shaker adjusted to 100 rpm
4.	Environmental conditions (in-life period)	
	Temperature:	23.1 to 23.4°C (Environmental growth chamber)
	Photoperiod:	24 hour light (100 to 110 μEin/m2sec/ 6800 to 8100 lux)

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

25-April-2000 to 17-July-2000

2. Experimental treatments

A study was conducted to determine the effect of Oxamyl 10SL on the growth and growth rate of the green alga *Pseudokirchneriella subcapitata* (formerly known as *Selenastrum capricornutum*). The algae were exposed to an untreated control and five nominal concentrations of 4.0, 8.0, 15, 30, and 60 mg Oxamyl 10SL/L in AAP nutrient medium for 72 hours without test medium renewal. Each test concentration was tested as 3 replicates and the untreated control was tested as 6 replicates. After the initial 72-hour exposure period, the ability of the organisms to recover (algistatic/algicidal test) was assessed. Algae were collected from the 60 mg Oxamyl 10SL/L concentration 0.5 mL of solution from each replicate and brought up to 100 mL with fresh nutrient medium without Oxamyl 10SL and recovery assessed after an additional 96 hours.

3. Observations

Test concentrations were measured on Day 3 to verify stability of the test item. Healthy cell counts were recorded approximately 0, 24, 48, and 72 hours after test initiation. Healthy cell count (cell density), area under the growth curve, and growth rate were recorded and expressed as percent inhibition relative to the blank control following exposure to Oxamyl 10SL for 72 hours. To assess recovery of the algae after the initial 72-hour exposure period, cell counts were determined on Day 4 of recovery (96 hours). pH was determined in each test chamber at the beginning and end of the test.

4. Statistics

Results of the toxicity test were interpreted by standard statistical techniques. The 72-hour EC_{50} values were calculated using the nominal concentration of Oxamyl 10SL and the number of cells per mL, the

average specific growth rate, and the area under the growth curve by a weighted least squares non-linear regression technique described by Bruce and Versteeg. The slope of the concentration-response curve cannot be calculated by this method. The no observed effect concentration (NOEC) was determined using a one-way analysis of variance (ANOVA) and Bonferroni's test (TOXSTAT 3.3). It was calculated using the number of cells/mL, the average specific growth rate, and the area under the growth curve.

II. RESULTS AND DISCUSSION

A. FINDINGS

Initial measured concentrations of the active ingredient, oxamyl, were 0.427, 0.869, 1.67, 3.25, and 6.60 mg/L, and ranged from 107 to 111% of nominal, indicating accuracy of the test concentration solutions. After 3 days, the mean, measured concentrations of the test item were <LOQ, <LOQ, <LOQ, 1.44, and 3.61 mg oxamyl/L. The untreated control solutions contained no detectable concentrations of oxamyl on both Day 0 and Day 3. Oxamyl 10SL was determined not to be stable over the course of the test, based on the analysis of 72h samples as shown in the table below All validation criteria were met.

Nominal concentrations of Oxamyl 10L, mg/L	Test media control and 4.0, 8.0, 15, 30, and 60
Initial, measured concentrations of Oxamyl[a], mg/L	<LOQ[b] (test media control), 0.427, 0.869, 1.67, 3.25, and 6.60
Final, measured concentrations of Oxamyl[a], mg/L	<LOQ[b] (test media control), <LOQ, <LOQ, <LOQ, 1.44, and 3.61
72 hour EC_{50} for Oxamyl 10L, mg/L, based on nominal concentrations	16 (cell per ml), 34 (growth rate), 16 (area under growth curve)

[a] Oxamyl 10L contains 10.02% Oxamyl (active ingredient) by analysis.
[b] <LOQ denotes below the limit of quantitation of 0.0142 mg/L.

No effects (size differences, unusual cell shapes, colors, flocculations, adherence of cells to test containers, or aggregation of cells) were noted during the test.

Average Specific Growth Rate and Percent of Control from the Toxicity Test with the Freshwater Alga, *Selenastrum capricornutum,* and Oxamyl 10L

Nominal Total Formulation Concentration of Oxamyl 10L (mg/L)	Average Specific Growth Rate		
	24 hour	48 hour	72 hour
0 (control)	0.053	0.073	0.076
4.0	0.051	0.072	0.073
8.0	0.051	0.065	0.072
15	0.035	0.062	0.066
30	0.017	0.041	0.046
60	0.004	0.004	0.007

Nominal Total Formulation Concentration of Oxamyl 10L (mg/L)	Percent of Control		
	24 hour	48 hour	72 hour
0 (control)	--	--	--
4.0	96	99	96
8.0	96	89	95
15	66	85	87
30	32	56	61
60	8	5	9

A summary of algal growth inhibition following exposure of *Pseudokirchneriella subcapitata* to Oxamyl 10SL for 72 hours is presented in the table that follows.

Table 13 Summary of algal growth inhibition following exposure of *Pseudokirchneriella subcapitata* to Oxamyl 10SL for 72 hours

Nominal Oxamyl 10SL concentration (mg/L)	**% Inhibition relative to control[a]**		
	Cell density	**Average Specific Growth Rate**	**Area Under the Growth Curve**
Untreated Control (0.0)	—	—	—
4.0	20[b]	4[b]	16[b]
8.0	22[b]	5[b]	25[b]
15	49[b]	13[b]	48[b]
30	89[b]	39[b]	87[b]
60	99[b]	91[b]	>99[b]

[a] positive values indicate stimulation; negative values indicate inhibition

[b] Significantly different from control by the Bonferroni's test criteria, $p < 0.05$.

The 60 mg Oxamyl 10SL/L concentration exhibited greater than 50% inhibition. Algae from this concentration was used to assess recovery. During the algistatic/algicidal test set up for 96 hours, algae increased from a calculated cell concentration of approximately 250 cells per mL to 710,000 cells/mL. Recovery data indicate that the effect of Oxamyl 10SL at nominal concentrations equal to or below 60 mg/L are algistatic rather than algicidal.

III. CONCLUSIONS

The effects of Oxamyl 10SL on growth and growth rate of *Pseudokirchneriella subcapitata* expressed as mg/L (nominal) were as follows:

Healthy Cell Count (density):	72-hr E_bC_{50} = 16 mg Oxamyl 10SL (15 -18 mg/L) 72-hr NOEC = <4.0 mg Oxamyl 10SL
Area Under the Growth Curve:	72-hr E_bC_{50} = 16 mg Oxamyl 10SL (15 -18 mg/L) 72-hr NOEC = <4.0 mg Oxamyl 10SL
Growth Rate:	72-hr E_rC_{50} = 34 mg Oxamyl 10SL (33 to 35 mg/L) 72-hr NOEC = <4.0mg Oxamyl 10SL

The effects on growth and growth rate of *Pseudokirchneriella subcapitata* were found to be algistatic, *i.e*., the number of healthy cells increased at least 16X within 96 hours (4 days), at concentrations less than or equal to 60 mg Oxamyl 10SL/L.

(Boeri, R.L., Ward, T.J., 2000)

RMS comments and conclusion

The RMS has corrected some mistakes in the summary and has included additional information/tables.

The test was carried in 2000 and followed the OECD 201 dated 1984 which was the adopted version at the time of testing. The RMS re-evaluated the study according to current version of the guideline (2006-2011).

The validity criteria (analyzed with Toxrat 3.2 Professional) were met: 1)The biomass in the control cultures have increased exponentially by a factor of >16 within the 72-hour test period (actual 59.5). 2) The mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is lower than 35% (actual 30.9%). 3) The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was < 7% (actual 3.1%).

The following deviations were noted:

In the control replicates, the initial pH was 7.4-7.5 while at the end of the 72h test period the pH was 10.3. The pH increased by 2.8 unit, i.e. much more than the 1.5 unit allowed in the guideline.

The OECD 201 guideline recommends that the cultures should be maintained at a temperature in the range of 21 to 24°C, controlled at ± 2°C. The reports says that the temperature of the growth chamber, measured and recorded **daily**, was 23.1 to 23.4°C, but the temperature measured continuously in a representative vessel incubated among the test vessels "was not always 24 ± 2°C, however the daily recorded temperatures were always within the specified range and this had no effect on the outcome of the study". It seems that the growth chamber was not able to maintain the chosen temperature

during the day, but. no further information is given about the amplitude and duration of this deviation (temperature raised above 26°C).

The nominal concentrations of the active ingredient, oxamyl, were not maintained during the test, hence the results should be expressed as geomean concentrations. In any case, a full concentration-effect curve cannot be established because the three lowest oxamyl, concentration dropped below the LOQ.

The GLP compliance statement states that "Personnel responsible for the preparation of analytical standards and sample analysis lacked adequate training and experience (the preparation and analysis of these samples was supervised by the analytical laboratory manager and was sufficient in lieu of training)"

Conclusion: taking into account the observed deviations and the lack of adequate concentration data, the **results are not considered reliable.**

Non-target aquatic plants

This is not an EU data requirement.

Aquatic field testing

No aquatic field testing was required for Oxamyl 10SL, oxamyl, and the major aquatic metabolites.

B.9.3.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Residue data in fish (long-term)

Residues in fish were not measured for Oxamyl 10SL since the potential for bioconcentration is low for oxamyl (see the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU).

Chronic toxicity (28-day exposure) to juvenile fish

The studies conducted with oxamyl can be used to predict the toxicity of the formulated product (see the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU). Therefore, no juvenile fish studies were conducted with the formulated product.

Fish early life stage toxicity test

The studies conducted with oxamyl can be used to predict the toxicity of the formulated product (see the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU).

Fish life cycle test

The studies conducted with oxamyl can be used to predict the toxicity of the formulated product (see the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU). Additionally, risk assessments for acute and chronic exposures in fish were acceptable and no additional studies were triggered. Therefore, no fish life cycle studies were conducted with the formulated product.

Chronic toxicity to *Daphnia magna* (21-day)

The studies conducted with oxamyl can be used to predict the toxicity of the formulated product (see RAR a.s. Vol 3, B9 and the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU and). Therefore, no chronic *Daphnia* studies were conducted with the formulated product.

Chronic toxicity for a representative species of aquatic insects

The studies conducted with oxamyl can be used to predict the toxicity of the formulated product (see RAR a.s. Vol 3, B9 and the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU). Therefore, no chronic studies were conducted with aquatic insects and the formulated product.

Chronic toxicity for a representative species of aquatic gastropod molluscs

No chronic toxicity studies were conducted with aquatic gastropod molluscs because there is no validated test guideline available. However, a study was conducted with a bivalve mollusc for a country-specific requirement in the U.S. and the study is summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

Organism	Test substance	Endpoint value	Reference[a]
Crassostrea virginica	Oxamyl a.s.	48-hour EC_{50} = 27.5 mg a.s./L (mean measured)	DuPont-34273

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

B.9.3.3 Further testing on aquatic organisms

TERs for the respective sensitive organisms pass the respective acute or long term triggers, so there is no need for further testing.

B.9.4 Risk assessment for aquatic organisms

Aquatic application conditions, exposure scenario, and risk assessment assumptions

For applications in glasshouses, drainage, condensation, and discharge of the recirculation water are the only relevant entry route to surface water. For application under permanent glasshouse conditions, an exposure of aquatic organisms as a consequence of accidental entry of the compound into the environmental compartments occupied by organisms *via* the usual entry paths for normal agricultural application such as spray drift, drainage, and run-off is low, when compared to outdoor applications. The aquatic risk assessment will consider the worst-case exposure scenario of Oxamyl 10SL applied at 20 + 10 + 10 + 10 kg product/ha by drip irrigation to tomatoes or at 55 kg product/ha for soil sterilization (solarisation). Predicted Environmental Concentrations (PECs) of the active substance oxamyl and its soil and water metabolites following application in glasshouses have been calculated and are provided in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10SL, DuPont-42129 EU. Good Agricultural Practices are summarised in the Oxamyl EU Renewal Dossier, Document D, Part 1, DuPont-40925 EU.

The formulated product, Oxamyl 10SL, and its active substance, oxamyl, were tested on a range of aquatic species in accordance with established test guidelines (B.9.3.1 and B.9.3.2 in this document and the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU). Effect levels were analytically determined in all studies except where exposure concentrations were below the limit of quantification. Testing for effects onsediment dwelling organisms was not carried out, because effects were not observed in invertebrate species at the exposure levels likely to arise following spray drift or run-off—direct application to water bodies is not proposed. A bioconcentration test was not carried out since Log P_{ow} value for oxamyl is <3, the trigger value used to determine when such testing is required, and since repeated exposure does not occur.

The major metabolites of oxamyl and their environmental compartments are summarised in Table 2. The effects of the active substance oxamyl and its major metabolites are presented in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU and Vol 3 a.s. B9 .

Aquatic toxicity endpoints

A summary of the acute and chronic aquatic toxicity profile of Oxamyl 10SL and the active substance oxamyl is provided in Table 14-16. A summary of the acute and chronic aquatic toxicity profile of metabolites of oxamyl active substance is provided in Table 17.

Table 14 Oxamyl aquatic toxicity endpoint values

Species	Test/duration	Measurement endpoint	Endpoint value (mg a.s./L)	Reference[a]
Rainbow trout	acute (96 h)	LC_{50}	3.13	DuPont-2907
Bluegill sunfish	acute (96 h)	LC_{50}	6.12	DuPont-2908
Daphnia magna	acute (48 h)	EC_{50}	0.319	DuPont-2553
Pseudokirchneriella subcapitata	chronic (120 h) not valid- data gap			DuPont-2909
Lemna gibba	chronic (7-d)	E_yC_{50} E_rC_{50}	1.670 3.30	DuPont-34272
Chironomus tentans	acute (48 h)	LC_{50}	0.350	DuPont-37400
Chimarra atterima	acute (48 h)	LC_{50}	0.096	DuPont-37402
Centroptilum triangulifer	acute (48 h)	LC_{50}	0.067	DuPont-37401
Hyalella azteca	acute (48 h)	LC_{50}	0.320	DuPont-37397
Daphnia pulex	acute (48 h) not valid	EC_{50}	not valid	DuPont-37398
Ceriodaphnia dubia	acute (48 h)	EC_{50}	0.094	DuPont-37399
Americamysis bahia	acute (48 h)	LC_{50}	0.0465	DuPont-34271
Crassostrea virginica	Acute (96 h)	EC_{50}	27.5	DuPont-34273

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

Table 15 Acute toxicity of Oxamyl 10SL to aquatic organisms

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

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

[b] Studies are summarised in this document.

Table 16 Chronic toxicity of oxamyl to aquatic organisms

Test species	Test duration	Test conc.	Effect endpoint	NOEC (mg a.s./L)	Effect parameter	Reference[a]
Fathead minnow	Early life stage (28 d)	M	NOEC	0.500 Supportive informatio	Hatch/Survival/Growth	HLR 877-81
Rainbow trout	early life stage (90 d) not valid	M			Hatch/Survival/Growth	HLR 468-88
Sheepshead minnow	early life stage (29 d)	M	NOEC	0.356	Hatch/Survival/Growth	DuPont-34270
Daphnia magna	chronic (21 d)	M	NOEC	0.0268	Immobilisation/ Reproduction	DuPont-2554
Americamysis bahia	chronic (28 d)	M	NOEC	0.0189	Immobilisation/ Reproduction	DuPont-34269

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

Table 17 Aquatic toxicity endpoint values for the metabolites of oxamyl

Metabolite	Species	Test/duration	Measurement endpoint	Endpoint value (mg met/L)	Reference[a]
IN-A2213	Rainbow trout	acute (96 h)	LC_{50}	>132	DuPont-2500
	Daphnia magna	acute (48 h)	EC_{50}	>125	DuPont-2502
	Pseudokirchneriella subcapitata	acute (72 h)	EC_{50}	>122 Supportive information	DuPont-2505
IN-D2708	Rainbow trout	acute (96 h)	LC_{50}	93.8 Supportive data	DuPont-2507
	Daphnia magna	acute 48 h)	EC_{50}	>134	DuPont-2510
	Pseudokirchneriella subcapitata	data gap			DuPont-2511
	Daphnia magna	chronic (21 d)	NOEC	66.1	DuPont-3909
IN-N0079	Rainbow trout	acute (96 h)	LC_{50}	22.4	DuPont-2512
	Daphnia magna	acute (48 h)	EC_{50}	>128	DuPont-2513
	Pseudokirchneriella subcapitata	acute (72 h) Data gap			DuPont-2514
IN-T2921	Rainbow trout	acute (96 h)	LC_{50}	>127	DuPont-4439
	Daphnia magna	acute (48 h)	EC_{50}	>123	DuPont-4441
	Pseudokirchneriella subcapitata	acute (72 h)	EC_{50}	>113	DuPont-4442

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

Exposure assessment (predicted environmental concentrations [PEC])

Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for oxamyl and its major metabolites (aquatic and soil) based on the maximum application rates in tomatoes and for solarisation using the latest FOCUS surface water exposure assessment tools (FOCUS, 2001). On the basis of the worst-case toxicity values and the relevant worst-case PEC_{sw} values, toxicity exposure ratios (TER) were calculated for acute exposure of aquatic organisms.

FOCUS Step 1-2:

The assumptions at Step 1 and 2 are very conservative and are essentially based on drift values calculated from BBA (2000) and an estimation of the potential loading of pesticides to surface water *via* run-off, erosion, and/or drainage. This "run-off" loading represents any entry of pesticide from the treated field to the associated water body at the edge of the field.

Details of the methods and assumptions used in the Step 1 and 2 calculation of PEC surface water (PEC_{sw}), and PEC sediment (PEC_{sed}) are presented in DuPont-40935, summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10SL, DuPont-42129 EU.

A summary of the predicted environmental concentrations for Oxamyl 10SL and metabolites for the purposes of calculating toxicity exposure ratios for aquatic species is provided in Table 18.

Table 18 Summary of Step 1 and 2 calculations for oxamyl and its metabolites for glasshouse uses

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[a]			
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[b]	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[b]	109.239	-	25.847	-

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

[b] 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.

FOCUS Step-3:

Ten realistic worst-case scenarios for the surface water compartment have been defined for Step 3, which collectively represent agriculture in the EU (roughly 33% of the area is covered by the scenarios). These worst-case scenarios will be used to assess the Predicted Environmental Concentration in surface water (PEC_{sw}) at the EU level for the review of active substances under Regulation (EC) 546/2011. Of these scenarios, D6 is considered the most representative of the main use areas of Oxamyl 10SL and was used for the surface water exposure assessment. Drainage of the active substance under the respective scenario is a function of soil properties, climatic variability, and chemical properties. Drift loading into the aquatic systems is based on fixed buffer widths predetermined as a function of crop type and water body. Details of the modelling parameters are presented in in the Oxamyl EU Renewal Dossier, Document M-CA, Section 9, DuPont-40934 EU. Step-3a modelling results (maximum, 7- and 14-day time weighted average PEC values for water and sediment) for Oxamyl 10SL are presented in Table 19 and Table 20. Step-3d modelling results are presented in Table 21.

Table 19 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 20 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.

Table 21 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.

TER_a for fish

On the basis of the worst-case toxicity values and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for acute exposure of fish were calculated (Table 22). The TER_a value for Oxamyl 10SL are below trigger levels of 100 for acute exposure indicating a need for further refinements, which are presented in Table 23. It can be concluded that the proposed applications of Oxamyl 10SL pose low acute risks to fish.

Table 22 Worst-case fish acute toxicity exposure ratios (TER_a) for oxamyl and its major metabolites based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 2 modelling)

Compound	PEC_{sw} (µg/L)	Fish LC_{50} (µg/L)	Fish acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Oxamyl	389.336	2700	6.93	100
IN-A2213	49.768	>132000	2652	100
IN-D2708	170.176	93800 (supportive data)	551	100
IN-N0079	1.888	22400	11864	100
IN-T2921	23.498	>127000	5405	100
Solarisation 1 × 5500 g a.s./ha				
Oxamyl	428.270	2700	6.3	100
IN-A2213	699.172	>132000	189	100
IN-D2708	761.166	93800 (supportive data)	123	100
IN-N0079	83.077	22400	270	100
IN-T2921	109.239	>127000	1163	100

Table 23 Refined fish acute toxicity exposure ratios (TER_a) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 3 modelling)

Scenario	PEC_{sw} (µg/L)	Fish LC_{50} (µg/L)	Fish acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
D6 Ditch, Step 3a	11.386	2700	**237**	100
Solarisation 1 × 5500 g a.s./ha				
D6 Ditch, Step 3a Application begins August 1	0.014	2700	**192857**	100

TER_{lt} for fish

On the basis of the worst-case toxicity values and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for chronic exposure of fish were calculated (Table 24). The TER_{lt} values do not exceed the trigger level of 10 for long-term exposure indicating a need for further refinements, which are presented Table 25. It can be concluded that the proposed applications of Oxamyl 10SL pose low chronic risks to fish.

Table 24 Worst-case fish chronic toxicity exposure ratios (TER_{lt}) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 2 modelling)

Compound	Initial PEC surface water southern EU (µg a.s./L)	Fish chronic NOEC (µg a.s./L)	Fish chronic TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Oxamyl	389.336	356	0.91	10
Solarisation 1 × 5500 g a.s./ha				
Oxamyl	428.270	356	0.83	10

Table 25 Refined fish chronic toxicity exposure ratios (TER_{lt}) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 3 modelling)

Scenario	Maximum PEC surface water southern EU (mg a.s./L)	Fish chronic NOEC (mg a.s./L)	Fish chronic TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
D6 Ditch, Step 3a	11.386	356	31	10
Solarisation 1 × 5500 g a.s./ha				
D6 Ditch, Step 3a Application begins August 1	0.014	356	25428	10

TER_a for *Daphnia*

On the basis of the worst-case toxicity values and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for acute exposure of aquatic invertebrates *(Daphnia magna)* were calculated (Table 26). The TER_a values for oxamyl are below the trigger levels of 100 for acute exposure indicating a need for refinements, which are presented in Table 27. It can be concluded that the proposed applications of Oxamyl 10SL pose low acute risks to *Daphnia*.

Table 26 Worst-case *Daphnia* acute toxicity exposure ratios (TERa) for oxamyl and its major metabolites based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	*Daphnia* EC_{50} (µg a.s./L)	*Daphnia* acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Oxamyl	389.336	300	0.77	100
IN-A2213	49.768	>125000	2512	100
IN-D2708	170.176	>134000	787	100
IN-N0079	1.888	>128000	67796	100
IN-T2921	23.498	>123000	5234	100
Solarisation 1 × 5500 g a.s./ha				
Oxamyl	428.270	300	0.7	100
IN-A2213	699.172	>125000	179	100
IN-D2708	761.166	>134000	176	100
IN-N0079	83.077	>128000	1541	100
IN-T2921	109.239	>123000	1126	100

Table 27 Refined *Daphnia* acute toxicity exposure ratios (TERa) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 3a and 3d modelling)

Scenario	Initial PEC_{sw} (µg a.s./L)	*Daphnia* EC_{50} (µg a.s./L)	*Daphnia* acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Step 3a	11.386	300	26.3	100
Step 3d	0.002	300	150000	100
Solarisation 1× 5500 g a.s./ha				
Step 3a	0.014	300	21428	100

TER_{lt} for *Daphnia*

On the basis of the available chronic toxicity data and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for long-term exposure of aquatic invertebrates *(Daphnia magna)* were calculated (Table 28). The TER_{lt} values for oxamyl are below the trigger levels of 10 for long-term exposure indicating a need for refinements, which are presented in Table 29. It can be concluded that the proposed applications of Oxamyl 10SL pose low chronic risks to *Daphnia*.

Table 28 Worst-case *Daphnia* chronic aquatic toxicity exposure ratios (TERs) for oxamyl and its residual major metabolites based on initial PECs from applications to tomatoes or soil solarisation (FOCUS step 2 modelling)

Compound	Initial PEC surface water southern EU (µg a.s./L)	*Daphnia* chronic NOEC (µg a.s./L)	*Daphnia* chronic TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Oxamyl	389.336	26.8	0.069	10
IN-D2708	170.176	66100	388	10
Solarisation 1 × 5500 g a.s./ha				
Oxamyl	1810.000	26.8	0.015	10
IN-D2708	187.193	66100	353	10

Table 29 Refined *Daphnia* chronic toxicity exposure ratios (TER_{lt}) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 3a and 3d modelling)

Scenario	Initial PEC_{sw} (µg a.s./L)	*Daphnia* EC_{50} (µg a.s./L)	*Daphnia* acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Step 3a	11.386	26.8	2.4	10
Step 3d	0.002	26.8	13400	10
Solarisation 1 × 5500 g a.s./ha				
Step 3a	0.014	26.8	1914	10

TER_a for an aquatic insect species

Oxamyl 10SL is an insecticide and is not a growth regulator. The acute toxicity of oxamyl a.s. to aquatic insect species was determined in multiple species; studies are summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU. It can be concluded that the proposed applications of Oxamyl 10SL pose low acute risk to aquatic insects.

TER_{lt} for an aquatic insect species

The chronic toxicity of oxamyl a.s. to an aquatic insect species was not determined. Oxamyl is not a persistent substance in water/sediment systems. Persistence endpoints for the total water sediment system in two streams were: Red Oak Stream DT_{50} = 0.82, DT_{90} = 8.31 days and for Town Park Pond DT_{50} = 0.69, DT_{90} = 2.28 days (Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10SL, DuPont-42129 EU).

An acute toxicity test was carried out with first instar (2–3 days old) *Chironomus tentans* (48-h water-only study). The onset of effects is rapid. Oxamyl is of similar toxicity to *Chironomus tentans* compared to *Daphnia magna*, thus no chronic study was triggered with *Chironomus* sp. It can be concluded that the proposed applications of Oxamyl 10SL pose low chronic risk to aquatic insects.

TER_a for an aquatic crustacean species

An acute toxicity study was conducted for the mysid shrimp, *Americamysis bahia.* On the basis of the relevant endpoint and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for acute exposure of *Americamysis bahia* were calculated (Table 30 and Table 31). The TER_a values for oxamyl are below the trigger levels of 100 for acute exposure indicating a need for refinements, which are presented in Table 31. It can be concluded that the proposed applications of Oxamyl 10SL pose low acute risk to aquatic crustaceans.

Table 30 Worst-case aquatic crustacean acute toxicity exposure ratios (TERs) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	Mysid EC_{50} (µg a.s./L)	Mysid acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Oxamyl	389.336	46.5	0.11	100
Solarisation 1 × 5500 g a.s./ha				
Oxamyl	1810.000	46.5	0.02	100

Table 31 Refined crustacean toxicity exposure ratios (TER_a) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 3a and 3d modelling)

Scenario	Initial PEC_{sw} (µg a.s./L)	Mysid EC_{50} (µg a.s./L)	Mysid acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 +1000 g a.s./ha				
Step 3a	11.386	46.5	4.08	100
Step 3d	0.002	46.5	23250	100
Solarisation 1 × 5500 g a.s./ha				
Step 3a	0.014	46.5	3321	100

TER_{lt} for an aquatic crustacean species

A chronic toxicity study was conducted for the mysid shrimp, *Americamysis bahia.* On the basis of this toxicity value and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for chronic exposure of aquatic invertebrates *(Daphnia magna)* were calculated (Table 32). The $TER_{chronic}$ values for oxamyl are below the trigger levels of 10 for long-term exposure indicating a need for refinements. It can be concluded that the proposed applications of Oxamyl 10SL pose low chronic risks to aquatic crustaceans.

Table 32 Worst-case aquatic crustacean chronic toxicity exposure ratios (TERs) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	Mysid EC_{50} (µg a.s./L)	Mysid acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Oxamyl	389.336	18.9	0.04	100
Solarisation 1 × 5500 g a.s./ha				
Oxamyl	1810.000	18.9	0.01	100

Table 33 Refined aquatic crustacean chronic toxicity exposure ratios (TERs) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS Steps 3a and 3d modelling)

Scenario	Initial PEC_{sw} (µg a.s./L)	Mysid EC_{50} (µg a.s./L)	Mysid acute TER	Trigger
Tomatoes, 2000 + 1000 + 1000 + 1000 g a.s./ha				
Step 3a	11.386	18.9	1.65	100
Step 3d	0.002	18.9	9450	
Solarisation 1 × 5500 g a.s./ha				
Step 3a	0.014	18.9	1350	100

TER_a for an aquatic gastropod species

TER_a values for aquatic gastropod molluscs are not required since the risk assessments for *Daphnia magna* indicated that Oxamyl 10SL poses low acute risk to aquatic invertebrates. In addition, this data point is not relevant since Oxamyl 10SL is not intended for use directly on surface waters. It can be concluded that the proposed applications of Oxamyl 10SL pose low acute risks to aquatic gastropods.

TER_{lt} for an aquatic gastropod species

TER_{lt} values for aquatic gastropod molluscs are not required since the risk assessments for *Daphnia magna* indicated that Oxamyl 10SL poses low chronic risk to aquatic invertebrates. In addition, this data point is not relevant since Oxamyl 10SL is not intended for use directly on surface waters. It can be concluded that the proposed applications of Oxamyl 10SL pose low chronic risk to aquatic gastropods.

TER_{lt} for algae

RMS: The risk that Oxamyl 10SL poses to algae species cannot be assessed because reliable data are missing.

For the metabolites IN-A2213 and IN-T2921 the risk is acceptable. For the metabolites IN-D2708 and IN-N0079 reliable data are not available, hence the risk cannot be assessed (see Table 34).

On the basis of the worst-case toxicity values and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for exposure of algae were calculated (Table 34).

Table 34 Worst-case algae chronic toxicity exposure ratios (TERs) for oxamyl and its major metabolites based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	Algae EC_{50} (µg a.s./L)	Algae chronic TER	Trigger
Tomatoes, 2000+1000+1000+1000 g a.s./ha				
Oxamyl		Data gap		10
IN-A2213	49.768	>122000 Supportive data	2451	10
IN-D2708	170.176	Data gap		10
IN-N0079	1.888	Data gap		10
IN-T2921	23.498	>113000	4809	10
Solarisation 1× 5500 g a.s./ha				
Oxamyl	1810.000	Data gap		10
IN-A2213	699.172	>122000 Supportive data	174	10
IN-D2708	761.166	Data gap		10
IN-N0079	83.077	Data gap		10
IN-T2921	109.239	>113000	1034	10

TER_{lt} for aquatic macrophytes

On the basis of the E_rC_{50} = 3.30 mg a.s./L available for the active substance Oxamyl (relevant endpoint) and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for exposure of *Lemna gibba* were calculated (Table 35).

Table 35 Worst-case *Lemna* toxicity exposure ratios (TERs) for Oxamyl 10SL based on initial PECs (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	*Lemna* EC_{50} (µg a.s./L)	*Lemna gibba* TER	Trigger
Tomatoes, 2000+1000+1000+1000 g a.s./ha				
Oxamyl 10SL	389.336	3300	8.47	10
Solarisation 1× 5500 g a.s./ha				
Oxamyl 10SL	428.270	3300	7.71	10

The TER values estimated indicate that potential risks arise for *Lemna gibba*. As a result, PEC_{sw} values for oxamyl active ingredient were further refined using FOCUS Step-3 modelling. These results are shown in Table 36.

Table 36 Refined *Lemna* toxicity exposure ratios (TERs) for oxamyl based on initial PECs from applications of Oxamyl 10SL to tomatoes or soil solarisation (FOCUS step 3a modelling)

Scenario	Initial PEC_{sw} (µg/L)	*Lemna* EC_{50} (µg a.s./L)	*Lemna gibba* chronic TER	Trigger
Tomatoes, 2000+1000+1000+1000 g a.s./ha				
Step 3a D6/ditch	11.386	3300	290	10
Solarisation 1× 5500 g a.s./ha				
Step 3a D6/ditch	0.014	3300	235714	10

The calculated Step-3a PEC_{sw} values resulted in acceptable TER values for Oxamyl 10SL for *Lemna*. The TER values for oxamyl active ingredient exceed the trigger levels of 10 for exposure indicating that the proposed applications of Oxamyl 10SL pose low risk to *Lemna* species.

B.9.5 Effects on arthropods

B.9.5.1 Effects on bees

B.9.5.1.1 Acute toxicity to bees

B.9.5.1.1.1 Acute oral toxicity to bees

Study submitted in the EU Dossier in 2001 for the Oxamyl 10GR formulation and included in the first EU approval review.

B.9.5.1.1.1/01

Reference --	**Report:**	Schur, A. (1999); Oxamyl 10L: Acute oral and contact toxicity to the honey bee, *Apis mellifera* L. **DuPont Report No.:** DuPont-2718 **Guidelines:** EPPO 170 (1992) **Deviations:** None that affect the validity of the study. **Testing Facility:** GAB Biotechnologie, GmbH, Neifern-Oschelbronn, Germany **Testing Facility Report No.:** 99299/01-BLEU **GLP:** Yes **Certifying Authority:** Ministrium fur Umwelt und Verkehr (Baden-Wurttemberg, Germany)

1. Test material: Oxamyl 10SL
   Lot/Batch #: D1410-381
   Purity: 100 g a.s./L

Executive summary:

Acute 48-hour oral and contact toxicity tests on honey bees (*Apis mellifera* L.) were conducted with Oxamyl 10SL in the laboratory under EPPO Guideline 170 contact portion that essentially conforms to the EPA Pesticide Assessment Guidelines L: 141-1 (1982) and EPA guideline OPPTS 850.3020 (1996, draft). Treatments consisted of four toxic standard treatment rates, a sucrose solution control (oral) or water control (contact), and five nominal concentrations of 0.10, 0.20, 0.40, 0.80, and 1.60 µg Oxamyl 10SL/bee. The LD_{50} and NOEC for honeybees exposed to Oxamyl 10SL for 48 hours in the acute oral test were 0.26 µg product/bee and 0.09 µg product/L, respectively, based on mean measured concentration. The LD_{50} and NOEC for honeybees exposed to Oxamyl 10SL for 48 hours in the acute contact test were 0.23 µg product/bee and 0.10 µg product/L, respectively, based on mean measured concentration.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Oxamyl 10SL
   Lot/Batch #: D1410-381
   Purity: 100 g a.s./L
   Description: Green liquid
   CAS#: None for the formulation
   23135-22-0 for oxamyl active substance
   Stability of test compound: Shown to be stable under the conditions of the test
2. Vehicle and/or positive control: tap water; Perfekthion" (containing 395.7 g/L dimethoate)
3. Test organism: Honey bees, worker, collected in a non-systematic manner from the outer combs of the bottom unit of the colony, approximately 20 hours before test initiation.
   Species: *Apis mellifera*
   Strain: Carnica
   Source: Bee hives located in Rheinland-Pfalz, Germany
   Acclimation period: Not stated
   Diet: 50% sucrose solution
   Water: Not applicable - see Diet
   Test chamber: High grade steel cage
   (10 cm wide × 5 cm deep × 8.5 cm high)
4. Environmental conditions
   Temperature: 26 to 28°C
   Relative humidity: Oral study: 49 to 61%; Contact study: 49 to 61%
   Photoperiod: Continuous dark

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

   31-August-1999 to 09-September-1999

2. Experimental treatments

   The acute 48-hour oral and contact toxicity of Oxamyl 10SL was determined in honeybees (*Apis mellifera* L.). Treatments consisted of four toxic standard treatment rates (Oral: 0.09, 0.13, 0.19 and 0.25 µg a.s./bee; Contact: 0.18; 0.26; 0.38 and 0.50 µg a.s./bee), a sucrose solution control (oral) or water control (contact), and five nominal concentrations of 0.10, 0.20, 0.40, 0.80, and 1.60 µg Oxamyl 10SL/bee. Five replicates per treatment and 10 honey bees per replicate (total 50 bees per treatment) were used for the test item concentration, control, and toxic reference. Dimethoate (BASF) was the toxic standard used in these tests. In the oral test, bees were offered the test solutions in 50% aqueous

sugar solution. Before treatment the bees were starved for 15 hours 40 minutes. A quantity of 250 µL of treated sucrose solution was offered to each cage of 10 bees to ensure a sufficient intake of test item.

In the contact test bees were dosed with Oxamyl 10SL by topical application to the ventral thorax of each bee

3. Observations

Assessments for mortalities and sublethal effects were carried out 2, 4, 24, and 48 hours after treatment. The rates producing the oral and contact LD_{50} (rate resulting in 50% inhibitory response) and the NOEC (no observable effect concentration), the highest dosing level not statistically different from the controls, were determined.

4. Statistics

Schneider-Orelli (1947): Correction for control mortality.

Easy Assay Critical Values computer program (Ratte, 1995), (α=0.05): LD_{50}

Maximum Likelihood method (Finney, 1971; Schuemer *et al*., 1990), (α=0.05): Estimation of Probit straight line

Fisher's Exact test, (α=0.05): NOEL

II. RESULTS AND DISCUSSION

A. FINDINGS

Control mortality in the oral and contact test after 48 h was 0 and 0%, respectively. A maximum cumulative mortality of 94.0% occurred at the dose level of 0.8 µg Oxamyl 10SL/bee in the oral test after 48 hours. Cumulative mortality in the oral test ranged from 6.0 to 94.0% across all treatment concentrations. In the highest tested dose of 1.60 µg Oxamyl 10SL/bee in the contact test the cumulative mortality was 98% after 48 h. In the contact test, cumulative mortality ranged from 4.0 to 98.0% after 48 h across all treatment concentrations. No sublethal effects were observed during this study. The oral and contact toxicity of the toxic reference standard, dimethoate, to honey bees in these tests fell within the accepted range, indicating the validity of these tests.

Actual test item intake in the oral tests and mortality results for the oral and contact tests at 24 and 48 hours are reported in the summary tables below.

Table 37 Acute oral toxicity of Oxamyl 10SL to honey bees

Treatment[a]		**Test item intake**[b]		**Cumulative mortality (%)**[c]	
µg oxamyl a.s./ bee	**µg Oxamyl 10SL/ bee**	**µg oxamyl a.s./ bee**	**µg Oxamyl 10SL/ bee**	**24 hours**	**48 hours**
0	N/A	N/A	N/A	0.0	0.0
0.1	1.00	0.09	0.90	6.0	6.0
0.2	2.00	0.16	1.60	12.0	12.0
0.4	4.00	0.30	2.99	58.0	60.0
0.8	7.98	0.53	5.29	90.0	94.0
1.6	15.97	1.10	10.98	76.0	76.0

[a] Treatments are specified as intended uptake, in mean µg a.s. or formulated material/bee per treatment rate.

[b] Test substance intake is specified as actual uptake, in mean µg a.s. or formulated material/bee per treatment rate.

[c] Test mortality for treatments is corrected for control mortality (mortality at 0 µg a.s. or formulated material/bee).

Table 38 Acute contact toxicity of Oxamyl 10SL to honey bees

Treatment[a]		Cumulative Mortality (%)	
µg oxamyl a.s./bee	µg Oxamyl 10SL/bee	24 hours	48 hours
0	N/A	0.0	0.0
0.1	1.00	2.0	4.0
0.2	2.00	42.0	44.0
0.4	4.00	92.0	92.0
0.8	7.98	94.0	94.0
1.6	15.97	98.0	98.0

[a] Treatments are specified as mean µg a.s. or formulated material/bee per treatment rate, applied ventrally.

III. CONCLUSIONS

Acute Endpoint	µg Oxamyl a.s./bee	µg Oxamyl 10SL/bee
Oral LD_{50}	0.26	2.60
Oral NOEL	0.09	0.90
Contact LD_{50}	0.23	2.30
Contact NOEL	0.10	1.00

The LD_{50} for honey bees exposed to Oxamyl 10SL for 48 hours in an acute oral test was 0.26 µg product/bee and the NOEC was 0.09 µg product/bee, based on mean measured concentration. The LD_{50} for honey bees exposed to Oxamyl 10SL for 48 hours in an acute contact test was 0.23 µg product/L and the NOEC was 0.10 µg product/bee, respectively, based on mean measured concentration.

(Schur, A., 1999)

RMS: The acute oral toxicity to bees study DuPont-2718, originally submitted under EU Rev8 Point IIA 10.4.1 and conducted with test material Oxamyl 10SL, was conducted under guideline EPPO 170 (1992). The study has been reviewed according to EPPO 1/170 (4), 2010 and ECD 213, 1998 and OECD 214, 1998).

Deviations:

Maximum temperature was 28 instead of 27°C.

In the contact test bees product was applied to ventral thorax as recommended in OECD 214, 1998.

The bees in the oral toxicity test were starved for 15 hours 40 minutes instead of up to 2 hours as recommended. Reason: When collecting bees from combs smoke was used to make the bees calm. The bees filled their honey-sac with nectar and to guarantee a high food uptake of the bees in the oral toxicity test we have to starve them longer. The impact on study is considered low as there was no control mortality in the oral toxicity test, which is evidence that the longer starvation period had no adverse impact on the health of the bees.

The 48-hour oral LD50 of the toxic substance was 0.16 µg a.s./bee (0.14 to 0.18 µg a.s./b /bee, which falls within accepted published oral 48-hour LD50 results of Gough et al. (1994) for technical dimethoate, which ranged from 0.100 µg a.s./bee to 0.318 µg a.s./bee (mean 0.166 µg a.s./bee). The 48-hour contact LD50 was determined as 0.20 µg a.s./bee with 95% confidence limits of 0.18 to 0.23 µg a.s./bee (see Table 13 in the Appendix A1). In the published results of Gough et al. (1994) the contact values ranged from 0.105 µg a.s./bee to 0.237 µg a.s./bee (mean 0.152 µg a.s./bee).

Conclusion: the study is acceptable.

B.9.5.1.1.2 Acute contact toxicity to bees

Study submitted in the EU Dossier in 2001 for the Oxamyl 10GR formulation and included in the first EU approval review.

B.9.5.1.1.2/01

Reference --	**Report:**	Schur, A. (1999); Oxamyl 10L: Acute oral and contact toxicity to the honey bee, *Apis mellifera* L. **DuPont Report No.:** DuPont-2718 **Guidelines:** EPPO 170 (1992)

1. Test material: Oxamyl 10SL
   Lot/Batch #: D1410-381
   Purity: 100 g a.s./L

The acute contact toxicity to bees study DuPont-2718, originally submitted under EU Rev8 Point IIA 10.4.1 and conducted with test material Oxamyl 10SL, was conducted under guideline EPPO 170 (1992). A review of this study indicates that it fully meets the current guideline (OECD 213, 1998 and OECD 214, 1998).

Acute oral and contact toxicity testing for bees is conducted in the same study. For convenience of the reviewer, the complete OECD study summary is provided in Point B.9.5.1.1.1 in this document.

B.9.5.1.2 Chronic toxicity to bees

Chronic testing was conducted with the active substance.

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

B-9.5.1.2/01

Reference: CP 10.3.1.2/01	**Report:**	Balluff, M. (2002); Oxamyl (DPX-D1410) 10L - Evaluation of the side-effects on bumble bees (*Bombus terrestris* L.) after drip-irrigation treatment to tomato plants in greenhouse compartments **DuPont Report No.:** DuPont-5748 **Guidelines:** SETAC/ESCORT recommendations (Barrett *et al.* 1994), EPPO 170 **Deviations:** None that affect the validity of the study. **Testing Facility:** GAB Biotechnologie, GmbH, Niefern-Oschelbronn, Germany **Testing Facility Report No.:** 20013004/S1-BFBt **GLP:** Yes **Certifying Authority:** Ministerium fur Umwelt und Verkehr (Baden-Wurttemberg, Germany)

Executive summary:

This study aimed to evaluate the side-effects of Oxamyl 10SL on bumble bee (*Bombus terrestris)* activity and crop pollination under greenhouse conditions. The test was based on general SETAC/ESCORT recommendations (Barrett *et al*. 1994) and EPPO 170 and was performed in 2001/2002 in Mazarron in Spain. Oxamyl 10SL was applied six times at 1000 g a.s./ha at 14 day intervals *via* drip irrigation. An untreated plot was used as control. Each treatment consisted of 6 replicates. One hive per replicate was introduced into the greenhouse on the evening before the last application and opened in the early morning of the following day before the application took place. Assessments of adult mortality, larval mortality, sugar solution consumption, colony mass, and foraging activity were performed regularly over a period of 28 days after the last application. An initial brood assessment was performed before transfer of the hives and a final assessment was performed 28 days after the last application. No notable effects on mortality of larvae and adults, pollination, hive weight and sugar consumption was observed. At a final brood assessment no effects compared to the control were noted. Oxamyl 10SL, when applied six times at 1000 g a.s./ha at 14 day intervals *via* drip irrigation, had no significant effects on mortality of bumble bee larvae and adults, crop pollination, hive weight, and sugar consumption or brood development.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-424
	Purity:	100 g a.s./L nominal
	Description:	Dark green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Shown to be stable under the conditions of the test
2.	Vehicle and/or positive control:	water
3.	Test organism:	Bumble bees.
	Species:	*Bombus terrestris*
	Source:	Koppert Sistemas Biologicos S.L., Finca Labradorcico del Medio s/n, Apartado de Correos 286, 30880 Aguilas (Murcia), Spain.
	Acclimation period:	Not stated
	Diet:	sugar solution of glucose, fructose, sulfate and citric acids (precise composition is a secret of the producer)
	Water:	Not applicable - see Diet
	Test chamber:	Hives were 24 cm × 27 cm × 18 cm in a plastic greenhouse 168 m × 71 m (11928 m^2), height 4.5 m with lateral windows covered with a dense net. Control and test item treatment were placed in the same greenhouse separated with a net. The plot size of each treatment was 5964 m². The plot of each treatment was divided into 6 subplots (size of 994 m²) separated by a net with a minimum mesh size of 5 mm.
4.	Environmental conditions	
	Temperature:	~5-35°C
	Humidity:	20-100%

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

15-October-2001 to 19-January-2002

The age of the worker bees was approx. 28 days and the number of worker bees per hives was between 64 and 105. For the test young normal queen right colonies, each with at least 30 worker bumble bees, were used. The colonies were comparable, comprising of similar amounts of brood (larvae and pupae). Therefore, uniform hives were selected at the first brood assessment.

2. Experimental treatments

Oxamyl 10SL was applied six times at 1000 g a.s./ha at 14 day intervals *via* drip irrigation to tomato plants in greenhouses in Spain. An untreated plot (no product or water) was used as control. Each treatment consisted of 6 replicates. One hive per replicate was introduced into the greenhouse on the evening before the last irrigation and opened in the early morning of the following day before the irrigation took place. Drippers had a flow rate of approx. 1.4 L/h and were installed in a distance of 30 cm.3. Observations

Assessments of adult mortality, larval mortality, sugar solution consumption, colony mass, and foragingactivity were performed regularly over a period of 28 days after the last application.

Adult mortality was checked inside the hive and for 2 m in all directions around the hives, and removed.
All dead larvae found in front of the hives during the test were counted and removed.
Each single bumble bee colony was fed with sugar solution ad libitum (tomato flowers produce no nectar). The sugar solution was in a bag and already been added by the producer. An indirect measure of the bumble bee activity during the test is ensured by weighing the entire bag.
Development of the Bumble bee Colonies was measured by colony mass. The total weight of the bumble bee colonies was determined during the test. Therefore complete colonies were weighed without sugar solution. This gave a measure for growth of the brood and collecting activity of bees during the test.
Foraging activity was determined because bees leave on flowers visited so called "bite marks", light brown spots on the pistil of the flower). 50 flowers (only the youngest flower of one truss will be checked) on 50 previously marked plants randomly selected (in at least 10 different rows and at least 5 plants distance in one row) were checked. The flowers were classified in 4 categories based on the number of bite marks and later on points were assigned to each category.
Condition of the Colonies and Development of Bumble bee Brood : an initial brood assessment was performed 1 day before transfer of the hives and a final assessment was performed 28 days after the last irrigation. The colonies had a sufficient amount of brood (eggs and young larvae) in the initial brood assessment to ensure that workers will forage for pollen. The brood was photographed using the same scale and direction for each colony of each treatment at the start and end of the trial for a qualitative observation of the development of bumble bee brood.
The number of living worker bumble bees was determined initially by the producer and at the final brood evaluation. At the end of the trial bumble bees were anaestised with carbon dioxide and the number of living worker bees was counted and weighed to determine the total adult biomass and to calculate the mean surviving adult weight.
Final evaluation of Brood Stages and Brood Development. Each hive was opened under red light in the Lab. Colonies were evaluated for effects on all brood stages, all malformations and differences compared to the control. This included counts or estimations of the following:
• Estimate of eggs and small larvae (L1-L3) count of big larvae (L4)
• Count of dead and alive young queens
• Count of dead and count and weighing of alive workers (which must be anaestizise)
• Count of dead and alive males
• Count of pupae
• Count of unhatched adults

4. Statistics

Continuous data (foraging activity, sugar consumption, hive weight, and mortality) were tested for normality using Shapiro-Wilk's or Bartlett test and homogeneity of variance using the Levene test. If assumptions were met the Bonferroni t-test was used to estimate significant differences from controls.

II. RESULTS AND DISCUSSION

A. FINDINGS

Pollination. Over the whole period tested, the number of bite marks was not significantly influenced in both test item treatments comparing to the control treatment (Table 39).

Table 39 Bite marks (total points per evaluation day, average of 6 replicates)

Days after last irrigation (DAI)	Date	Control[a]	Oxamyl 10SL[a]
DAI_1	21DEC01	50	50
DAI_0	22DEC01	77	75
DAI_1	23DEC01	72	75
DAI_2	24DEC01	120	119
DAI_4	26DEC01	162	155
DAI_8	30DEC01	177	170
DAI_{12}	03JAN02	149	156
DAI_{16}	07JAN02	142	153
DAI_{20}	11JAN02	141	148
DAI_{24}	15JAN02	149	149
DAI_{28}	19JAN02	152	159

[a] No significant difference between the treatments at all time points.

Weight of Colonies. The average hive weight was more or less stable in the control as well as in the Oxamyl 10SL treatments after opening of the hives. Due to unfavourable conditions in the winter period, the colonies did not grow. No statistically significant effect of Oxamyl 10SL was observed (Table 40).

Table 40 Weight of colonies (in grams, average of 6 replicates)

Days after last irrigation (DAI)	Date	Control[a]	Oxamyl 10SL[a]
DAI_1	21DEC01	589.5	626.2
DAI_0	22DEC01	591.7	623.5
DAI_1	23DEC01	586.0	635.0
DAI_2	24DEC01	588.3	634.3
DAI_4	26DEC01	569.3	619.5
DAI_8	30DEC01	557.3	615.2
DAI_{12}	03JAN02	555.2	610.5
DAI_{16}	07JAN02	553.2	605.2
DAI_{20}	11JAN02	545.2	587.0
DAI_{24}	15JAN02	539.0	579.3
DAI_{28}	19JAN02	556.2	601.8

[a] No significant difference between the treatments at all time points.

Sugar Solution Consumption. The sugar consumption of bumble bees showed no differences between the control and Oxamyl 10SL treated treatments. The sugar consumption was linear over the whole period Table 41). Generally consumption was higher in the oxamyl treated plots, which was very likely caused by the better hive development in these plots (as proved by the higher number of worker bees and the higher hive weight).

Table 41 Weight of consumed sugar solution (in grams, average of 6 replicates)

Days after last irrigation (DAI)	Date	Control[a]	Oxamyl 10SL[a]
DAI_1	21DEC01	0.0	0.0
DAI_0	22DEC01	29.8	31.0
DAI_1	23DEC01	55.2	58.0
DAI_2	24DEC01	82.3	83.2
DAI_4	26DEC01	136.5	151.3
DAI_8	30DEC01	187.8	224.8
DAI_{12}	03JAN02	247.2	309.0
DAI_{16}	07JAN02	289.2	389.7
DAI_{20}	11JAN02	323.5	426.0
DAI_{24}	15JAN02	345.0	465.2
DAI_{28}	19JAN02	406.3	554.2

[a] No significant difference between the treatments at all time points.

Mortality. No increased mortality of adult bumble-bees or larvae was observed in the field or in front of the hives after the exposure to flowering tomatoes treated with Oxamyl 10SL (Table 42). Occasionally increasing mortality is very likely caused by weather conditions or other unidentified factors.

Table 42 Mortality of worker bumble-bees (adults) or larvae found in the field including in front of the hive (field) or inside the hive (hive) (total of 6 replicates)

Date after last irrigation		In field or hive	Control		Oxamyl 10SL	
			adults	larvae	adults	larvae
DAI_0	22DEC01	field	7	3	7	3
		hive	10	0	4	0
DAI_1	23DEC01	field	3	2	0	0
		hive	3	2	2	5
DAI_2	24DEC01	field	0	0	2	0
		hive	4	2	3	11
DAI_4	26DEC01	field	0	1	1	1
		hive	0	26	4	16
DAI_8	30DEC01	field	0	4	0	1
		hive	2	35	2	39
DAI_{12}	03JAN02	field	0	4	0	2
		hive	3	15	4	25
DAI_{16}	07JAN02	field	0	0	0	0
		hive	2	19	3	13
DAI_{20}	11JAN02	field	1	0	1	0
		hive	7	8	4	9
DAI_{24}	15JAN02	field	0	0	0	0
		hive	1	0	1	2
DAI_{28}	19JAN02	field	0	0	0	0
		hive	14	40	12	36
TOTAL[a]	field		**11**	**14**	**11**	**7**
	hive		**46**	**147**	**39**	**156**
	field and hive		**57**	**161**	**50**	**163**
	adults and larvae of field and hive		**218**		**213**	

[a] No significant difference between the treatments

Brood. To demonstrate the homogeneity of bumble bee brood, the brood was photographed using the same scale and direction for one representative colony of each treatment at the start and at the end of the testing period. No negative impact of the test item was notable (Table 43).

Table 43 Brood Assessments (average of 6 replicates)

	Initial Assessment on 20 DEC 01		Final Assessment on 19 JAN 02	
	Control	Oxamyl 10SL	Control	Oxamyl 10SL
Living queen	yes	yes	yes	yes
Alive young queens	0	0	0	0
Number of worker bees alive	71	88	70	98
Average weight of worker bees (g)	n.a.	n.a.	16.8	20.2
Number of males	0	0	0	0
Number of brood cell cluster with eggs	2.3	2.5	2.0	2.0
Number of alive small larvae L1-L3	7.3	11.0	individuals not determined	
Number of alive big larvae L4	3.5	3.5		
Number of pupae	58	69	12	12

III. CONCLUSIONS

Oxamyl 10SL, when applied six times at 1000 g a.s./ha at 14 day intervals *via* drip irrigation, had no significant effects on mortality of bumble bee larvae and adults, crop pollination, hive weight, and sugar consumption or brood development.

(Balluff, M., 2002)

RMS comments and conclusion

The method is in line with EPPO 170 (2010), while adopting the modification needed to meet the purpose of the study.

No reference item was tested, this can be partly justified by the non standard application method.

B.9.5.1.3 Conclusion: the study is acceptable. **The product Oxamyl 10SL was applied six times at 1 Kg a.s./ha at 14 day intervals, while the proposed GAP is a maximum of 4 application at different rates (2 +1+1+1+1 Kg a.s./ha). A statement should be made by the Applicant that the test design represent a worst case compared to the GAP. Effects on honey bee development and other honey bee life stages**

Tests with larvae were conducted with the active substance and Oxamyl 10GR (Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10GR, DuPont-40954 EU). No further testing is needed with the formulated product.

B.9.5.1.4 Sub-lethal effects

Larval toxicity

Toxicity of oxamyl to larval honeybees and bumble bees was evaluated as part of higher tier studies with the formulated product, Oxamyl 10GR. Please see DuPont-39666 and DuPont-39667, summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10GR, DuPont-40954 EU.

Long residual tests

Long-term residual tests were evaluated as part of higher tier tunnel studies with the formulated product, Oxamyl 10GR. Please see DuPont-39666 and DuPont-39667, summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10GR, DuPont-40954 EU.

Disorienting effects on bees

Long-term tests to evaluate disorienting effects on honeybees and bumble bees were part of higher tier tunnel studies with the formulated product, Oxamyl 10GR. Please see DuPont-39666 and DuPont-39667, summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10GR, DuPont-40954 EU.

B.9.5.1.5 Cage and tunnel tests

Cage tests

Cage tests of oxamyl on honeybees were not conducted because higher tier tunnel tests were conducted.

Tunnel test to investigate effects of feeding on contaminated honey dew or flowers

Tunnel tests of oxamyl on honeybees and bumble bees were evaluated as part of a higher tier study with the formulated product, Oxamyl 10GR. Please see DuPont-39666 and DuPont-39667, summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10GR, DuPont-40954 EU.

B.9.5.1.6 Field tests with honey bees

Field tests were not conducted.

B.9.5.2 Effects on non-target arthropods other than bees

B.9.5.2.1 Standard laboratory testing for non-target arthropods

Testing for effects on arthropod species other than bees was carried out using the formulated products Oxamyl 10SL and Oxamyl 10GR rather than the active substance. Laboratory studies were conducted with Oxamyl 10SL to assess effects on the sensitive indicator species, the Phytoseiid mite, *Typhlodromus pyri*, and the parasitic wasp, *Aphidius rhopalosiphi,* and on four crop-relevant species (the predatory bug *Orius laevigatus,* spiders of the *Pardosa* species, the staphylinid beetle, *Aleochara bilineata, and Poecilus cupreus*). Summaries of the studies with Oxamyl 10SL are given below. Extended laboratory studies were conducted with Oxamyl 10GR on the ground dwelling species, *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp. and are summarised in the Oxamyl 10 GR dRAR Vol 3 B9.Extended laboratory testing, aged residue studies with non-target arthropods

Drip Irrigation: Extended laboratory testing was conducted on the ground dwelling species, *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp. Furthermore extended laboratory studies with aged residues were conducted with *Typhlodromus pyri*, *Aphidius rhopalosiphi* and *Orius laevigatus*. Summaries of these studies are below.

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

B.9.5.2.2/01

Reference: CP 10.3.2.2/01	**Report:**	Adelberger, I. (2002); Oxamyl (DPX-D1410) 10L: An extended laboratory study using field aged residues to evaluate the effects on the predatory mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) **DuPont Report No.:** DuPont-6133 **Guidelines:** IOBC (Overmeer, 1988 and Oomen, 1988), IOBC (Blumel *et al.* 2000) and SETAC-ESCORT I (1994) **Deviations:** None that affect the validity of the study. **Testing Facility:** GAB Biotechnologie, GmbH, Niefern-Oeschelbronn, Germany **Testing Facility Report No.:** 20011214/01-NETp **GLP:** Yes **Certifying Authority:** Ministrium fur Umwelt und Verkehr (Baden-Wurttemberg, Germany)

Executive summary:

A 14dhour extended laboratory study on the predatory mite, *Typhlodromus pyri* was conducted in the laboratory according to IOBC (Overmeer, 1988 and Oomen, 1988), IOBC (Blumel *et al.*, 2000) and SETAC-ESCORT (1994). The test organisms were exposed for 7 days and 14 days to residues of Oxamyl 10SL on sweet pepper leaves. The test substance was applied 6 times at 1.0 kg a.s./ha *via* a simulated drip irrigation system. *Typhlodromus pyri* was exposed to residues in leaves either 3 days after the 1st application or after the

6th application. The test substance was allowed to be distributed equally in the plants for 3 days, before the test leaves were sampled. A control group on untreated leaves was also tested. No toxic reference was tested, since there is no toxic standard for drip irrigation application available. Oxamyl 10SL applied to sweet pepper plants *via* drip irrigation at 1.0 kg a.s./ha had no adverse effect on *Typhlodromus pyri*. Six applications at 1.0 kg a.s./ha resulted in a mortality of 8.3%.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-424
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Not determined in the test system
2.	Control:	Tap water
	Test vehicle:	Tap water
	Toxic reference:	None
3.	Test organism	
	Species:	*Typhlodromus pyri*
	Age at dosing:	Protonymphs (<24 hours old)
	Source:	PK Nützlingszuchten, Welzheim, Germany
	Diet:	*Vicia faba* and *Betula pendula* pollen, supplied before and at test initiation and replenished three times per week.
	Water:	Tap water, *ad libitum*
	Test chamber (exposure period):	The test unit consisted of a sweet pepper leaf (leaf stalk sealed with bee wax), a small petri dish (diameter approx. 15 cm) and a cotton pad.
4.	Environmental conditions (in-life period)	
	Temperature:	22 to 25.0 first exposure 24 to 26°C second exposure
	Relative humidity:	55 to 80%first exposure 65 to 81% second exposurew
	Photoperiod	16 hour photoperiod (3500 lux)

B. STUDY DESIGN AND METHODS

1 In-life initiated/completed

06-July-2001 to 01-October-2001

2. Experimental treatments

In an extended laboratory study, the predatory mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) were exposed to residues of Oxamyl 10SL on sweet pepper leaves. The test substance was applied 6 times at 1.0 kg a.s./ha *via* a simulated drip irrigation system. To simulate a drip irrigation in a greenhouse the amount of test substance was calculated per plant. For the sweet pepper 20 000 plants/ha are good agricultural practice in Spain. Therefore the total amount of test substance per plant was 0.35 g a.s. Six applications (with 1.0 kg a.s./ha each, corresponding to 0.05 g a.s./plant) were performed in 14 day intervals. Every application was split into four runs applied at regular 2 hours intervals. At each application run a quarter of the total amount (0.25 kg a.s./ha corresponding to 0.0125 g a.s./plant) of test substance was applied. The volume of water applied for each application was 600 mL/plant (corresponding to 150 mL/plant per application run). *Typhlodromus pyri* was exposed to residues in leaves either 3 days after the 1st application or after the 6th application. The test substance was allowed to be distributed equally in the plants for 3 days, before the test leaves were sampled. A control group on untreated leaves was also tested. No toxic reference was tested, since there is no toxic

standard for drip irrigation application available. The test was comprised of 10 replicates of 10 individuals (5 male and 5 female) for each treatment.

Juvenile mortality was evaluated after 7 days of exposure and the reproduction capacity after 14 days of exposure.After 7 days, rf necessary, males were redistributed between replicates of the same treatment group to achieve a ratio of at least one male to:5 females. On Days 10, 11, and 14, the number of eggs and juveniles were counted and removed.

3. Observations

Assessments for adult wasp mortality were carried out on Days 3 and 7. To assess effects on reproduction (fecundity), the number of number of eggs + number of juvenile mites was counted on Days 10, 11, and 14. Eggs laid until day 7 inclusive were not considered.

4. Statistics

Mortality and fecundity data were tested for normality and homoscedasticity (homogeneity of variances) using Shapiro-Wilk's test and residual analysis (ZAR, 1984). As according to Shapiro Wilk's test the mortality data did not meet the normal distribution criteria ($p \leq 0.1$). Kruskal-Wallis Test was used to analyse mortality data for significance. Reproduction data were tested for significance using Dunnett's Test. The statistical software program SAS release 8 was used for the statistical analysis.

II. RESULTS AND DISCUSSION

A. FINDINGS

Adult mortality in the control groups which run in parallel with the exposure after 1 and 6 applications was <20 % on day 7 (actual 11.1 and 4.0%, respectively). The cumulative mean number of offspring per female was > 4 eggs in the control group (actual 10.1 in both exposures). All validation criteria were met. The results for mortality and reproduction of *Typhlodromus pyri* are given Table 44.

Table 44 The effects on mortality and reproduction of *Typhlodromus pyri* exposed to Oxamyl 10SL applied to natural substrate in the laboratory

Nominal oxamyl concentration (kg a.s./ha)	Mortality (%)	Corrected mortality (%)[a]	Offspring/ female (mean)	Reduction in reproduction (%)
Untreated control (0.0) first exposure	11.1	-	10.1	-
1.0 first exposure	10.0	-1.2	10.3	[b]
Untreated control (0.0) second exposure	4.0	-	10.1	-
1.0 (6.0 total) second exposure	12.0	8.3[c]	10.2	[b]

[a] Schneider-Orelli's Correction

[b] There were no significant differences from the control (Dunnett's Test., alpha = 0.05)

[c] Significantly different from the control (Statistical test, alpha = 0.05)

III. CONCLUSION

Oxamyl 10SL applied to sweet pepper plants *via* drip irrigation at 1.0 kg a.s./ha had no adverse effect on *Typhlodromus pyri*. Six applications at 1.0 kg a.s./ha resulted in a mortality of 8.3%.

(Adelberger, I., 2002)

RMS:

RMS comments and conclusion

Deviations from BLÜMEL et al. 2000 are noted, which do not affect the reliability of the results:

-Minor deviation related to the temperature in the first exposure which fell below the min of 23°C (22.5, 22.5, -22°C) in three consecutive days for 2, 8,8 hours respectively.
-In the control group of the first exposure, one replicate was excluded because flooded accidentally.
-A reference toxicant was not tested, hence the related validity criterion cannot be verified. The RMS comments that the sensitivity of the organisms could have been checked anyhow using a standard spray application.

Conclusion: To simulate a drip irrigation in a greenhouse the amount of test substance was calculated per plant based on 20 000 plants/ha of sweet pepper plants. The applicant should justify the extrapolation to the proposed use in tomatoes in greenhouse also with respect to the GAP of 2+1+1+1 kG/ha.
Since no reference toxicant was tested, the study is considered not reliable.

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

B.9.5.2.2/02

Reference: **CP 10.3.2.2/02**	**Report:**	Bargen, H. (2002); Oxamyl (DPX-D1410) 10L - an extended laboratory study using aged residues to evaluate the effects on predatory bug *Orius laevigatus* Fieber (Heteroptera, Anthocoridae) **DuPont Report No.:** DuPont-6132 **Guidelines:** IOBC (Staubli, A. and Pasquier, D., 1988), Bakker *et al.* (2000) and SETAC-ESCORT (1994) **Deviations:** None that affect the validity of the study. **Testing Facility:** GAB Biotechnologie, GmbH, Niefern-Oeschelbronn, Germany **Testing Facility Report No.:** 20011214/01-NEOr **GLP:** Yes **Certifying Authority:** Ministrium fur Umwelt und Verkehr (Baden-Wurttemberg, Germany)

Executive summary:

An extended laboratory study on the predatory bug *Orius laevigatus* was conducted in the laboratory according to IOBC (Staubli, A. and Pasquier, D., 1988), Bakker *et al.* (2000), and SETAC-ESCORT (1994). The test organisms were exposed to residues of Oxamyl 10SL on sweet pepper leaves (at Day 11 only those organisms which were not adult on Day 8). The test substance was applied 7 times at 1.0 kg a.s./ha *via* a simulated drip irrigation system. *Orius laevigatus* was exposed to residues in leaves either 3 days after the 1st application or after the 7th application. The test substance was allowed to be distributed equally in the plants for 3 days, before the test leaves were sampled. A control group on untreated leaves was also tested. No toxic reference was tested, since there is no toxic standard for drip irrigation application available. Oxamyl 10SL applied to sweet pepper plants *via* drip irrigation at 1.0 kg a.s./ha or seven applications at 1.0 kg a.s./ha had no adverse effect on *Orius laevigatus*.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-424
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Not determined in the test system
2.	Control:	Tap water
	Test vehicle:	Tap water
	Toxic reference:	None
3.	Test organism	
	Species:	*Orius laevigatus*
	Age at dosing:	Nymphs (approximately 4 days old)
	Source:	Novartis BCM Limited, Aldam, Colchester, Essex, UK
	Diet:	*Ephestia kuehniella* eggs
	Water:	Tap water, *ad libitum*
	Test chamber (exposure period):	Leaves (upper side top) were placed on a wet cotton wool disc which lay in a petri-dish with a perforated bottom. Exposure units were positioned in seed trays (56 x 36 x 6 cm).
4.	Environmental conditions (in-life period)	
	Temperature:	25 ± 2°C maximum temperature was 28.0 °C for approximately 8 h and 27.5 °C for approximately 2 h
	Relative humidity:	70 ± 15 % minimum humidity was 52 % for approximately 6 h and 50 % for approximately 10 h.
	Photoperiod	16 h light/8 h darkness

B. STUDY DESIGN AND METHODS

1 In-life initiated/completed

06-July-2001 to 24-October-2001

2. Experimental treatments

In an extended laboratory study, predatory bugs *Orius laevigatus* Fieber (Heteroptera, Anthocoridae) were exposed to Oxamyl 10SL. The test organisms were exposed to residues of Oxamyl 10SL on sweet pepper leaves (at Day 11 only those organisms which were not adult on Day 8). The test substance was applied 7 times at 1.0 kg a.s./ha (corresponding to 0.05 g a.s./plant) *via* a simulated drip irrigation system with application interval 14 days ± 1 day. Every application was split into four runs applied at regular 2 hours intervals. At each application run a quarter of the total amount (0.25 kg a.s./ha corresponding to 0.0125 g a.s./plant) of test substance was applied. The volume of water applied for each application was 600 mL/plant (corresponding to 150 mL/plant per application run).

Orius laevigatus was exposed to residues in leaves either 3 days after the 1st application or after the 7th application. The test substance was allowed to be distributed equally in the plants for 3 days, before the test leaves were sampled. A control group on untreated leaves was also tested. No toxic reference was tested, since there is no toxic standard for drip irrigation application available. The test was comprised of 25 replicates of 2 individuals (nymphs,second instar) for each treatment rate. The predatory bugs were observed for lethal effects. As the corrected mortality was ≤ 50 % after exposure, the test continued through to the reproduction phase. The reproduction test was carried out in all treatment groups, because in all treatment groups the corrected mortality was < 50 %. The reproduction test started on day +8, when at least 80 % of the control test organisms had developed to adults. Fourteen to 19 of the surviving females per treatment group were transferred (in groups of 2-4 females) into

mating boxes, which contained 2 males (3 males, if there were 4 females in the box).
After at least two days, the females were transferred to oviposition units (one per unit, maximum of 15 per treatment), and were offered fresh bean leaves as oviposition substrates.
In the first exposure, fresh oviposition substrates were offered 4 times at 2-day intervals to control and treatment females. In the second exposure, fresh oviposition substrates were offered 3 times, at 2-day intervals.. At the end of each oviposition period the number of eggs present on the substrate was determined. From these data the total number of eggs per female over the 6 day period (for the first exposure: 8 day period) was determined. The oviposition substrates containing either the first or third batch of eggs were incubated for 5 days to allow for embryonic development and hatching. For the second exposure the third oviposition substrate was incubated 5 more days after counting eggs. Hatching was assessed on these substrates, because the first substrate was infected with fungi and a determination of hatching rate was not possible.

3. Observations

Assessments for adult wasp mortality were carried out on Days 0, 4, 7, 8, and 11.

4. Statistics

Data were tested for normality and homoscedascity using Shapiro-Wilk's test and residual analysis. When these assumptions were met Dunnett Test was used. If these assumptions were not met the Kruskal-Wallis test was used. The statistical software program SAS release 8.02 was used for the statistical analysis.

II. RESULTS AND DISCUSSION

A. FINDINGS

Adult mortality in the control groups which run in parallel with the exposure after 1 and 7 applications was 16.00 and 4.00%, respectively. All validation criteria were met. The results for mortality and reproduction rate of *Orius laevigatus* are given Table 45.

Table 45 The effects on mortality and reproduction of *Orius laevigatus* exposed to Oxamyl 10SL applied to natural substrate in the laboratory

Nominal oxamyl concentration (kg a.s./ha)	Mortality (%)	Corrected mortality (%)[a]	Number of eggs/female (mean)	Reduction in reproduction (%)	Eggs hatched (%)
Untreated control (0.0) first exposure	16.00	-	7.05	-	85.45
1.0 first exposure	12.00	-4.76	5.98	15.18	83.01
Untreated control (0.0) second exposure	4.00	-	5.76	-	94.25
1.0 (7.0 total) second exposure	4.00	0.00	6.04	-4.86	94.61

[a] Schneider-Orelli's Correction

III. CONCLUSION

Oxamyl 10SL applied to sweet pepper plants *via* drip irrigation at 1.0 kg a.s./ha or seven applications at 1.0 kg a.s./ha had no adverse effect on *Orius laevigatus*.

(Bargen, H., 2002)

RMS comments and conclusion

Some deviations from the current Bakker et al (2002) guideline were found:

No toxic reference was tested.
The test comprised of 25 replicates of 2 individuals, while guideline recommends that 8 replicates with 10 bugs each would be needed for an acceptable statistical power. In the study report it is not documented if the test design achieved the minimum statistical power of 80% to detect significant differences.
Further, the egg production should be assessed for two consecutive 2d interval, while in the study the total number of eggs per female over the 6 day period (for the first exposure: 8 day period) was determined, which were based on 3 ovodepositions (second exposure, 7 x 1.0 kg a.s./ha) and 4 ovodepositions (first exposure, 1 x 1.0 kg a.s./ha). As a consequence the reported number of eggs/female/day are calculated for the first on 4 ovodepositions.
For the second exposure (7 x 1.0 kg a.s./ha), hatching was determined on the third substrate.

The results are not reliable and the study is not considered acceptable.

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

B.9.5.2.2/03

Reference: CP 10.3.2.2/03	**Report:**	Bruhnke, C. (2000); Oxamyl 10L: An extended laboratory study to evaluate the effects on the spider *Pardosa spec* L. (Araneae, Lycosidae) **DuPont Report No.:** DuPont-3912 **Guidelines:** BBA VI 23-2.1.9 (1994), Heimbach et al. (draft 2000) **Deviations:** None that affect the validity of the study. **Testing Facility:** Dr. U. Noack-Laboratorium for Angewandte Biologie, Sarstedt, Germany **Testing Facility Report No.:** IPE72341 **GLP:** Yes **Certifying Authority:** Niedersachsisches Umweltministerium (Hanover, Germany)

Executive summary:

An extended laboratory study on spiders of the *Pardosa* species was conducted in the laboratory according to BBA VI 23-2.1.9 (1994). Standard soil LUFA 2.1 was treated with 7.0, 15.0, and 23.0 mg oxamyl/kg dry soil with Oxamyl 10SL. As control untreated LUFA soil 2.1 was used and as reference item Karate (50 g/L Lambda-cyhalothrin) with an amount of 60 mL/ha (3.0 g a.s./ha) in 400 L/ha demineralised water was tested. Mortality of *Pardosa* spp. was 52.9% after 21 days when Oxamyl 10SL was applied at a rate of 7.0 mg a.s./kg dry soil and 100% at rates of 15.0 and 23.0 mg a.s./kg dry soil. Mean feeding rates of the test item groups were 2.2, 1.6, and 1.1 flies/spider/day, respectively.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-393
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Not determined in the test system
2.	Control:	Untreated LUFA soil 2.1 moistened to 55% of maximum water holding capacity.
	Test vehicle:	LUFA soil 2.1
	Toxic reference:	Karate (Lambda-cyhalothrin a.s.)
3.	Test organism	
	Species:	*Pardosa* spp. Adapted for 3d before the test.
	Age at dosing:	Adults
	Source:	Natural population collected on meadows near Hildesheim, Germany
	Diet:	Frozen adult *Drosophilia hydrii* on day 0,1,2,3,7,10,14,17.
	Test chamber	

(exposure period):

Bellaplast boxes (inner size 9.5 × 9.5 × 6 cm) filled with 125 g (dry weight) LUFA soil 2.1.

4. Environmental conditions (in-life period)

Temperature:	18 to 21°C
Relative humidity:	62 to 100%
Photoperiod	16 hour photoperiod (763 to 1385 lux)

B. STUDY DESIGN AND METHODS

1 In-life initiated/completed

22-May-2000 to 12-June-2000

2. Experimental treatments

In an extended laboratory study, spiders of the species *Pardosa* (Araneae, Lycosidae) were exposed to Oxamyl 10SL. Standard soil LUFA 2.1 was treated with 7.0, 15.0, and 23.0 mg oxamyl/kg dry soil with Oxamyl 10SL mixed to soil. Karate (50 g/L Lambda-cyhalothrin) with an amount of 60 mL/h a (3.0 g a.s./ha) in 400 L/ha demineralised water was sprayed onto the test units The duration of the test was prolonget to 21 days as the mean feeding rates in the 15 and 23 mg oxamyl/kg dry soil groups were reduced by more than 50% below the value of the control in the second week. The test was comprised of 34 replicates of 1 individual (17 male and 17 female) for each treatment rate, control, and toxic reference.

3. Observations

Assessments for spider mortality and behaviour were carried out approximately 2 hours and 1, 2, 3, 4, 7, 10, 14, 17, and 21 days after treatment. To assess effects on feeding rate, the number of flies eaten was determined 1, 2, 3, 4, 8, 18, 15, and 18 days after treatment.

4. Statistics

Fisher Exact Test was used for comparison of mortality of test item and reference item versus control and t-test for comparison of feeding rates for each feeding interval of test and reference item groups versus control (p = 0.05). Calculations were carried out using software SigmaStat rel. 2.03 (1992-1997), SPSS Inc. and Excel 2000 (Microsoft).

II. RESULTS AND DISCUSSION

A. FINDINGS

89% of test organisms belonged to Pardosa agrestis. Two juveniles in the reference toxicant group belonged to Throcosa instead of Pardosa spp. Mortality in the control and toxic standard groups was 0 and 100%, respectively. All validation criteria were met.

Mortality

Day	Mortality [%]				
	Control	Test Item			Reference Item
		7 mg a.i./kg	15 mg a.i./kg	23 mg a.i./kg	
0 (2 h)	0.0	0.0	0.0	0.0	0.0
1	0.0	0.0	0.0	0.0	70.6
2	0.0	0.0	5.9	2.9	70.6
3	0.0	5.9	8.8	32.4	97.1
4	0.0	8.8	38.2	76.5	100.0
7	0.0	32.4	64.7	88.2	-
10	0.0	35.3	82.4	97.1	-
14	0.0	52.9	100.0	100.0	-
17	0.0	52.9	-	-	-
21	0.0	52.9	-	-	-

- = all spiders were dead

Feeding rate

Day	Eaten flies / alive spiders per day				
	Control	Test Item			Reference Item
		7 mg a.i./kg	15 mg a.i./kg	23 mg a.i./kg	
1	3.2	3.3	3.3	2.7	0.0
2	2.6	2.6	1.8	1.3	0.0
3	2.4	2.1	1.7	1.7	0.0
4	1.6	1.3	1.0	0.6	-
8	1.7	2.0	1.0	0.5	-
11	1.9	1.5	0.8	0.0	-
15	3.0	2.6	-	-	-
18	2.1	2.2	-	-	-
∑ day 1 - 4	9.8	9.3	7.8	6.3	0.0
∑ day 7 - 14	3.6	3.5	1.8	0.5	-
∑ day 15 - 21	5.1	4.8	-	-	-
∑ overall	18.5	17.6	9.6	6.8	0.0
Mean feeding rate (flies / spider and day)	2.3	2.2	1.6	1.1	0.0
Feeding capacity	-	0.96	0.70	0.48	0.0
Total number of consumed flies	623	469	262	182	0

The results for mortality and feeding rate of *Pardosa* spp are given Table 46. The mortality in all the treatment groups was significantly different from the control. The mean feeding rate was statistically significant at 23.0 mg oxamyl/kg.

Table 46 The effects on mortality and feeding rate of *Pardosa* spp. exposed to Oxamyl 10SL applied to soil in the laboratory

Nominal oxamyl concentration (mg a.s./kg)	Mortality (%)	Feeding rate (mean)	% reduction feeding rate*
Untreated control (0.0)	0	2.3	---
Toxic standard (3.0 g Lambda-cyhalothrin/ha)	100[a]	-	
7.0	52.9[a]	2.2	4.3
15.0	100[a]	1.6	30.4
23.0	100[a]	1.1[a]	52.2

[a] Significantly different from the control (t-test, alpha = 0.05)

*Added by the RMS.

III. CONCLUSION

Mortality of *Pardosa* spp. was 52.9% after 21 days when Oxamyl 10SL was applied at a rate of 7.0 mg a.s./kg dry soil and 100% at rates of 15.0 and 23.0 mg a.s./kg dry soil. Mean feeding rates of the control and test item group were 2.3, 2.2, 1.6, and 1.1 flies/spider/day, respectively.

(Bruhnke, C., 2000)

RMS comments and conclusion

The relative humidity was up to 100% (instead of a maximum of 90%), this did not affect the control performance.

Two juveniles in the reference toxicant group belonged to Throcosa instead of Pardosa spp. Taking into account the 100% lethal and sublethal effects in this group, the deviation did not impact the validity of the test.

The validity criteria are met:

Control mortality < 14.7% (5 spider/34 replicates, 21d test duration). Fulfilled (actual 0%).

Mortality in the reference group should be >30%. Fulfilled (actual 100%).

Lethal and sublethal effects around 50% were observed but in both cases only half of the dose response curve can be drawn. The ER50/LR50 has not been calculated.

The study is acceptable.

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

B.9.5.2.2/04

Reference: CP 10.3.2.2/04	**Report:**	Drexler, A. (2000); Oxamyl 10L (DPX-D1410): An extended laboratory study to evaluate the effects on the staphylinid beetle, *Aleochara bilineata* Gyll. **DuPont Report No.:** DuPont-3910 **Guidelines:** BBA VI 23-2.1.9 (1994) **Deviations:** None that affect the validity of the study. **Testing Facility:** IBACON, Rossdorf, Germany **Testing Facility Report No.:** 7933071 **GLP:** Yes **Certifying Authority:** Hessisches Ministerium fur Umwelt, Landwirtschaft und Forsten

Executive summary:

An extended laboratory study on the staphylinid beetle, *Aleochara bilineata* Gyll. was conducted in the laboratory according to BBA VI 23-2.1.9 (1994). Emergence of the F-1 generation of *Aleochara bilineata* and the parasitism success on *Delia* pupae were evaluated following a 4-week exposure period. Adult beetles were placed in beakers containing natural soil substrate (LUFA 2.1). The test item was applied by dispersing in the water necessary for adjusting the water amount of the soil and by mixing of this dispersion evenly into the dry soil. Four rates were tested: 15, 20, 25, and 30 mg Oxamyl 10SL/kg soil. This equates to 1.5, 2.0, 2.5, and 3.0 mg oxamyl/kg soil. After application the test organisms were introduced into the exposure units. An untreated control and toxic standard [1.08 kg pyrazophos/ha in 400 L water/ha (spray application)] were also tested. Oxamyl 10SL incorporated into natural soil (LUFA 2.1) at 15, 20, 25, or 30 mg Oxamyl 10SL/kg soil had no effect on adult behavior and resulted in a statistically significant reduction in reproduction of 9.0, 10.4, 21.9, or 29.3%, respectively.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-381
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	9.84% of the formulation stayed in solution after agitation
2.	Control:	LUFA 2.1 soil (moistened to 10% (v/v) with deionised water)
	Test vehicle:	Deionised water
	Toxic reference:	Afugan 30 EC (pyrazophos a.s.30.6%)
3.	Test organism	
	Species:	*Aleochara bilineata*
	Age at dosing:	1-3 day old adults
	Source:	De groene Vlieg, Duivenwaardsdedijk 1; NL- 3244
	Diet:	Frozen midge larvae
	Water:	Deionised water, *ad libitum*
	Test chamber	
	(exposure period):	Glass beakers (154 cm^2, diameter 15 cm, height 7.5 cm), covered with watch-glasses (diameter 15 cm), half-filled at 4 cm with 800g natural soil (LUFA 2.1).
	(parasitation period):	Funnel (height 8 cm; diameter 13 cm) placed on a glass beaker (height 14 cm; diameter 8 cm). Bottom of funnel perforated with holes (diameter 2 mm).
	Host species:	*Delia antiqua* Meig.
	Test age:	Pupae
	Source:	De groene Vlieg, Duivenwaardsdedijk 1; NL- 3244
4.	Environmental conditions (in-life period)	
	Temperature:	18 to 21°C acclimatisation and esposure; 18 to 25°C post exposure
	Photoperiod (exposure):	16 hour photoperiod (410 to 1580 lux)
	Photoperiod (post exposure)	16 hour photoperiod (220 to 1460 lux)

B. STUDY DESIGN AND METHODS

1 In-life initiated/completed

14-July-2000 to 11-October-2000

2. Experimental treatments

In an extended laboratory study, the staphylinid beetle, *Aleochara bilineata* Gyll. was exposed to Oxamyl 10SL. Emergence of the F-1 generation of *Aleochara bilineata* and the parasitism success on *Delia* pupae were evaluated following a 4-week exposure period. Adult beetles were placed in beakers containing 800g of natural soil substrate (LUFA 2.1 moistened to 10%). The test item was applied by dispersing in the water necessary for adjusting the water amount of the soil and by mixing of this dispersion evenly into the dry soil. Four rates were tested: 15, 20, 25, and 30 mg Oxamyl 10SL/kg soil. This equates to 1.5, 2.0, 2.5, and 3.0 mg oxamyl/kg soil. Test item application rates were based on the results of a non-GLP range finding study. A toxic reference, 3.6L Afugan 30 EC (1.1 kg pyrazophos a.s./ha), was included in the test applied applied as spray at 4 mg/cm2, The test was comprised of 4 replicates of 20 individuals (10 male and 10 female) for each treatment rate, control, and toxic reference.

On Days 7, 14, and 21, 500 live *Delia antique* pupae were added to the exposure chambers. On Day 28, the pupae were transferred to emergence chambers. Emerging beetles were counted and removed at

least 3 times per week until 3 consecutive days without beetle emergence was observed (approximately 8-9 weeks).

3. Observations

Assessments for beetle mortality were carried out 1, 3, and 7 days after exposure began. The larvae that hatched from the eggs laid in the soil by the females beetles parasitized the fly pupae. To assess effects on reproduction (fecundity), the number of F-1 beetles emerged from the parasitized fly pupae was counted.

4. Statistics

Data were arcsin transformed. Reproduction data were tested for normal distribution and homogeneity of variance using Kolmogoroff-Smirnov-Test (α= 0.05) and Cochran-test (α = 0.05). Because reproduction data were not normally distributed and not variance homogenous, Mann and Whitney-U-Test (pairwise comparison, one sided smaller), α = 0.05, was used. The software used to perform the statistical analyses was EASY ASSAY Multiple Testing, ©SpiRiT Version 4.0.

II. RESULTS AND DISCUSSION

A. FINDINGS

Adult mortality in the control and toxic standard groups was 0 and 22.5%, respectively. All validation criteria were met. No behavioural abnormalities were observed in any group. The results for mortality and reduction in reproduction of *Aleochara bilineata* Gyll. are given Table 47.

Table 47 The effects on mortality and reproduction of *Aleochara bilineata* Gyll. exposed to Oxamyl 10SL applied to soil in the laboratory

Nominal oxamyl concentration (g a.s./ha)	Mortality after 7d exposure (%)	Emerged beetles/replicate (mean)	Reduction in reproduction (%)
Untreated control (0.0)	0.00	874	-
Toxic standard (1.08 kg pyrazophos/ha)	22.50	240	72.5%.
1.5	2.50	795[a]	9.0[a]
2.0	3.75	783[a]	10.4[a]
2.5	1.25	683[a]	21.9[a]
3.0	0.00	618[a]	29.3[a]

[a] Significantly different from the control (Mann-Whitney U-test, alpha = 0.05)

III. CONCLUSION

Oxamyl 10SL incorporated into natural soil (LUFA 2.1) at 15, 20, 25, or 30 mg product/kg soil had no effect on adult behavior and resulted in a statistically significant reduction in reproduction of 9.0, 10.4, 21.9, or 29.3%, respectively, with *Aleochara bilineata*. Reproductive effects were <30% up to 3 mg a.s./kg soil.

(Drexler, A., 2000)

RMS comments and conclusion
The study was evaluated against the current Grimm et al. (2000) guideline.

The toxic reference pyrazophos a.s.30.6% was tested at 3.4 L Afugan EC 30/ha instead of at 1L (the test was done in natural soil, not in sand).

The following deviations were observed:
Temperature was 18 to 25°C (25°C for 13.5h) instead of 20 ±2°C
The relative humidity dropped for several days at 55%, below the minimum of 60%.The two validity criteria were fulfilled:

The mean number of beetles emerging from parasitised fly pupae in the control treatment should be > 400 per replicate (nominally 27% of those provided): actual 87.4 beetles per female)
The mean number of beetles emerging in the toxic reference treatment should be reduced by > 50%, relative to the control: actual 72.5%.

Conclusion: the test is acceptable.

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

B.9.5.2.2/05

Reference: CP 10.3.2.2/05	**Report:**	Schmitzer, S. (2000); Oxamyl 10L (DPX-D1410): An extended laboratory study to evaluate the effects on the ground beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) **DuPont Report No.:** DuPont-3911 **Guidelines:** BBA VI 23-2.1.8 (1991),Heimbach U., DRAFT 1999, ring-test group protocol, Versailles, France, 1999 **Deviations:** None that affect the validity of the study. **Testing Facility:** IBACON, Rossdorf, Germany **Testing Facility Report No.:** 7932007 **GLP:** Yes **Certifying Authority:** Hessisches Ministerium fur Umwelt, Landwirtschaft und Forsten

Executive summary:

An extended laboratory study on the ground beetle, *Poecilus cupreus* L. was conducted in the laboratory according to BBA VI 23-2.1.8 (1991). The test item was mixed into standardised soil LUFA 2.1 at a concentration of 330 or 33 mg Oxamyl 10SL/kg soil. This equates to 33 and 3.3 mg a.s oxamyl/kg soil. An untreated control and toxic standard (spray application of 2.5 L Afugan 30 EC/ha) were also tested. Oxamyl 10SL mixed into standardised LUFA 2.1 soil at 330 mg product/kg soil, resulted in 10.0% mortality and reduction in food consumption of -6.7% relative to the control group. Oxamyl 10SL mixed into standardised LUFA 2.1 soil at 33 mg product/kg soil, resulted in 6.7% mortality and reduction in food consumption of -7.4% relative to the control group.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	DPX-D1410-381
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	9.84 % of the formulation stayed in solution after one hour of agitation
2.	Control:	LUFA 2.1 soil at 55 % ± 5% WHC
	Test vehicle:	Deionised water
	Toxic reference:	Afugan 30 EC (pyrazophos a.s.)
3.	Test organism	
	Species:	*Poecilus cupreus* L.
	Age at dosing:	Adults, 3 weeks old.
	Source:	Bio-Test Labor GmbH
	Diet:	Punctured deep-frozen *Musca domestica* pupae on day 0, 2, 4, 7, and 10 after application (1 pupa per viable beetle).
	Water:	*ad libitum*
	Test chamber (exposure period):	Plastic boxes (18.3 cm × 13.6 cm × 6 cm; length, width, height; substrate surface of about 175 cm^2) containing a layer of 2 cm depth dry LUFA 2.1 soil
4.	Environmental conditions (in-life period)	
	Temperature:	19 to 21°C
	Relative humidity:	55 to 70%
	Photoperiod (exposure):	16 hour photoperiod (830 to 1520 lux)

B. STUDY DESIGN AND METHODS

1 In-life initiated/completed

17-July-2000 to 31-July-2000

2. Experimental treatments

In an extended laboratory study, the ground beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) were exposed to Oxamyl 10SL for 14 days.. Beetles were acclimatised 3 days before the test. The test item was mixed into standardised soil LUFA 2.1 at a concentration of 330 or 33 mg Oxamyl 10SL/kg soil. This equates to 33 and 3.3 mg a.s oxamyl/kg soil. A toxic reference, Afugan 30 EC (pyrazophos a.s., 30.6 %), was included in the test (spray application of 2.5 L Afugan 30 EC/ha on LUFA 2.1 soil). The test system contained a layer of 2 cm depth dry soil (500 g dry soil moistened to about 55 % of its maximum water holding capacity (about 80 g deionized water),The test was comprised of 5 replicates of 6 individuals (3 male and 3 female) for each treatment rate, control, and toxic reference.

3. Observations

Assessments for adult beetle mortality and food consumption (and count of damaged beetles) were carried out approximately 2 hours and 1, 2, 4, 7, 10, and 14 days after treatment. At the last assessment the sand was searched for missing beetles; damaged beetles were placed at one corner of the trays and were counted as dead, if they were still there 24 hours later. Missing pupae were also denoted as consumed;

4. Statistics

Mortality data were tested for significant differences using Fisher's Exact Test (pairwise comparison), $p = 0.05$. Food consumption was tested for normal distribution and homogeneity of variance using

Kolmogoroff-Smirnov-Test (p = 0.05) and Cochran-Test (p = 0.05). For the food consumption data, Mann and Whitney U-Test (pairwise comparison), p = 0.05, was used. The software used to perform the statistical analysis was EASY ASSAY, Multiple Testing, © SPiRiT, Version 4.0 and SYSTAT Version 9, © SPSS Inc., 1998.

II. RESULTS AND DISCUSSION

A. FINDINGS

Adult mortality in the control and toxic standard groups was 0 and 100%, respectively. All validation criteria were met. The toxic standard Afugan 30 EC (2.5 L/ha) led to a 100 % mortality. No control mortality occurred. Mortalities and food consumption in the toxic standard groups were significantly different from the control; no other statistically significant differences in mortality or food consumption were detected (mortality: Fisher's Exact Test, p = 0.05; food consumption: Mann & Whitney-U-Test, p = 0.05).

Mortality and behavioural abnormalities

	Oxamyl 10 L (33 mg a.i./kg soil)		Oxamyl 10 L (3.3 mg a.i./kg soil)		Control		Toxic standard	
Time[a]	Mortality[b] % ± SD	Beh. abn.[c] % ± SD	Mortality % ± SD	Beh. abn. % ± SD	Mortality % ± SD	Beh. abn. % ± SD	Mortality % ± SD	Beh. abn. % ± SD
2 hours	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
24 hours	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	60.0 ± 14.9	0.0 ± 0.0
2nd day	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	80.0 ± 13.9	0.0 ± 0.0
4th day	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	80.0 ± 13.9	0.0 ± 0.0
7th day	0.0 ± 0.0	6.7 ± 14.9	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	86.7 ± 7.5	0.0 ± 0.0
10th day	0.0 ± 0.0	0.0 ± 0.0	3.3 ± 7.5	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	86.7 ± 7.5	0.0 ± 0.0
14th day	10.0 ± 14.9	0.0 ± 0.0	6.7 ± 9.1	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	100.0 ± 0.0	0.0 ± 0.0

the tabulated results represent rounded results calculated on the exact raw data

[a] time period after application

[b] percentage values represent group means ± standard deviation from five replicates

[c] Beh. abn. = Behavioural abnormalities

Food consumption

	Oxamyl 10 L (33 mg a.i./kg soil)		Oxamyl 10 L (3.3 mg a.i./kg soil)		Control		Toxic standard	
Time[a]	Pupae/ beetle #	Consumption[b] %	Pupae/ beetle #	Consumption %	Pupae/ beetle #	Consumption %	Pupae/ beetle #	Consumption %
days 0 - 7	2.8	106.3 %	3.0	112.7 %	2.6	100.0 %	0.8	29.1 %
days 7 - 14	2.0	107.1 %	1.9	100.0 %	1.9	100.0 %	0.0	0.0 %
days 0 - 14	4.8	106.7 %	4.8	107.4 %	4.5	100.0 %	0.8	17.0 %

the tabulated results represent rounded results calculated on the exact raw data

[a] time period after application

[b] compared with the control, calculated with exact data

The summary of results for mortality and food consumption effects of *Poecilus cupreus* L. are given in Table 48.

Table 48 The effects on mortality and food consumption of *Poecilus cupreus* L. exposed to Oxamyl 10SL applied to soil in the laboratory

Nominal oxamyl concentration (mg a.s./kg soil)	Mean Mortality (%)	Food consumption (%)	Reduction in food consumption (%)
Untreated control (0.0)	0.0	100.0	-
Toxic standard (2.5 L Afugan 30 EC/ha)	100	17.0	-
3.3	6.7	107.4	-7.4
33	10.0	106.7	-6.7

III. CONCLUSION

Oxamyl 10SL mixed into standardised LUFA 2.1 soil at 330 mg product/kg soil, resulted in 10.0% mortality and reduction in food consumption of -6.7% relative to the control group. Oxamyl 10SL mixed into standardised LUFA 2.1 soil at 33 mg product/kg soil, resulted in 6.7% mortality and reduction in food consumption of -7.4% relative to the control group.

(Schmitzer, S., 2000)

RMS comments and conclusion

The study was evaluated according to Heimbach (2000).

The filling height was 2 cm instead of the recommended 1 cm. The toxic reference was applied at higher concentration (recommened 1 L/ha).

The validity criteria are met:

Control Mortality: validity criteria: ≤6.7 %; resulted in 0.0 % at day 14.
Toxic Standard Mortality: validity criteria: 65 % ± 35 %; resulted in 100 % mortality.

Conclusion: the test is acceptable. The LR50 cannot be calculated due to the lack of effects.

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

B.9.5.2.2/06

Reference: CP 10.3.2.2/06	**Report:**	Schmitzer, S. (2001); Oxamyl 10L (DPX-D1410): An extended multi-rate laboratory study to evaluate the effects on the wolf spider, *Pardosa spec* L. (Araneae, Lycosidae) **DuPont Report No.:** DuPont-5162 **Guidelines:** BBA VI 23-2.1.9 (1994) (Heimbach U., DRAFT 2000) and recent ring-test group results, 2000. **Deviations:** None that affect the validity of the study. **Testing Facility:** IBACON, Rossdorf, Germany **Testing Facility Report No.:** 10001066 **GLP:** Yes **Certifying Authority:** Hessisches Ministerium fur Umwelt, Landwirtschaft und Forsten

Executive summary:

An extended laboratory study on wolf spiders, *Pardosa* spp., was conducted in the laboratory according to BBA VI 23-2.1.9 (1994). Standard soil LUFA 2.1 was treated with 2.0, 4.0 and 6.0 mg a.s./kg dry soil with Oxamyl 10SL. As a control, untreated LUFA soil 2.1 was used and as a reference item 900 g Perfekthion (dimethoate) in 400 L/ha water was tested. Mortality of *Pardosa* spp. was 8.8% after 21 days when Oxamyl 10SL was applied at a rate of 2.0 mg a.s./kg dry soil and 35.3% at rates of 4.0 and 6.0 mg a.s./kg dry soil. Mean feeding rates did not differ significantly between control and treatment groups.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-381
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	9.84% of the formulation stayed in solution after one hour under agitation
2.	Control:	Water
	Test vehicle:	Deinoised water
	Toxic reference:	Perfekthion (dimethoate a.s.)
3.	Test organism	
	Species:	*Pardosa* spp.
	Age at dosing:	Adults and subadults
	Source:	Collected from uncultivated land from Münster, Westfalen, Germany
	Diet:	deep frozen adult flies *Drosophila spec.* at day 0, 1, 2, 3, 7, 10, 14 and 17 after application at a rate of 5 flies per spider.
	Water:	Water checkedon Days 0, 2, 4, 7, 9, 11, 14, 16 to ensure that no more than 50 % of the water content was lost
	Test chamber (exposure period):	Plastic boxes (11.5 cm × 11.5 cm × 6 cm; length, width, height); containing a layer of about 1 cm natural soil (LUFA 2.1; 125 ± 1 g dry soil) moistened at the beginning to about 55 % of its maximum water holding capacity.
4.	Environmental conditions (in-life period)	
	Temperature:	20 to 23°C
	Relative humidity:	50 to 90%
	Photoperiod	16 hour photoperiod (685 to 1060 lux)

B. STUDY DESIGN AND METHODS

1 In-life initiated/completed

07-May-2001 to 28-May-2001

2. Experimental treatments

In an extended laboratory study, wolf spiders of the *Pardosa* species (Araneae, Lycosidae) were exposed to Oxamyl 10SL. All individuals of the experiment were determined and the following species were found: Pardosa amentata (74.0 %), Pardosa proxima (15.0 %), Pardosa pullata (0.5 %), Pardosa prativaga (4.0 %) and subadults (6.5 %). Acclimatisation Conditions were 7 days before test start under room temperature and 3 days before test start under test conditions. Standard soil LUFA 2.1 was treated with 2.0, 4.0 and 6.0 mg a.s./kg dry soil with Oxamyl 10SL. A toxic reference, Perfekthion (dimethoate a.s.), was included in the test (900 g dimethoate in 400 L/ha water, sprayed at rate of 4 mg/cm²). The test was comprised of 34 replicates of 1 individual (17 male and 17 female) for each treatment rate, control, and toxic reference. Because of increasing mortality in the 2nd week the experiment was prolonged for one further week up to 21 days-

3. Observations

Assessments for adult wasp mortality were carried out approximately 2 hours and 1, 2, 3, 4, 7, 10, 14, 17 and 21 days after treatment. To assess effects on feeding rate, the number of flies eaten was determined on Days 1, 2, 3, 4, 8, 11, 15, and 18. Missing flies are denoted consumed. number of

damaged spiders (e.g. uncoordinated movements, crookedness, drawing up the legs) counted at day 0 (ca. 2 hours after application), 1, 2, 3, 4, 7, 8, 10, 11, 14, 15, 17, 18 and 21 days after application.

4. Statistics

Mortality data were analysed for significance using Fisher Exact Test, which is a distribution-free test and does not require testing for normality or homogeneity prior analysis. Because food consumption of the surviving spiders in the test item treatment groups was higher compared to the control group, no statistical analysis were performed. The software used to perform the statistical analysis was SYSTAT Version 9, © SPSS Inc., 1998.

II. RESULTS AND DISCUSSION

A. FINDINGS

Adult mortality in the control and toxic standard groups was 0 and 94.1%, respectively. All validation criteria were met.

Mortality and behavioural abnormalities of the spiders.

	Oxamyl 10 L (6 mg a.i./kg soil)		Oxamyl 10 L (4 mg a.i./kg soil)		Oxamyl 10 L (2 mg a.i./kg soil)		Control (water treated)		Toxic Standard	
time	mort.[a, b] [%]	beh. abn.[c] [%]	mort.[b] [%]	beh. abn.[c] [%]	mort.[b] [%]	beh. abn.[c] [%]	mort.[b] [%]	beh. abn.[c] [%]	mort.[b] [%]	beh. abn.[c] [%]
day 0										
2 hours	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
day 1	0.0	5.9	0.0	5.9	0.0	0.0	0.0	0.0	91.2	2.9
day 2	0.0	2.9	0.0	5.9	0.0	0.0	0.0	0.0	94.1	0.0
day 3	2.9	2.9	2.9	5.9	0.0	2.9	0.0	0.0	94.1	0.0
day 4	2.9	2.9	5.9	2.9	0.0	2.9	0.0	0.0	94.1	0.0
day 7	2.9	11.8	11.8	2.9	2.9	0.0	0.0	0.0	94.1	0.0
day 8	14.7	2.9	14.7	0.0	5.9	0.0	0.0	0.0	94.1	0.0
day 10	23.5	2.9	17.6	5.9	5.9	0.0	0.0	0.0	94.1	0.0
day 11	26.5	2.9	20.6	0.0	5.9	0.0	0.0	0.0	94.1	0.0
day 14	29.4	0.0	23.5	2.9	5.9	0.0	0.0	0.0	94.1	0.0
day 15	35.3	0.0	32.4	0.0	8.8	0.0	0.0	0.0	94.1	0.0
day 17	35.3	0.0	32.4	0.0	8.8	0.0	0.0	0.0	94.1	0.0
day 18	35.3	0.0	32.4	0.0	8.8	0.0	0.0	0.0	94.1	0.0
day 21	35.3	0.0	35.3	0.0	8.8	0.0	0.0	0.0	94.1	0.0

[a] The tabulated results represent rounded results calculated on the exact raw data
[b] mort. = mortality (17 females and 17 males spider per treatment group)
[c] beh. abn. = behavioural abnormalities (17 females and 17 males spider per treatment group)

Food consumption of the spiders

	Oxamyl 10 L (6 mg a.i./kg soil) flies/spider/day[a, b] days				Oxamyl 10 L (4 mg a.i./kg soil) flies/spider/day days				Oxamyl 10 L (2 mg a.i./ kg soil) flies/spider/day days				Control flies/spider/day days				Toxic Standard flies/spider/day days			
	1-4	8-11	15-18	1-18	1-4	8-11	15-18	1-18	1-4	8-11	15-18	1-18	1-4	8-11	15-18	1-18	1-4	8-11	15-18	1-18
females	4.4	4.8	3.3	4.4	4.4	4.6	3.0	4.2	4.4	4.0	3.5	4.2	3.4	4.1	3.0	3.5	3.9	5.0	5.0	4.4
males	1.9	2.3	3.1	2.4	1.9	2.5	2.1	2.1	2.6	2.9	2.4	2.6	2.3	2.9	2.9	2.6	0.0	0.0	0.0	0.0
mean[c]	3.2	3.8	3.2	3.7	3.3	3.7	2.7	3.4	3.5	3.5	3.0	3.4	2.8	3.5	3.0	3.0	3.9	5.0	5.0	4.4

[a] the tabulated results represent rounded results calculated on the exact raw data
[b] the values are calculated taking into consideration the living spiders only
[c] average consumed flies per living female and male spiders over the indicated period

The results for mortality and food consumption of *Pardosa* spp. are given Table 49.

Table 49 The effects on mortality and food consumption of *Pardosa* spp. exposed to Oxamyl 10SL applied to soil in the laboratory

Nominal oxamyl concentration (g a.s./ha)	Mortality (%)	Food consumption (%)
Untreated control (0.0)	0.0	100
Toxic standard (900 g dimethoate in 400 L/ha water)	94.1	147
2.0	8.8	114
4.0	35.3[a]	112
6.0	35.3[a]	121

[a] Significantly different from the control (Fisher's Exact test, alpha = 0.05)

During the first and second week discoordinated movements, apathy or laying on the back of a few spiders were observed, preceeding the mortality of the spiders in all test item groups. In the 3rd week no further behavioural impairments occurred.

III. CONCLUSION

Mortality of *Pardosa* spp. was 8.8% after 21 days when Oxamyl 10SL was applied at a rate of 2.0 mg a.s./kg dry soil and 35.3% at rates of 4.0 and 6.0 mg a.s./kg dry soil. Mean feeding rates did not differ significantly between control and treatment groups. Food consumption of the surviving spiders was not adversely affected.

(Schmitzer, S., 2001)

RMS comment and conclusion

Very minor deviation: the temperature increased up to 23 °C during one day and for < 1 hr.

The validity criteria were met:

-Control Mortality: validity criteria: should not exceed 14% for a test at 21d: % (actual 0%).

-Toxic Standard Mortality: validity criteria: 65 % ± 35 % (actual 94.1%).

The study is acceptable.

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

B.9.5.2.2/07

Reference: CP 10.3.2.2/07	**Report:**	Schuld, M. (2002); Oxamyl (DPX-D1410) 10L: An extended laboratory study using field aged residues to evaluate the effects on the aphid parasitoid, *Aphidius rhopalosiphi de Stefani Perez* (Hymenoptera, Braconidae) **DuPont Report No.:** DuPont-6131 **Guidelines:** Polgar (1988), Mead-Briggs (1992, 1996), SETAC-ESCORT (1994) and the guideline of the ring testing group (Mead-Briggs *et al.* 2000) **Deviations:** None that affect the validity of the study. **Testing Facility:** GAB Biotechnologie, GmbH, Niefern-Oeschelbronn, Germany **Testing Facility Report No.:** 20011214/01-NEAp **GLP:** Yes **Certifying Authority:** Ministrium fur Umwelt und Verkehr (Baden-Wurttemberg, Germany)

Executive summary:

An extended laboratory study on the parasitic wasp *Aphidius rhopalosiphi* was conducted in the laboratory according to Polgar (1988), Mead-Briggs (1992, 1996), Mead-Briggs *et al.* (2000), and SETAC-ESCORT (1994). The test organisms were exposed to an untreated control and residues of Oxamyl 10SL applied to sweet pepper leaves. The test substance was applied 6 times at 1.0 kg a.s./ha *via* a simulated drip irrigation system. *Aphidius rhopalosiphi* was exposed to residues in leaves either 3 days after the 1st application or after the 6th application. The test substance was allowed to be distributed equally in the plants for 3 days, before the test leaves were sampled. No toxic reference was tested, since there is no toxic standard for drip irrigation application available. Oxamyl 10SL applied to sweet pepper plants *via* drip irrigation at 1.0 kg a.s./ha or six applications at 1.0 kg a.s./ha had no adverse effect on *Aphidius rhopalosiphi*.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-424
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Not determined in the test system
2.	Control:	Tap water
	Test vehicle:	Tap water
	Toxic reference:	None
3.	Test organism	
	Species:	*Aphidius rhopalosiphi*
	Age at dosing:	48-hour old adults
	Source:	PK Nützlingszuchten, Welzheim, Germany
	Diet:	Honey-agar-water solution
	Water:	Tap water, *ad libitum*
	Test chamber	
	(exposure period):	Sweet pepper leaves distributed on the bottom glass plate of exposure cage. The exposure cage consisted of 2 glass plates (length of edges: 13 cm), which were assembled to cages with an aluminum frame (length of edges: 13 cm, height: 1.5 cm, width: 1 cm).
	(parasitation period):	A pot containing 8-10 barley seedlings (10-15 cm tall) infested with about 50-100 *Rhopalosiphum padi* of different stages (all instar stages and adults) was placed on a seed tray. Plexiglas tubes (diameter: approx. 10 cm; length: approx. 25 cm) were placed upon each pot.
	Host species:	*Rhopalosiphum padi* (L.) Homoptera:Aphidae
	Source:	In-house laboratory culture (GAB Biotechnologie GmbH)
4.	Environmental conditions (in-life period)	
	Temperature:	Exposure 1: 18.0 / 23.0°C Exposure 2: 18.0 / 22.0°C
	Relative humidity:	Exposure 1: 56 / 84 % Exposure 2: 69 / 85 %
	Photoperiod	16 hour photoperiod (1000 lux for mortality phase and 5900 lux for reproduction)

B. STUDY DESIGN AND METHODS

1 In-life initiated/completed

06-July-2001 to 02-October-2001

2. Experimental treatments

In an extended laboratory study, parasitic wasps of the species *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) were exposed to Oxamyl 10SL. The test organisms were exposed to an untreated control and residues of Oxamyl 10SL applied to sweet pepper leaves. The test substance was applied 6 times at 1.0 kg a.s./ha *via* a simulated drip irrigation system. To simulate a drip irrigation in a greenhouse the amount of test substance was calculated per plant. For the sweet pepper 20 000 plants/ha are good agricultural practice in Spain. Therefore the total amount of test substance per plant was 0.35 g a.s. Thirty sweet pepper plants were used for the control and for the treatment. Six applications (with 1.0 kg a.s./ha each, corresponding to 0.05 g a.s./plant) were performed in 14 day intervals. Every application was split into four runs applied at regular 2 hours intervals. At each application run a quarter of the total amount (0.25 kg a.s./ha corresponding to 0.0125 g a.s./plant) of test substance was applied. The volume

of water applied for each application was 600 mL/plant (corresponding to 150 mL/plant per application run).

Aphidius rhopalosiphi was exposed to residues in leaves either 3 days after the 1st application or after the 6th application. The test substance was allowed to be distributed equally in the plants for 3 days, before the test leaves were sampled. No toxic reference was tested, since there is no toxic standard for drip irrigation application available. Each exposure included 4 replicates containing 10 wasps (5 males and 5 females).

After the exposure period, reproduction (parasitation rate) was evaluated by transferring 15 living female wasps per treatments group to individual test chambers containing aphids. After a 24-hour parasitation period the aphids (parasitised) were held for 12 or 13 days. At this time the number of parasitised aphids (aphid mummies) per female wasp was determined.

3. Observations

Assessments for adult wasp mortality were carried out approximately 1, 2, 24, and 48 hours after treatment. To assess effects on reproduction (fecundity), the number of aphid mummies present was counted 12 or 13 days after the 24-hour parasitation period.

4. Statistics

Mortality data were analysed for significance using Fisher's Exact test, which is a distribution-free test and does not require testing for normality or homoscedascity prior to analysis. Kruskal Wallis Test was used to analyse significant differences in the reproduction rate between control and treatment effects as normality and homoscedascity were not met. The statistical software program SAS release 8 was used for the statistical analysis.

II. RESULTS AND DISCUSSION

A. FINDINGS

Condition of *Aphidius rhopalosiphi* after 2d exposure to leaves detached from plants watered by drip irrigation with Ozamyl 10L and to tap water control.

Exposure 1	Assessment	Oxamyl 10L (1.0 kg a.s./ha)	Control
09 JUL 2001 Exposed 3 days after the first drip irrigation	No. of wasps introduced	40	40
	alive	37	37
	affected	0	0
	moribund	0	0
	dead	3	3
	Mean mortality (1) [%]	7.50	7.50
	Corrected mortality [%]	0.00	-
Exposure 2	**Assessment**	**Oxamyl 10L (6.0 kg a.s./ha)**	**Control**
17 SEP 2001 Exposed 3 days after the sixth drip irrigation	No. of wasps introduced	40	40
	alive	39	36
	affected	0	0
	moribund	0	1
	dead	1	3
	Mean mortality (1) [%]	2.50	10.00
	Corrected mortality [%]	-8.33	-

(1): Mean mortality based on the number of moribund and dead wasps

Fecundity of *Aphidius rhopalosiphi* after exposure to leaves detached from plants watered by drip irrigation with Ozamyl 10L and to tap water control.

Exposure 1	Assessment	Oxamyl 10L (1.0 kg a.s./ha)	Control
09 JUL 2001 Exposed 3 days after the first drip irrigation	No. of females tested	15	15
	No. of produced mummies	166	190
	No. of mummies/female ± SD	11.07 ± 11.76	12.67 ± 9.16
	Reproduction factor	0.87	-
Exposure 2	**Assessment**	**Oxamyl 10L (6.0 kg a.s./ha)**	**Control**
17 SEP 2001 Exposed 3 days after the sixth drip irrigation	No. of females tested	15	15
	No. of produced mummies	193	126
	No. of mummies/female ± SD	12.87 ± 9.04	8.40 ± 7.18
	Reproduction factor	1.53	-

SD: Standard deviation

Adult mortality in the control groups which run in parallel with the exposure after 1 and 6 applications was 7.50 and 10.00%, respectively. All validation criteria were met. The results for mortality and reduction in reproduction (parasitation rate) of *Aphidius rhopalosiphi* are given Table 50.

Table 50 The effects on mortality and reproduction of *Aphidius rhopalosiphi* exposed to fresh dried residue of Oxamyl 10SL applied to natural substrate in the laboratory

Nominal oxamyl concentration (kg a.s./ha)	Mortality (%)	Corrected mortality (%)[a]	Parasitised aphid/female (mean)	Reduction in reproduction (%)
Untreated control (0.0) first exposure	7.50	-	12.67± 9.16 11.6	-
1.0 first exposure	7.50	0.00	11.07± 11.76	[b]
Untreated control (0.0) second exposure	10.00	-	8.40± 7.18 7.7	-
1.0 (6.0 total) second exposure	2.50	-8.33	12.87± 9.04 12.4	[b]

[a] Schneider-Orelli's Correction

[b] There were no significant differences from the control (Kruskal Wallis Test)

III. CONCLUSION

Oxamyl 10SL applied to sweet pepper plants *via* drip irrigation at 1.0 kg a.s./ha or six applications at 1.0 kg a.s./ha had no adverse effect on *Aphidius rhopalosiphi*.

(Schuld, M., 2002)

RMS comments and conclusion

The study was re-evaluated according to Mead-Briggs et al (2010):

Minor deviations from the recommended range of temperature and RU are noted in exposure 1, which do not affect the reliability of the results.

During the exposure phase, there were 4 replicates with10 wasps (5 males and 5 females), instead of six replicate arenas (i.e. 30 wasps in total) in each treatment as recommended for the limit-rate tests. Due to the negligible effects observed, this deviation is not considered to invalidate the test.

Other deviations are justified because the Mead-Briggs et al (2010) method was designed for spray application.

According to Mead-Briggs et al (2010), only results for the wasps found alive when insects were being removed after the 24-h parasitisation period are to be used for the analyses of reproduction.
After the 24h parasitism, in the first exposure, one female was not found in the control and in the second exposure one female was dead in the control and one female was not found in the treated group, hence it should be excluded from analysis. Table 51 should read:

Table 51 The effects on mortality and reproduction of *Aphidius rhopalosiphi* exposed to fresh dried residue of Oxamyl 10SL applied to natural substrate in the laboratory

Nominal oxamyl concentration (kg a.s./ha)	Mortality (%)	Corrected mortality (%)[a]	Parasitised aphid/female (mean)	Reduction in reproduction (%)
Untreated control (0.0) first exposure	7.50	-	11.6	-
1.0 first exposure	7.50	0.00	11.07	4.8
Untreated control (0.0) second exposure	10.00	-	7.7	-
1.0 (6.0 total) second exposure	2.50	-8.33	12.4	-6.1%

[a] Schneider-Orelli's Correction

[b] There were no significant differences from the control (Kruskal Wallis Test)

Validity criteria:

- The mean mortality (dead and moribund wasps) in the control group was ≤ 10 %. Fulfilled.
- The mean number of mummies/female in the control group was ≥ 5 mummies per female

and no more than two females of the control group failed to produce mummies. Fulfilled.

- A reference toxicant was not tested because the lack of a substance for drip irrigation exposure, hence the related validity criterion cannot be verified. The RMS comments that the sensitivity of the organisms could have been checked anyhow using a standard spray application.

Conclusion: To simulate a drip irrigation in a greenhouse the amount of test substance was calculated per plant based on 20 000 plants/ha of sweet pepper plants. The applicant should justify the extrapolation to use in tomatoes in greenhouse.
Since a toxicant reference was not tested, the study is judged not reliable.

B.9.5.2.2 emi-field studies with non-target arthropods

On the basis it is unlikely that the use of Oxamyl 10SL will result in significant adverse effects on non-target terrestrial arthropods, semi-field testing was not carried out.

B.9.5.2.3 Field studies with non-target arthropods

Oxamyl 10SL demonstrated very low toxicity to non-target arthropods in Tier I studies. No effects on mortality >10% were observed on any of the species at the maximum labeled rate. This value was substantially below the 50% trigger value, indicating that no further studies were warranted.

B.9.5.2.4 Other routes of exposure for non-target arthropods

No other routes of exposure for non-target arthropods were considered necessary fr evaluation at this time.

B.9.6 Risk assessment for arthropods

B.9.6.1 Risk assessment for bees

Ecotoxicological endpoints for bees

Active substance	Endpoint value	Reference
Oxamyl (honey bees)	Oral (48 h) LD_{50} (in water): 0.38 µg a.s./honey bee Contact (48 h) LD_{50} (in water): 0.47 g a.s./honey bee	DuPont-2740[a]
Oxamyl 10SL (honey bees)	Oral 48-h LD_{50}: 0.26 µg a.s./honey bee Contact 48-h LD_{50}: 0.23 µg a.s./honey bee	DuPont-2718[b]
Oxamyl (bumble bee)	Oral (48 h) LD_{50} (in water): 0.36 µg a.s./bumble bee Contact (48 h) LD_{50} (in water): 39.3 g a.s./bumble bee	DuPont-39670

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

[b] Study summarised in Point B.9.5.1.1.1 in this document.

RMS NOTE: The following risk assessment has been presented by the Applicant, the comments by the RMS are given following each statement.

Application conditions, exposure and risk assessment assumptions

Solarisation: According to the Applicant, "there will be no exposure of honey bees or bumble bees to oxamyl residues after soil solarisation in glasshouses. It can be concluded that solarisation is a safe use".**RMS: The** exposure of honey bees will be negligible only in "closed" glasshouses, not in the "open" ones. This should be specified.

Tomatoes: The Applicant states that "Due to glasshouse application, direct or indirect exposure of honey bees to Oxamyl 10SL will be negligible".

RMS: The exposure of honey bees will be negligible only in "closed" glasshouses, not in the "open" ones. This should be specified.

However, exposure to bumblebees could occur. The EPPO (2010) guidance document on the risk assessment of plant protection products on bees provides no guidance for a risk assessment after drip irrigation in permanent glasshouses. A reasoned approach to assessing risks to bumble bees is presented below.In a worst-case glasshouse study, tomatoes were irrigated 6-times with Oxamyl 10SL at a rate equivalent to 1.0 kg oxamyl/ha and an application interval of 14 days (DuPont-5748; summarised in Point B.9.5.1.2 in this document). Directly following the sixth drip irrigation, bumblebees (commercial bumblebee hives of *Bombus terrestris*) were allowed to pollinate the tomato crop for 4 weeks in six separate oxamyl-treated and six separate untreated glasshouse plots. In the glasshouse study, bumble bees were forced to forage exclusively on the only food source available, the tomato crop that had been treated six times with Oxamyl 10SL *via* drip irrigation. In this situation, selective foraging by pollinators (*i.e.*, migration, avoidance, infrequent foraging through diversifying food sources) is excluded, and the potential for exposure to oxamyl is maximised.

RMS: in the glasshouse study, each single bumble bee colony was fed with sugar solution ad libitum because tomato flowers produce no nectar. This is recognized as a limit intrinsic in the tests with Bombus.

No notable effects on mortality of bumble bee adults and larvae, crop pollination, hive weight, and sugar consumption were observed. Also, at a final brood assessment, no effects compared to the control were noted. It was concluded that oxamyl, when applied six times at 1.0 kg oxamyl/ha with a 14-day application interval *via* drip irrigation had no significant effects on bumble bee adults and larvae, crop pollination, hive weight, and sugar consumption or on brood development.

These findings are in line with internet recommendations from commercial bumble bee producers (*e.g.*, Biobest [www.biobest.be], Koppert [www.koppert.nl]) that drip irrigation of oxamyl can be combined with the safe use of bumblebees in glasshouses to pollinate flowering crops (*e.g.*, tomato).

Exposure—tomatoes

Residues in honey bee matrices: Two studies are available that document residue concentrations of oxamyl active ingredient in pollinator food items after at-plant soil applications to *Phacelia* and potatoes (Table 52). Please see DuPont-39666 and DuPont-39667 for detailed study summaries (the Oxamyl EU Renewal Dossier, Document MC-P, Section 10 for Oxamyl 10GR, DuPont-40954 EU).

Table 52 Residues of oxamyl active ingredient in bee matrices

Test material	Matrix	Application rate	Mean concentration (mg a.s./kg)	Reference[a]
Oxamyl 10GR	*Phacelia* nectar in comb	Equivalent to 3.0 kg a.s./ha (in-furrow)	0.070–0.082	DuPont-39667
	Phacelia pollen		0.041–0.049	
	Phacelia flowers		0.333–0.495	
Oxamyl 10GR	Potato pollen	1.0 kg a.s./ha (in-furrow)	ND–0.008	Dupont-39666
	Potato flowers		ND–0.019	

[a] Studies are summarised in the Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10GR, DuPont-40954 EU.

The maximum oxamyl residue in comb nectar was 0.082 mg a.s./L and in pollen was 0.049 mg a.s./kg after a 3000 g a.s./ha at-plant application in furrow with *Phacelia* seeds (Table 52). Residues in potato pollen or flowers were lower or not detectable. Assuming the in-furrow application to *Phacelia* is relevant to drip irrigation to tomatoes, the predicted maximum residue in tomato nectar and pollen after a 2000 g a.s./ha application would be 0.054 and 0.032 mg a.s./kg, respectively.

RMS: the assumption that the residues in nectar and pollen determined after in-furrow application to Phacelia are relevant to tomatoes after drip irrigation (max single application rate of 2 kg a.s./ha) is not sufficiently discussed and supported (possible higher root uptake?).

Food intake rates and estimated exposure concentrations: The worst-case food ingestion rate is 149 mg sugar/bumblebee/d (EFSA 2014). The maximum residue in nectar would be 0.054 mg a.s./kg (or µg/mg) after a 2000 g a.s./ha application. Based on these assumptions, the worst-case daily oxamyl uptake of a forager bumblebee would be 149 mg nectar per day × 0.000054 µg oxamyl/mg (nectar estimate) = 0.0081 µg oxamyl/bumblebee/day assuming that the bumblebees would exclusively feed on treated nectar.

Forager bumblebees may take up to 30.3 mg pollen/bee/d (EFSA 2014). The maximum residue in pollen would be 0.032 mg a.s./kg (or µg/mg) after a 2000 g application. Based on these assumptions, the worst-case daily oxamyl uptake of a forager bumblebee would be 30.3 mg pollen per day × 0.000032 µg oxamyl/mg (pollen estimate) = 0.0009 µg oxamyl/bumblebee/day assuming that the bumblebees would exclusively feed on treated pollen.

Toxicity

In the acute oral toxicity study with oxamyl technical, an oral LD_{50} of 0.36 µg oxamyl/bumble bee was determined (DuPont-39670, summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU). The oral LD_{50} is much higher than the maximally estimated oxamyl consumption per bumblebee (0.0081 µg oxamyl/bumblebee/day) indicating low risk for bumblebees for the use of Oxamyl 10SL in glasshouse tomatoes and assuming that the bumblebees would exclusively forage on comb nectar or pollen from oxamyl treated tomato plants.

Tier 1 risk assessment: The Tier 1 risk assessment is

TER = Oral LD_{50}/Exposure
= Oral LD_{50}/Generic residue value × food ingestion
= 0.36 μg a.s./bee/(0.054 mg a.s./kg × 149 mg/bee/day)
= 0.36 μg/0.0081 μg
= 44 (Trigger of 10 is met)

The resulting TER value is above the proposed trigger value of 10, indicating safe use in tomatoes.

The conclusion is supported by a chronic study of bumblebees exposed to drip irrigated-tomatoes in a glasshouse (DuPont-5748, Point B.9.5.1.2 in this document), where no effects occurred after six applications of 1 kg a.s./ha.

RMS: In the TER calculation presented by the Applicant, the exposure does not take into account of the pollen intake, Some elements of conservatism are present in the risk assessment (nectar is not produced by tomato flowers), but the extrapolation of the residues levels measured in Phacelia after in-furrow treatment to the residue expected in tomato after drip irrigation should be better supported. The comments made by the RMS in the text of chapter B.9.6.1 above should be addressed.

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

B.9.6.2 Risk assessment for non-target arthropods

A summary of the relevant endpoints is given in Table 53.

Table 53 Summary of effects of Oxamyl 10SL on non-target arthropods

Species	Test (and test substance and test rate)	Measurement endpoint	Endpoint value	Reference
Aphidius rhopalosiphi Study not acceptable	Laboratory Tier 1 (Oxamyl 10L dose response)			DuPont-2609[a]
Aphidius rhopalosiphi Study not reliable. Additional information	Laboratory Tier 2 (Oxamyl 10L) sweet pepper leaves 3d after exposure via drip irrigation at 1.0 kg a.s./ha or after six applications at 1.0 kg a.s./ha	48h Corrected mortality: Reduction in reproduction (versus control):	0% and -8.33% 4.8% and -61%	DuPont-6131
Typhlodromus pyri Supportive information	Laboratory Tier 1 (Oxamyl 10L dose response)	7 d LR_{50} 7 d LR_{30} 30% effect on reproduction	1.8 g a.s/ha 1.0 g a.s/ha ≥0.8 g a.s/ha	DuPont-4037[a]
Typhlodromus pyri Study not reliable. Additional information	Laboratory Tier 2 (Oxamyl 10L) 1.0 kg a.s./ha and 6.0 kg a.s./ha (1 kg a.s./ha x 6 applications)	7-d Mortality: 14d Reduction in reproduction (versus control)	1.2 and 8.3% 0% and 0%	DuPont-6133
Orius laevigatus Study not reliable	Laboratory Tier 2 (Oxamyl 10L) 1.0 kg a.s./ha and 7.0 kg a.s./ha (1 kg a.s./ha x 7 applications)			DuPont-6132
Aleochara bilineata	Laboratory Tier 2 Oxamyl 10L (0, 1.5, 2, 2.5, 3 mg a.s./kg dry soil)	7-d Mortality: 28d Reduction in reproduction (versus control):	0.00% 2.50 3.75 1.25 0% 9.0 10.4 21.9 29.3	DuPont-3910[b]
Poecilus cupreus	Laboratory Tier 2 Oxamyl 10L (3.3 and 33 mg a.s./kg dry soil)	14-d Corrected mortality: % Reduction in feeding rate (versus control):	6.7, 10% -7.4, -6.7	DuPont-3911[b]
Pardosa spp.	Laboratory Tier 2 Oxamyl 10L (7, 15, 23 mg a.s./kg dry soil)	21-d Corrected mortality: Mean feeding rate	52.9, 100, 100% 2.2, 2.6, 1.1	DuPont-3912[b]

		(flies/spider/day): % reduction in feeding rate (versus control)	 4.3, 30.4, 52.2	
Prdosa spp.	Laboratory Tier 2 Oxamyl 10L (2, 4, 6 mg a.s./kg dry soil)	21-d Corrected mortality: Mean feeding rate (flies/spider/day): % reduction in feeding rate (versus control)	8.8%, 35.3%, 35.3% 3.7, 3.4, 3.4, 3.0 (Control), 4.4 (toxic standard) -23.3, -13.3, -13.3	DuPont-5162[b]

[a] Study is summarised in the Oxamyl dRAR Vol 3 a.s. B.9. .
[b] Study summarised in this document

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. In dRAR Vol. 3 B8, no PECsoil were calculated as not applicable for permanent glasshouses.

For a risk assessment with non-target arthropods, a reasoned approach is provided below. PECsoil as calculated by the Applicant in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10SL, DuPont-42129 EU were used for a quantitative risk assessment.Solarisation:

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

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

In order to demonstrate the potential for recovery, three ground-dwelling species (*Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp.) were exposed to soil residues of oxamyl after application of Oxamyl 10SL on LUFA 2.1 soil.

Feeding rates of carabid beetles and spiders were not significantly affected after exposure to formulation at PEC_{soil} equivalent to 3.85 mg a.s./kg dry soil (5.5 kg a.s./ha, 10-cm soil depth). Reproduction of staphilinid beetles *Aleochara bilineata* was not significantly affected (<30% effect) after exposure to formulation at 3.0 mg a.s./kg dry soil (10-cm soil depth).

Taking into account the soil DT_{50} = 11.1 days (worst case at 20°C), and the maximum PEC_{soil} value for solarisation as presented in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10SL, DuPont-42129 EU ($PEC_{soil, max,}$ = is 7.333 mg a.s./kg dry soil for the standard soil depth of 5 cm), it would take less than 2 weeks for the soil concentration to decline below concentrations evaluated in the extended laboratory

studies on *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp. This demonstrates that there is a potential for recovery/re-colonisation for soil dwelling arthropods, beginning 2 weeks after the solarisation process is over.

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

Drip Irrigation to Tomatoes:

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

For application as soil injection, or soil incorporation, tests with soil arthropods are more relevant than tests with foliar dwelling arthropods. Tests on three soil dwelling arthropods are available. For *Aleochara bilineata*, *Pardosa* spp, and *Poecilus cupreus*, lethal and sublethal effects were <50% at application rates above the maximum predicted PEC of 2.839 mg a.s./kg soil. It should be kept in mind that *P. cupreus* and *Pardosa* sp mainly occur on the soil surface. Since exposure in the test and in the glasshouse is only in-soil, these species might not be the most representative for in-soil living arthropods. *A. bilineata* has a sensitive in-soil life stage, which was also tested in the study. Thus this study is the most representative.

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

Normally two relevant species should be tested. However, the following arguments should be taken into account:

- Tested relevant soil living species showed effects <50% at relevant application rates
- Less relevant soil dwelling arthropods showed effects <50% at relevant application rates
- $DT_{50field}$ for oxamyl is 6.0 days and DT_{50lab} is 11.1d (worst case) / 5.3 days (geomean).
- No exposure outside the glasshouse is expected, and thus the off-field risk is acceptable
- Therefore, the potential for recovery within a year, as required for the glasshouse situation, is high.

Based on these arguments, an acceptable risk is expected for closed glasshouse applications.

Furthermore, IPM is possible in glasshouse uses. For IPM, effects should be below 25% at relevant test rates. For both *A. bilineata* and *Pardosa spp*., significant effects >25% were found at 4.0 and 6.0 kg a.s./ha. Therefore, the following mitigation should be considered:

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

B.9.7 Effects on non-target soil meso- and macrofauna

B.9.7.1 Earthworms

B.9.7.1.1 Earthworms - sub-lethal effects

Effects of oxamyl a.s., Oxamyl 10SL, IN-A2213, IN-D2708, and IN-N0079 were tested with chronic studies on earthworms. Studies of a.s. and metabolites are summarised in the dRAR Vol.3 a.s. B9 and in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU. Toxicity endpoint values for soil macro organisms are summarised in Table 55. Oxamyl and the soil metabolites IN-A2213, IN-D2708, and IN-N0079 are not persistent substances, thus no risk assessment for soil organisms was submitted by the Applicant. A chronic study was nevertheless submitted, which has been summarized and evaluated below.

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

B.9.7.1.1/01

Reference: **CP 10.4.1.1/01**	**Report:**	Luhrs, U. (2001); Oxamyl 10L (10% w/w): Effects on reproduction and growth of the earthworm, *Eisenia fetida* (Savigny 1826), in artificial soil **DuPont Report No.:** DuPont-3345 **Guidelines:** ISO 11268-2, 1998; BBA VI 2-2, 1994 **Deviations:** None that affect the validity of the study. **Testing Facility:** IBACON, Rossdorf, Germany **Testing Facility Report No.:** 7935022 **GLP:** Yes **Certifying Authority:** Hessisches Ministerium fur Umwelt, Landwirtschaft und Forsten

Executive summary:

The sublethal toxicity of Oxamyl 10SL to earthworms, *Eisenia fetida*, was determined in a 56-day soil exposure laboratory study according to OECD 207 (1984) and ISO-Guideline 11268-1 (1993). Adult earthworms were exposed to artificial soil (prepared according to OECD 207) treated with five nominal concentrations of 62.5, 125, 250, 500, or 1000 mg Oxamyl 10SL/kg dry weight soil, an untreated control, and to the toxic standard, Derosal SC 360 g/L, at 2.18 mg carbendazim/kg. Mortality and growth (body weight) of the earthworm were assessed after 28 days and the effects on reproduction (number of juveniles produced) were assessed after 56 days. The NOEC for earthworms based on reproductive effects and nominal concentrations was 32.0 mg Oxamyl 10SL/kg dry weight soil (equivalent to 3.2 mg oxamyl/kg dry weight soil).

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL
	Lot/Batch #:	D1410-381
	Purity:	100 g a.s./L
	Description:	Green liquid
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
	Stability of test compound:	Not determined in the test system
2.	Control:	Deionised water
	Test vehicle:	Deionised water
	Toxic reference:	Carbendazim, at 2.18 mg /kg.
3.	Test organism:	Earthworm
	Species:	*Eisenia fetida*
	Age at dosing:	Approximately 11 months; life stage: adult with clitellum
	Weight at dosing:	300 to 500 mg
	Source:	IBACON
	Test chamber:	Plastic boxes (18.3 × 13.6 × 6 cm), the height of the soil layer was approximately 5 cm
	Test medium:	Artificial soil prepared according to OECD 207
	Diet:	Finely ground cow manure
	Water content of soil:	Test initiation: 27.2 to 27.7% (equivalent to 53.5 to 54.5% of the maximum water holding capacity) Test termination: 27.8 to 31.3% (equivalent to 54.7 to 61.6% of the maximum water holding capacity)
	Soil pH:	Test initiation: 6.4 to 6.5; Test termination: 6.2 to 6.3
4.	Environmental conditions (in-life period)	
	Temperature:	18 to 21°C
	Photoperiod:	24 hour photoperiod (435 to 791 lux)

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

01-August-2000 to 11-December-2000

2. Experimental treatments

The sublethal toxicity of Oxamyl 10SL to earthworms, *Eisenia fetida*, was determined in a 56-day soil exposure laboratory study. Four replicates of ten clitellated adult earthworms were each exposed to five nominal concentrations of 62.5, 125, 250, 500, or 1000 mg Oxamyl 10SL/kg dry weight soil, an untreated control, and the toxic standard, Derosal SC 360 g/L, at 2.18 mg Carbendazim/kg..

3. Observations

Worms were assessed for mortality and sublethal (behavioural) effects after 28 days of exposure. Body weight change (adults) was assessed at test start (Day 0) and at 28 days after application. For reproduction, soil was replaced in the test container and juveniles were allowed to grow for another 28 days (Day 56), at which time they were removed from the soil, counted, and reproduction effects assessed.

4. Statistics

Data of body weight changes were tested for normal distribution and homogeneity of variance using Kolmogoroff-Smirnov-test and Cochran-test. Because data of body weight changes of the test item treated group were normally distributed and homogeneous Dunnett-Test; $\alpha = 0.05$ (multiple comparison, two-sided) was used. Data of body weight changes of the toxic standard were compared for significance using Student-t-test (pairwise comparison, two-sided), $\alpha = 0.05$. Reproduction data were

tested for normal distribution and homogeneity of variance using Kolmogoroff-Smirnov-test and Cochran-Test. Because data of reproduction were normally distributed and homogeneous Dunnett-Test; $\alpha = 0.05$ (multiple comparison, two-sided) was used. Because data of reproduction of the toxic standard were normally distributed and homogeneous Student-t test (pairwise comparison for homogeneous variances, one-sided), $\alpha = 0.05$ was used. The software to perform the statistical analysis was EASY ASSAY, Multiple Testing, © SPiRiT, Version 4.0.

II. RESULTS AND DISCUSSION

A. FINDINGS

Reproduction in the toxic standard treatment was lowered by 83.2%. The body weight decrease in the toxic standard treatment was significantly different, compared to the control. All validation criteria were within acceptable limits indicating the validity of this test.

No significant effects on mortality and body weight were observed in any of the groups treated with Oxamyl 10SL. Reproduction was not significantly affected up to the concentration of 32.0 mg/kg, but was significantly reduced at a concentration of 64.0 mg/kg. Cumulative mortality and weight change (of adults) at 28 days, and reproduction at 56 days are reported in Table 54. The amount of food added to the test containers over the entire experimental time was 21.5 ± 1.0 g/container in the control and from 18.0 to 21.0 g/container in the groups treated with Oxamyl 10L (10 % w/w). In the toxic reference 19.0 ± 0.0 g food per container were added (Table 6 Amount of food added to the test containers). The results show that the food consumption of those earthworms exposed to the five different rates of the test item and to the toxic standard item was comparable to the control.

Table 54 Sublethal toxicity of Oxamyl 10SL to earthworms

Nominal Oxamyl 10SL concentration (mg/kg dry soil)	28-day Cumulative mortality (%)[a]	28-day Cumulative weight change (%)	56-day Reproduction (# of juveniles)
Untreated control (0.0)	0.0	15.9	358
Toxic standard (7.0)	0.0	3.3[b]	60[b]
4.0	0.0	16.8	321
8.0	0.0	14.6	323
16.0	0.0	14.2	296
32.0	0.0	7.5	308
64.0	0.0	9.2	232[b]

[a] There were no significant differences from the control (Dunnett-test, $\alpha = 0.05$)

[b] Significantly different from the control (Test concentrations: Dunnett-test, alpha = 0.05) (Toxic reference: Student's t-test, $\alpha = 0.05$)

III. CONCLUSIONS

The NOEC for earthworms based on reproductive effects and nominal concentrations was 32.0 mg Oxamyl 10SL/kg dry weight soil (equivalent to 3.2 mg oxamyl/kg dry weight soil).

(Lührs, U., 2001)

RMS comments and conclusion

The study was conducted under guideline BBA VI 2-2 (1994). A review of this study indicates that it fully meets the current guideline (OECD 222, 2004).

The validity criteria are fulfilled: Mean control mortality was 0 %, there were more than 30 juveniles per control unit after the 8 week testing period (actual 358), the coefficient of variance for the mean number of juveniles in the untreated control did not exceed 30% (actual 15.5%).

Due to the data set (no statistically significant effects at all concentrations) the EC10/EC20 cannot be calculated.

Conclusion. The study is acceptable.

B.9.7.1.2 Earthworms - field tests

Three field studies were conducted with Oxamyl 10GR and are summarised in the dRAR Vol 3 Oxamyl 10GR B9. The results may be extrapolated to effects of Oxamyl 10 SL. The RMS could not evaluate the studies because they were not submitted.

B.9.7.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

B.9.7.2.1 Species level testing

Effects of oxamyl a.s., IN-A2213, IN-D2708, and IN-N0079 were tested with chronic studies on Collembola and *Hypoaspis*. Toxicity endpoint values for soil macro organisms are summarised in Table 55. Oxamyl and the soil metabolites IN-A2213, IN-D2708, and IN-N0079 are not persistent substances, thus no risk assessment for soil was submitted by the Applicant.

Table 55 Toxicity endpoint values for non-target soil meso- and macrofauna

Test item	Species	Test/duration	Endpoint	Endpoint value (mg a.s. or met./kg dry wt soil)[a]	Reference
Oxamyl	*Eisenia fetida*	Acute, 14 d	LC_{50}	112	
Oxamyl 10SL	*Eisenia fetida*	Sub-lethal, 56 d	EC_{50} NOEC	> 6.4 mg a.s. 3.2 mg a.s.	DuPont-3345[b]
IN-A2213	*Eisenia fetida*	Acute, 14 d	LC_{50}	>1000	
IN-A2213	*Eisenia fetida*	Sub-lethal, 56 d	EC_{50} NOEC EC_{10}	>100 25 26.6	DuPont-39672[c]
IN-D2708	*Eisenia fetida*	Acute, 14 d	LC_{50}	>1000	
IN-D2708	*Eisenia fetida*	Sub-lethal, 56 d	EC_{50} NOEC	>100 100	DuPont-41042[c]
IN-N0079	*Eisenia fetida*	Acute, 14 d	LC_{50}	640	
IN-N0079	*Eisenia fetida*	Sub-lethal, 56 d	EC_{50} NOEC	>100 50	DuPont-41045[c]
Oxamyl	*Folsomia candida*	Sub-lethal, 28 d	EC_{50} NOEC EC_{10}	1.663 0.25 0.435	DuPont-39676[c]
IN-A2213	*Folsomia candida*	Sub-lethal, 28 d	EC_{50} NOEC EC_{10}	>100 100 >100	DuPont-39673[c]
IN-D2708	*Folsomia candida*	Sub-lethal, 28 d	EC_{50} NOEC	>100 100	DuPont-41043[c]
IN-N0079	*Folsomia candida*	Sub-lethal, 28 d	EC_{50} NOEC	43.37 25	DuPont-41046[c]
Oxamyl	*Hypoaspis aculeifer*	Sub-lethal, 14 d	EC_{50} NOEC	>32 16	DuPont-39677[c]
IN-A2213	*Hypoaspis aculeifer*	Sub-lethal, 14 d	EC_{50} NOEC	>100 100	DuPont-39674[c]
IN-D2708	*Hypoaspis aculeifer*	Sub-lethal, 14 d	EC_{50} NOEC	>100 100	DuPont-41044[c]
IN-N0079	*Hypoaspis aculeifer*	Sub-lethal, 14 d	EC_{50} NOEC EC_{10}	60.49 25 38.71	DuPont-41047[c]

[a] Represents the highest concentration tested.

[b] Study summarised in Point B.9.7.1.1 in this document.

[c] Studies are summarised in the Oxamyl dRAR Vol 3 a.s. B9.

B.9.7.2.2 Higher tier testing

No additional testing in soil macroorganisms other than earthworms was conducted. Oxamyl 10SL, when applied according to its proposed use, is expected to pose negligible risk to other soil non-target macro-organisms outside the permanent glasshouses.

B.9.8 Risk assessment for non-target soil meso- and macrofauna

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

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.

The RMS highlights that, in absence of a risk assessment, at MS level it should be specified that the product can be applied only in "permanent" glasshouses.

B.9.9 Effects on soil nitrogen transformation

B.9.9.1 Laboratory test to investigate impact on soil microbial activity

B.9.9.1.1 Laboratory test to investigate impact on soil microbial activity

The following laboratory studies on effects on soil microbial activity performed on oxamyl, its metabolites, and Oxamyl 10SL were already assessed in the EU review.

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

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

[b] Summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU

Oxamyl

Although a risk assessment for soil micro-organisms was not required, studies were performed and are presented here as additional information.

Metabolites: IN-A2213, IN-D2708, IN-F6L99, and IN-N0079

Although a risk assessment for soil micro-organisms was not required, studies were performed and are presented here as additional information.

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

B.9.1.1/01

Reference: CP 10.5/01	**Report:**	Wachter, S. (2001); Oxamyl (DPX-D1410) 10L: Assessment of effects on soil microflora **DuPont Report No.:** DuPont-4114 **Guidelines:** BBA VI 1-1 (1990),SETAC Europe (1995) **Deviations:** None that affect the validity of the study. **Testing Facility:** GAB Biotechnologie, GmbH, Neifern-Oschelbronn, Germany **Testing Facility Report No.:** 20001131/01-ABMF **GLP:** Yes **Certifying Authority:** Ministrium fur Umwelt und Verkehr (Baden-Wurttemberg, Germany)

Executive summary:

The effects of Oxamyl 10SL on nitrogen transformation and soil respiration were investigated in a loamy silt soil and a loamy sand soil in a laboratory study. The study was conducted according to BBA VI 1-1 (1990), SETAC Europe (1995). Both soils were treated with Oxamyl 10SL at rates of 1.5 and 15.0 kg a.s./ha (1 and 10 times the field application rate for drip irrigation in Mediterranean crops) and at 230 mg a.s./kg soil dry weight (maximum PEC after 5 applications at the recommended application rate in Mediterranean crops). A control (deionised water) and a toxic reference (Herbogil liquide at 40 L/ha) were also tested. At the end of 28 days, deviations in nitrate formation rate at concentrations up to and including 15.0 kg oxamyl/ha compared to the control were <25%, the effect threshold specified by the OECD test guidelines. At the end of 28 days, deviations in respiration rates at concentrations up to and including 15.0 kg oxamyl/ha compared to the control were <25%, the effect threshold specified by the OECD guidelines.

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10SL	
	Lot/Batch#:	D1410-381	
	Purity:	100 g a.s./L	
	Description:	Green liquid	
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance	
	Stability of test compound:	Not determined in the test system	
2.	Control:	Soil treated with deionised water	
	Test vehicle:	Deionised water	
	Toxic standard:	Herbogil (Dinoterb acetate) applied at 40 L/ha	
3.	Test organism:	Soil microflora	
	Source:	Purchased from LUFA, taken in Rheinland-Pfalz, Germany	
	Test chamber	Nitrogen transformation test: 1000 mL glass bottles, closed loosely with screw caps, containing approximately 800 g soil Respiration test: 1000 mL glass bottles, closed loosely with screw caps, containing approximately 1200 g soil	
	Substrates:	Lucerne meal 0.5 % of the soil dry weight. (nitrogen determination), Glucose (short-term respiration study)	
	Soil:	Natural soil	
	Soil type:	Loamy sand taken in D-76877 Offenbach, Rheinland-Pfalz	Loamy silt taken in D-76327 Sollingen
	Soil pH:	7.0	6.5
	% Total organic carbon:	0.71	2.78
	CEC (meg/100 g):	9.62	24.7
	Water holding capacity (%):	35.5	64.7
	Microbial biomass (% of total soil organic carbon):	8.12	49.28
	Clay (%) < 2 µm	8.4	9.6
	Silt (%) 63 µm to ≥ 2 µm	27.2	82.4
	Sand (%) ≥ 63 - 2000 µm	64.4	8.0
	NO_3^--N (mg/100 gdw)	1.43	3.16
4.	Environmental conditions		
	Temperature:	18 to 22°C	
	Photoperiod:	Continuous dark	

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

05-July-2000 to 10-August-2000

2. Experimental treatments

The effects of Oxamyl 10SL on nitrogen transformation and soil respiration were investigated in a loamy silt soil and a loamy sand soil in a laboratory study. Oxamyl 10SL was applied to the soil at nominal application rates of 1.5 and 15.0 kg a.s./ha (1 and 10 times the field application rate for drip irrigation in Mediterranean crops) and at 230 mg a.s./kg soil dry weight (maximum PEC after 5 applications at the recommended application rate in Mediterranean crops, 1.5 kg a.s/ha/season). The concentration to be applied to soil was based on assuming a penetration depth of 5 cm and a soil bulk density of 1.5 g/cm3. The control consisted of soil treated with deionised water. The toxic standard, Dinoterb acetate, tested concurrently, was applied to the soil at 40 L/ha (l0x field application rate). Prior to the initiation of the study, the moisture content of the soil was measured and the amount of water needed to bring the soil moisture content to 40% (loamy sand soil) and 45% (loamy silt soil) maximum water holding capacity (WHC) was determined.

Three replicates were tested per each group.

Samples for nitrogen and respiration determination were incubated for 28 days. Short term respiration was measured in soil after the addition of300 mg glucose/lOO g soil wet weight (loamy sand soil) and 400 mg glucose/1 00 g soil (loamy silt soil) with the OxiTop System". Soil nitrification was determined by measuring the NH_4^+, -N, $N0_3^-$-N and $N0_2^-$-N contents of aqueous soil extracts by means of calibrated ion sensitive electrodes and the Orion expandable Ionanalyzer, Model EA 940. The concentrations of NH_4^+, -N, $N0_3^-$-N and $N0_2^-$-N in the soil were then calculated from the measured values .

3. Observations

Samples were collected for determination of nitrogen transformation at 3h, and at days 14, and 28 following application of the test item.

Samples were collected for soil respiration determination at 3h, and days 14, and 28 following application of the test item.

4. Statistics

The results of the nitrification and short-term respiration measurements were submitted to a statistical analysis procedure for a pair-wise comparison of samples using the multiple-t-test according to Dunnett (Computer program EASY ASSAY, Multiple Testing). The stastistical program included a pre-test for homogeneities of variance according to Cochran.

II. RESULTS AND DISCUSSION

A. FINDINGS

In the concurrent test with the toxic references, the deviation between the control and the toxic reference was >25% in both the nitrogen transformation test and soil respiration test. All validation criteria were met indicating the validity of this study.

Nitrate-N /100 g dry weight, loamy sand soil

mg Nitrate-N/100 g dry weight (28 days)					
Sample	measured values mg/200 mL	% soil dry weight / 100	mg NO_3^--N / 100 g dry weight	mean NO_3^--N/100 g dry weight	% dev. from control
Control	6.04	0.882	3.10	3.14	-
	6.64	0.877	3.42		
	5.67	0.880	2.91		
Oxamyl 10L 1x field application rate	5.88	0.885	3.00	2.97	-5.41
	5.62	0.874	2.91		
	5.83	0.882	2.99		
Oxamyl 10L 10x field application rate	6.95	0.880	3.57	3.43	9.24
	7.01	0.872	3.63		
	5.90	0.865	3.08		
Oxamyl 10L Seasonal maximum PECsoil	6.82	0.872	3.54	3.53	12.42
	6.38	0.878	3.28		
	7.27	0.872	3.77		
Reference substance	7.88	0.876	4.07	4.52	43.95
	9.32	0.882	4.78		
	9.15	0.880	4.70		

Nitrate levels, nitrate formation rate, and respiration rate at the end of the study (Day 28 for nitrogen and respiration) and the percent deviation from the control are reported in Table 56 and Table 57.

Table 56 Summary of effects of Oxamyl 10SL on nitrate levels, nitrate formation rate, and short-term respiration in loamy sand soil

	Mean NO_3–N Levels (Day 28)		**Mean Formation rate NO3-N (Day 28)**		**Nitrogen transformation (Day 28)**		**Respiration rate (Day 28)**	
Nominal oxamyl concentration	**mg/100g dry soil**	**% Deviation from control[a]**	**mg /kg/d**	**% Deviation from control**	**mg/ 100g soil dry weight**	**% Deviation from control[a]**	**mg CO_2/hr/100g dry soil**	**% Deviation from control[a,b]**
Control (0.0)	3.14	--	0.61	--	3.14	--	0.33	--
1.5 kg a.s./ha	2.97	-5.41	0.55	-10	2.97	-5.41	0.32	-3.03
15.0 kg a.s./ha	3.43	9.24	0.71	16	3.43	9.24	0.30	-9.09
23 mg a.s./kg soil	3.53	12.42	0.75	23	3.53	12.42	0.28	-15.15
Reference substance	4.52	43.95*			5.77	83.76*	0.24	-27.27*

[a] Negative value = % inhibition, positive value = % stimulation

[b] There were no significant differences from the control

* statistically different from the control, two-sided.

Table 57 Summary of effects of Oxamyl 10SL on nitrate levels, nitrate formation rate, and short-term respiration in loamy silt soil

Nominal oxamyl concentration	Mean NO_3–N Levels (Day 28)		Nitrogen transformation (Day 28)		Respiration rate (Day 28)	
	mg/100 g dry soil	% Deviation from control[a,b]	mg/ 100g soil dry weight	% Deviation from control[a,b]	mg CO_2/hr/100 gdry soil	% Deviation from control[a,b]
Control (0.0)	6.11	--	6.55	--	1.97	--
1.5 kg a.s./ha	6.11	0.00	6.51	-0.61	2.17	10.15
15.0 kg a.s./ha	7.19	17.68*	7.55	15.27*	1.66	-15.74
23 mg a.s./kg soil	6.57	7.53*	7.02	7.18	2.24	13.71
Reference substance	8.93	46.15*	9.50	45.05*	1.40	-28.93

[a] Negative value = % inhibition, positive value = % simulation

[b] There were no significant differences from the control

* statistically different from the control, two-sided.

III. CONCLUSION

At the end of 28 days, deviations in respiration rates compared to the control were <25%, the effect threshold specified by the OECD guidelines. At the end of 28 days, deviations in nitrate formation rate compared to the control were <25%, the effect threshold specified by the OECD test guidelines. It can be concluded, therefore, that Oxamyl 10SL, at concentrations up to and including 15.0 kg oxamyl/ha, corresponding to 10x the maximum field application rate of 1.5 g oxamyl/ha, can be categorised as having low risk to soil microflora.

(Wachter, S., 2001)

RMS comments and conclusion

A review of this study according the current guideline (OECD 216, 2000) was conducted.

The RMS revised the summary by including tables, several additional information in the text and revising Table 56 and 57. The nitrate formation rate was also calculated and used to express the results, and added to table 56.

The loamy sand soil used in the study meet the characteristic for the soil recommended in the OECD 216 guideline and therefore the RMS evaluation focussed on this soil. Samples in the studies were examined at 3h, and at days 14, and 28 following application. Data at the sampling point at 7 d as recommended by OECD 216 are missing.

The application rates tested in the study were 1.5 and 15.0 kg a.s./ha, corresponding to a maximum of about 3 times the seasonal application rate of 5 K kg a.s./ha proposed in tomato by drip irrigation or 5.5 Kg a.s./ha proposed for solarisation. The treatment at 23 mg a.s./kg soil dry is expected to roughly correspond at 10x the maximum single application rate in tomato (drip irrigation, values not calculated in the Fate section), but lower than 5x times the single application rate for solarisation (PECsoil expected to be about 7 mg/Kg dry soil, value not available in the dRAR Vol 3 B8).

The validity criterion of the test is met. The guideline requires a CV of control replicates <= 15% to be valid. In the present test with loamy sand soil the CV for the nitrate formation rate at 28d was 12%.

Conclusion: The test is acceptable but for application in solarization, the highest tested concentration was not sufficiently high to meet the required upper concentration (5x) to be tested.

B.9.9.2 Further laboratory, glasshouse, or field testing to investigate impact on soil microbial activity

No additional testing submitted.

B.9.10 Risk assessment for soil nitrogen transformation

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

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

RMS: The Applicant has not submitted any risk assessment for the non-permanent protected structures. Hence the conclusion can only apply to permanent structures, and this should specified in the GAP and in product authorization label. For use in any other protected structures, a risk assessment should be presented.

B.9.11 Effects on terrestrial non-target higher plants

B.9.11.1 Summary of screening data

Oxamyl was a new compound discovered in the 1970s. Early screening data may have been collected at the time, but are no longer available. The current document summarises available data to support the AIR3 registration. Screening data should be considered supplemental to specific data generated from studies on soil microflora, sewage sludge, non-target arthropods, and non-target soil macrophytes presented elsewhere in this document.

Based on these regulatory studies, and the supplemental data from insect and plant screens, Oxamyl 10SL will pose low risk to non-target organisms when used according to Good Agricultural Practices.

B.9.11.2 Testing on non-target plants

The effects of Oxamyl 24SL on the germination, seedling emergence, vegetative vigour, and phytotoxicity of a range of terrestrial non-target plants were assessed in laboratory studies.

Vegetative vigour

The effects of Oxamyl 24SL on the vegetative vigour was assessed in DuPont-34275. Please see the detailed study summary in the Oxamyl dRAR a.s. Vol 3 B9. The full validity of the vegetative vigour study could not established, hence the results are to be considered as supportive information. it fully meets the current guideline (U.S. EPA 850.4100 (1996)). (Please see the Oxamyl dRAR a.s. Vol 3 B9).

Seedling emergence and seed germination

The effects of Oxamyl 24SL on seedling emergence was assessed in DuPont-5817, which was originally submitted under EU Rev8 Point IIA 8.6, conducted with test material Oxamyl 24SL, and conducted under guideline U.S. EPA 850.4100 (1996). A review of this study indicates that the seedling emergence test is not fully valid and the results can be used as additional information.

Extended laboratory studies on non-target plants

No extended laboratory studies were conducted on non-target plants.

B.9.11.3 Semi-field and field tests on non-target plants

This is not an EC data requirement. No extended laboratory studies were conducted on non-target plants.

B.9.12 Risk assessment for terrestrial non-target higher plants

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

B.9.13 Effects on other terrestrial organisms (flora and fauna)

Data from insecticide screening studies with oxamyl and metabolites of oxamyl are summarised in dRAR a.s. Vol 3 B9.

Screening data should be considered supplemental to specific data generated from studies on soil microflora, sewage sludge, non-target arthropods, and non-target soil macrophytes presented elsewhere in this document. Based on these regulatory studies, and the supplemental data from insect and plant screens, Oxamyl 10SL will pose low risk to non-target organisms when used according to Good Agricultural Practices.

RMS: for sewage sludge a toxicity test indicates a LC50> 100mg/L. A quantitative risk assessment with the PEC for STP should be submitted.

B.9.14 Risk assessment for other terrestrial organisms (flora and fauna)

No risk assessment for other terrestrial organisms is necessary.

B.9.15 Monitoring data

No monitoring data on other non-target species (flora and fauna) are needed to assess biological activity. It can be concluded that the proposed use of Oxamyl 10SLwill pose a low risk to other terrestrial organisms.

B.9.16 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	Justification if data protection is claimed	Owner
B.9.1.1.1/01	[redacted]	1999	Oxamyl 10L: An acute oral toxicity study with the northern bobwhite [redacted] DuPont-2956 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.3.1/01	[redacted]	2000b	Oxamyl 10L: Static, acute, 96-hour, (LC_{50}) test to rainbow trout, *Oncorhynchus mykiss* [redacted] DuPont-2910 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.3.1/02	[redacted]	2000c	Oxamyl 10L: Static-renewal, acute, 96-hour, (LC_{50}) test to bluegill sunfish, *Lepomis macrochirus* [redacted] DuPont-2911 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.3.1/03	Ward, T.J., Magazu, J.P., Boeri, R.L.	2000a	Oxamyl 10L: Acute, static-renewal, 48-hour EC_{50} to *Daphnia magna* T.R. Wilbury Laboratories, Inc. DuPont-2556 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont

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B.9.3.1/04	Boeri, R.L., Ward, T.J.	2000	Oxamyl 10L: Influence on growth and growth rate of the alga, *Selenastrum capricornutum* T.R. Wilbury Laboratories, Inc. DuPont-3913 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.5.1.1.1/01	Schur, A.	1999	Oxamyl 10L: Acute oral and contact toxicity to the honey bee, *Apis mellifera* L. GAB Biotechnologie, GmbH DuPont-2718 Previously submitted at the EU level for Annex I inclusion Published: No	N	N	DuPont	
B.9.5.1.1.2/01	Schur, A.	1999	Oxamyl 10L: Acute oral and contact toxicity to the honey bee, *Apis mellifera* L. GAB Biotechnologie, GmbH DuPont-2718 Previously submitted at the EU level for Annex I inclusion Published: No	N	N	DuPont	
B.9.5.1.2/01	Balluff, M.	2002	Oxamyl (DPX-D1410) 10L - Evaluation of the side-effects on bumble bees (*Bombus terrestris* L.) after drip-irrigation treatment to tomato plants in greenhouse compartments GAB Biotechnologie, GmbH DuPont-5748 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont

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B.9.5.2.2/01	Adelberger, I.	2002	Oxamyl (DPX-D1410) 10L: An extended laboratory study using field aged residues to evaluate the effects on the predatory mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) GAB Biotechnologie, GmbH DuPont-6133 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.5.2.2/02	Bargen, H.	2002	Oxamyl (DPX-D1410) 10L - an extended laboratory study using aged residues to evaluate the effects on predatory bug *Orius laevigatus* Fieber (Heteroptera, Anthocoridae) GAB Biotechnologie, GmbH DuPont-6132 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.5.2.2/03	Bruhnke, C.	2000	Oxamyl 10L: An extended laboratory study to evaluate the effects on the spider *Pardosa spec* L. (Araneae, Lycosidae) Dr. U. Noack-Laboratorium for Angewandte Biologie DuPont-3912 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont

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B.9.5.2.2/04	Drexler, A.	2000	Oxamyl 10L (DPX-D1410): An extended laboratory study to evaluate the effects on the staphylinid beetle, *Aleochara bilineata* Gyll. IBACON DuPont-3910 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.5.2.2/05	Schmitzer, S.	2000	Oxamyl 10L (DPX-D1410): An extended laboratory study to evaluate the effects on the ground beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) IBACON DuPont-3911 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.5.2.2/06	Schmitzer, S.	2001	Oxamyl 10L (DPX-D1410): An extended multi-rate laboratory study to evaluate the effects on the wolf spider, *Pardosa spec* L. (Araneae, Lycosidae) IBACON DuPont-5162 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont

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B.9.5.2.2/07	Schuld, M.	2002	Oxamyl (DPX-D1410) 10L: An extended laboratory study using field aged residues to evaluate the effects on the aphid parasitoid, *Aphidius rhopalosiphi de Stefani Perez* (Hymenoptera, Braconidae) GAB Biotechnologie, GmbH DuPont-6131 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.7.1.1/01	Luhrs, U.	2001	Oxamyl 10L (10% w/w): Effects on reproduction and growth of the earthworm, *Eisenia fetida* (Savigny 1826), in artificial soil IBACON DuPont-3345 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.9.9.1.2/01	Wachter, S.	2001	Oxamyl (DPX-D1410) 10L: Assessment of effects on soil microflora GAB Biotechnologie, GmbH DuPont-4114 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont

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