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Oxamyl

Volume 3

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

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May 2016	First RAR of Italy	
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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 10GR 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 10GR, DuPont-40953 EU.

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

Oxamyl 10GR

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.

Table 1 Test substance/material specifications

Test substance code	Type	Composition	Detailed specifications
Annex I inclusion EU approval review			
D1410-377	Formulated Oxamyl 10SL	100 g a.s./L	See Document J, Part 3
D1410-381	Formulated Oxamyl 10SL	100 g a.s./L	See Document J, Part 3
D1410-394	Formulated Oxamyl 10GR	100 g a.s./kg	See Document J, Part 3
D1410-477	Formulated Oxamyl 10GR	100 g a.s./kg	See Document J, Part 3
2015 renewal submission			
D1410-563	Formulated Oxamyl 10GR	100 g a.s./kg	See Document J, Part 3

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 10GR, DuPont-40953 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	51.0
		Water	42.8
		Sediment	4.4
		Plants (barley forage, straw)	13.4, 6.3
	IN-D2708	Soil	78.7
		Water	66.8
		Sediment	12.1
		Plants (barley grain, hay)	51.3, 8.2
	IN-N0079	Soil	10.2
		Water	52.9
		Sediment	3.7
		Plants (barley straw)	13.1
	IN-T2921	Soil	NA[b]
		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.

[b] Not applicable

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
- 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
- Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA Journal 2009; 7(12):1438
- 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
- 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 an Zee, The Netherlands: 8-11 March 2010/editors, Anne Alix, *et al.* 136 pages.

Oxamyl 10GR is used in outdoor field applications, at planting tobacco or of potatoes, in Central and Southern Europe. Granules are applied directly to soil, either in-furrow or broadcast, then immediately incorporated into the soil 10 cm deep (Appendix 1).

Tobacco: For use in tobacco, Oxamyl 10GR may be applied in-furrow at planting at a rate of 3 kg a.s./ha or by broadcast application to tobacco at 1 × 5500 g a.s./ha. Granules are immediately incorporated in the soil 10 cm deep.

Potatoes: For use in potatoes, Oxamyl 10GR may be applied in-furrow at planting at a rate of 1 kg a.s./ha. Granules are immediately incorporated in the soil 10 cm deep.

The proposed use patterns that will be assessed are shown in Table 3.

Table 3 Maximum recommended dose rates of Oxamyl 10GR—Representative uses

	Application			**Application rate**		
Crop	**Method/ kind**	**Timing/ growth stage of crop and season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg product/ ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Remarks**
Potato	In-furrow application	At planting (BBCH 00)	a) 1 b) 1	a) 10 b) 10	a) 1 b) 1	None
Tobacco	In-furrow application	At trans-planting (BBCH 00)	a) 1 b) 1	a) 30 b) 30	a) 3 b) 3	None
Tobacco	Evenly soil incorporated to a depth of 10cm	Pre-planting (BBCH 00)	a) 1 b) 1	a) 42.5–55 b) 42.5–55	a) 4.2–5.5 b) 4.2 –5.5	None

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

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.1.1.1/01

Reference: --	**Report**	[redacted] (1999); Oxamyl 10G: An acute oral toxicity study with the northern bobwhite **DuPont Report No.:** DuPont-2955 **Guidelines:** OPPTS 850.2100 (1996), U.S. EPA 71-1 (1988)

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s/kg

Materials and methods:

Oxamyl 10 GR was administered by single dose in reverse osmosis water, which was orally intubated directly into the crop or proventriculus of fasted northern bobwhite quail (*Colinus virginianus*; 19 weeks old). Five quail/sex/dose received doses of 0, 5, 10, 20, 40, 80, 160 and 320 mg Oxamyl 10 GR/kg bw (0, 0.5, 1, 2, 4, 8, 16 and 32 mg a.s./kg bw) at a dose volume of 4 mL/kg. Animals ranged in weight from 162 – 218g at test initiation. All birds were acclimatised to test conditions for approximately 4 weeks prior to the initiation of the test. Birds were fasted for a minimum of 18 hours prior to dosing and water and feed were provided ad libitum during the test.

Average room temperature during this study was 23.4 ±1.2°C with an average relative humidity of 51 ±1 %. 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. Average feed consumption was determined between days 0-3, 4-7 and 8-14.

Findings:

No regurgitation occurred in this study. Treatment related mortalities occurred at 4, 8, 16 and 32 mg a.s./kg bw (Table B.9.1.1-5). 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 groups 16 and 32 mg a.s./kg bw Oxamyl 10 GR, all surviving quail appeared normal by day 2 or earlier and throughout the remainder of the study (Table B.9.1.1-5). There were no test substance-related body weight or food intake effects noted. All birds that were found dead on the day of dosing (Day 0) had a clear to green fluid in their crops, assumed to be the dosing solution. One bird at the 8 mg a.s./kg treatment had slightly pale kidneys and one bird in the 32 mg a.s./kg treatment had a pale mottled spleen. All surviving birds were necropsied, as well. One bird at 32 mg a.s./kg bw had a possible treatment-related hyperemia in the small intestine.

Table 4 Summary of toxicological responses of northern bobwhite quail following a single oral dose of Oxamyl 10 GR

Dose (mg a.s./kg body wt.)	Sex	Toxicological resultsa	Duration of clinical signs	Time of death
Control	M	1[b]/0/5	--	Day 7
Control	F	0/05	--	--
0.5	M	0/0/5	--	--
0.5	F	0/0/5	--	--
1	M	0/0/5	--	--
1	F	0/0/5	--	--
2	M	0/3[c]/5	5 ½ hours	--
2	F	0/1/5	5 ½ hours	--
4	M	0/5/5	2 days	--
4	F	1/4/5	2 days	Day 0
8	M	1/4/5	2 days[d]	Day 0
8	F	3/2/5	2 days	Day 0
16	M	3/2/5	3 days	Day 0
16	F	5/0/5	--	Day 0
32	M	2/3/5	3 days	Day 0

32	F	5/0/5	--	Day 0

[a] number of animals which died/number of animals with clinical signs/number of animals used
[b] animal was euthanized due to a broken leg which occurred during handling
[c] sex of bird was not mentioned for these three birds
[d] one bird out of the ten (sex was not mentioned), displayed signs of toxicity on the morning of Day 3 and recovered by afternoon of Day 3

Table 5 Summary the relevant acute oral toxicity endpoints for northern bobwhite quail.

Test substance	Oxamyl a.s.	Oxamyl 10 GR
Test object	Northern bobwhite quail	Northern bobwhite quail ♂and ♀
LD_{50}	12 mg a.i./kg bw	120 mg Oxamyl 10 GR/kg bw
Lowest observed effect level (LOEL)	2 mg a.i./kg bw	20 mg Oxamyl 10 GR/kg bw
Highest tested dose without toxic effect (NOEL)	1 mg a.i./kg bw	10 mg Oxamyl 10 GR/kg bw

Conclusion:

The acute oral LD50 value for northern bobwhite quail exposed to Oxamyl 10 GR by single oral dose was calculated to be 120 mg Oxamyl 10 GR (12 mg a.s.)/kg bw, with a 95% confidence interval of 80 to 200 mg a.s./kg bw. The no mortality dosage was 20 mg Oxamyl 10 GR/kg bw. Based on signs of toxicity at the 20 mg Oxamyl 10 GR/kg dose, the NOEL was 10 mg Oxamyl 10 GR/kg bw.

RMS comments and conclusion

The study was conducted under guideline OPPTS 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 There was a single mortality in the control group. A male suffered a leg fracture during body weight procedures on Day 7 of the test, and as a result was euthanized. All other control birds were normal in appearance and behavior throughout the test period.

Therefore this study is relied upon.

B.9.1.1.2 Higher tier data on birds

Study submitted in the EU Dossier in 2008 and included in the first EU approval review.

B.9.1.1.2/01

Reference: --	**Report**	Thompson, H.M. (2005); Oxamyl 10G: Field monitoring of granule applications in commercial fields and effects on wildlife in the UK **DuPont Report No.:** DuPont-15823 **Guidelines:** Not applicable

1.	Test material:	Oxamyl 10GR. Irregular, angular, blue-green granules
	Lot/Batch #:	D1410-477 (granule dissipation study), batch no. not specified for commercial product used in fields
	Purity:	10% w/w nominal

GLP: No – not a standard study
Testing Facility: Central Science Laboratory, York, UK

Materials and methods:

Experimental treatments

The effects of the insecticide Oxamyl 10GR on wild birds and mammals in potatoes were assessed in a field trial in 30 potato fields located in the United Kingdom (in-life initiated 14-March-2005, completed 31-May-2005). No guidelines are available for this study type. Farmers in the region volunteered to allow their newly planted fields to be monitored immediately after field preparation, application of Oxamyl 10GR, and potato planting. The locations of the fields represent a cross-section of the major potato growing areas and soil types in which Oxamyl 10GR is used in the United Kingdom. Twenty-nine fields were broadcast incorporated applications and a single site in Scotland was an in-furrow application (this site was excluded from all further analysis of granule counts). Broadcast applications were made between 10 March to 11 May 2005 at rates between 37-55 kg product/ha (3.7-5.5 kg a.s./ha). Application/incorporation was achieved by a variety of techniques which can be considered representative for normal agricultural practice. The size of the sites varied according to local farming practice (timing of cultivation, application, and planting operations) and the field area monitored ranged from 0.4-14.3 ha.

Carcass Searches

Bird carcass searches were undertaken on 23 fields. An initial carcass search was performed to remove any animals that died from causes other than poisoning by granules. On the first visit to the field, the field may have only recently been ploughed or harrowed and any dead animals on the field would probably be buried. Therefore, on the first visit, the carcass search only concerned the field margins.

The main carcass searches were conducted within a 24 – 48 hour period after application, by 3 field team members. The team searched both the main field and the adjacent hedgerows.

If large numbers of earthworms were observed on the surface of the field, this was also noted.

Bird and mammal observations

The purpose of the bird surveys was to identify:

- Species that are seen on newly planted fields and are therefore potentially at highest risk of exposure to pesticides used there.
- Species that use surrounding field margin habitat and have a lower risk of exposure.
- Any evidence of sublethal effects (e.g., birds seen on or near newly planted fields behaving abnormally).

On each survey, the surveyor scanned the field using binoculars noting bird species, number, distance from the edge, and activity. They also conducted a survey of birds along a fixed length of field margin (hedgerow or ditch), again noting species seen or heard and activity.

Two surveys were carried out:

- one during the course of planting (when some bird species are expected to avoid the area, while other such as gulls and corvids may be attracted) and
- one 24-48 hours after completion of cultivation (when species normally disturbed by human presence (e.g. woodpigeons), are expected to be present).

Granule counts

Surface exposed granule counts were made on all 29 broadcast sites. Monitoring of exposed granules was undertaken on the headlands and main part of the field with 20 counts in each area. On the main field, 20 random counts were made across the diagonal of the field. On the headlands, 20 random counts were made and additional effort was focused on searching for spills in high-risk areas, e.g. row ends. The team focused on both random counts and searching for spills along the headlands/row ends. A maximum of 5 spills on each headland and the main field were assessed.

Dissipation of oxamyl from granules

Dissipation of oxamyl from granules was studied at 10 sites, representing a range of soils characteristic of potato growing areas of the United Kingdom. All granules were applied to the soil surface at the time that the main application was in progress on the field and in areas representative of the main field, *i.e*. same cultivation. Granules were collected 0, 4, 9, 24 and 48 hrs after application and oxamyl content analysed by HPLC. Additional information such as topsoil characteristics and soil moisture were characterized at each site at each sampling time and a record of rainfall and minimum/maximum air and soil temperatures were recorded during the two-day sampling period. Kinetic analysis of the observed data was performed in order to determine the rate of oxamyl dissipation from the granules.

Monitoring and Statistics

Field monitoring data were summarized as follows:

- Descriptive statistics (granule count data from the database was pasted into MS Excel 2000 spreadsheets for calculation of minimum, maximum, mean, and percentiles values (using the MIN, MAX, AVERAGE, and PERCENTILE statistical functions respectively) for granule densities per kg product applied/ha, categorized by planting equipment, application rate, or other relevant factors, e.g. soil type
- Descriptive data on occurrence (e.g., x of y fields) and locations of granule spills in fields
- List of species seen on or near fields during and after Oxamyl 10GR application
- Mean number and species of birds seen on newly planted fields and surrounding Habitat Descriptive data on wildlife casualties [species, occurrence (e.g., x of y fields) and locations in fields]. Tabular data summarizing likely cause of death for any carcass collected during or after field applications
- Summarized data on machinery and agronomy associated with Oxamyl 10GR granule application to potato fields in the United Kingdom
- Complete data on granule dissipation including active ingredient content, soil moisture, soil and air temperature, and rainfall for kinetic calculations.

Kinetic model selection, optimization, and evaluation were based on the draft guidance of FOCUS (2005). Each field data set was analysed using three kinetic models as briefly described below. Kinetic analyses were performed using the software ModelMaker 4.0. All default software settings were used except for the Marquardt optimization settings where initial lambda was set to 0.01 and the minimum change was set to 1E-05. Excel 2000 was used for calculation of fitting statistics ($\chi 2$, r2), t-test, and residuals.

Findings:

Application methods

Broadcast incorporated applications were made using a range of equipment and all except one (on a rotovator/power harrow) were driven independently of the machine on which they were mounted. Horstine Farmery equipment represented 83% of all application equipment used. Where the

applicator was not on the bedformer or ridger/destoner a spiked rotovator/baseliner was often used to ensure incorporation. The application rate of the granules was 37-55 kg/ha with 72% of the monitored applications falling between 50-55 kg/ha. A closed transfer system was used for all but one application.

Granule flow was stopped at row ends by a range of methods. The majority (83%) of the application machinery had a land-wheel, which stopped when the application machinery was lifted and in only one case was it reported not to stop dead on lifting. Other methods of stopping granule flow reported included a hydraulic clutch, air flow switches and electric switches and 38% of the operators reported manually switching off granule flow at row ends.

Carcass searches

Carcass searched performed on 23 sites 24-48 hours after application did not show any wildlife poisoning related to the use of Oxamyl 10GR.

Earthworms: There was only one site (Site 1) where earthworms were seen on the surface after the Oxamyl 10GR application and there were relatively few observed across the field (tens).

Bird and mammal observations

Surveys were carried out on 23 of the fields during which 1481 individual birds of 57 species were counted on the fields and in the field margins. Bird surveys on 23 sites indicated the most prevalent *i.e.*, most recorded species on the main field was the pied wagtail, followed by crow and rook, black-headed gull, woodpigeon, pheasant, jackdaw, red-legged partridge, and skylark (Figure B.9.1.4.2-1). Other observed species were seen on at most 2 fields. The most abundant species was the black-headed gull, followed by the pied wagtail, rook, crow, linnet, and common gull. Other species were observed at ≤25 individuals. On the field margins, the most prevalent species was the chaffinch, followed by the robin, blackbird, wren, woodpigeon, blue tit, great tit, yellowhammer, greenfinch, pied wagtail, and dunnock. Other observed species were seen on at most 4 fields. The most abundant species was the chaffinch, followed by the fieldfare, woodpigeon, robin, blue tit, and greenfinch. Other species were observed at ≤19 individuals (Figure B.9.1.4.2-2).

Figure B.9.1.4.2-1: Prevalence – Number of fields with species recorded on the main field

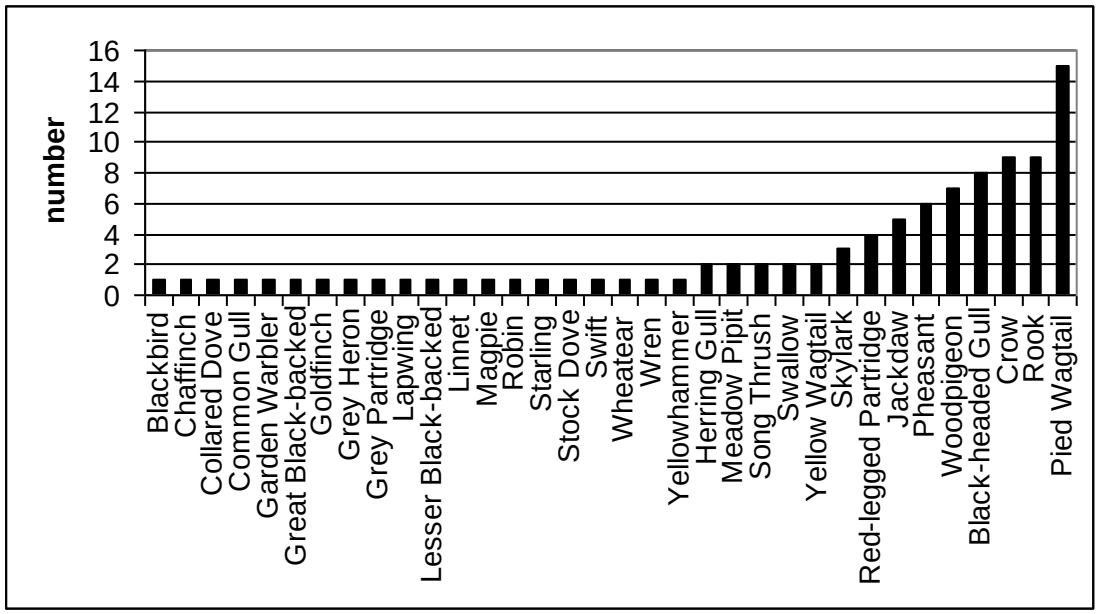
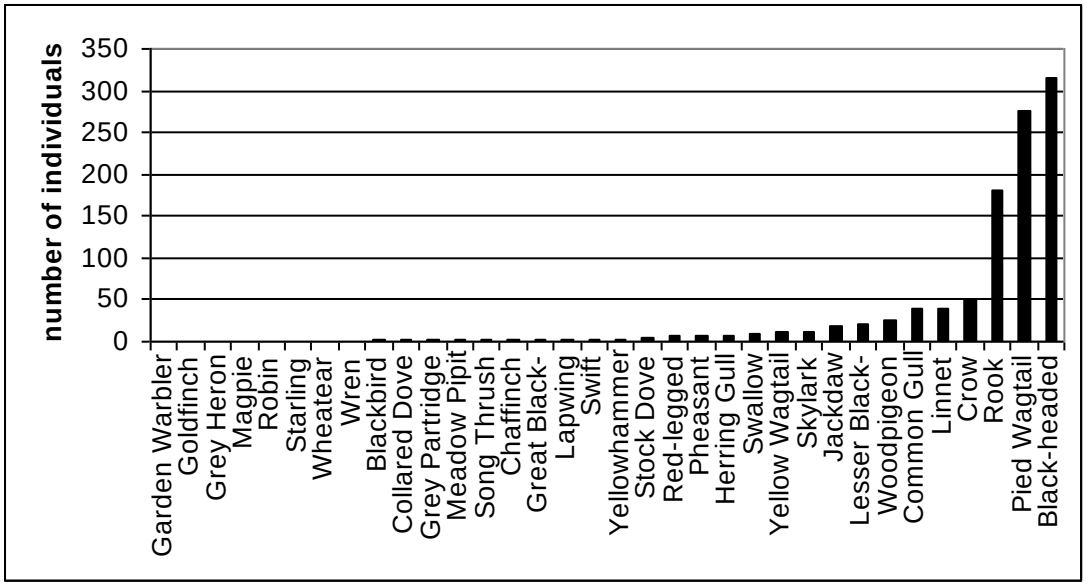


Figure B.9.1.4.2-2: Abundance - Number of individuals recorded on the main field of 23 sites



Granule counts and collections

The granule counts in quadrats across the main field and in the headlands are summarized in Table B.9.1.4.2-6 through Table B.9.1.4.2-3. Mean surface exposed granule counts (per 0.25 m^2) were 7.0, 14.5, and 8.3 for the main field, uncultivated headlands and cultivated headlands, respectively. All fields median values were 2, 0, and 0.5; 90th percentiles 16, 9.3, and 17.2 and 95th percentiles 25.1, 30.0, and 50.7, respectively. There was no apparent effect of soil type or application equipment on the granule counts on uncultivated headlands suggesting that the key in reducing granule counts is the timing of the cessation of granule flow at row ends.

Spills were identified on 17 of the 29 fields monitored (59%) and are summarized in Table B.9.1.4.2-4 (number of spills between 1 and 8, maximum spill per site 200-9000 granules/0.25 m^2). These spills were primarily located at row ends and headlands (due to incomplete incorporation, failure to stop granule flow, or replacement of containers). It was noted also that large spillages may be difficult to deal with solely by cultivating the affected area, e.g. at Site 1, a large spill was rotovated several times but granule counts were still over 200/0.25m^2.

Table B.9.1.4.2-1: Granule count data for the main field (number of granules on the surface/0.25 m^2)

Field number	minimum count	maximum count	mean count	median count	90th percentile	95th percentile
1	0	22	5.9	6	11.3	14.4
2	0	1	0.1	0	0.1	1.0
3	0	13	2.3	1	5.2	7.3
4	0	14	1.2	0	2.1	3.6
5	0	13	3.5	2	8.2	10.2
6	0	16	6.7	5.5	14.1	15.1
7	0	4	0.9	0	2.2	4.0
13	0	11	4.7	3.5	10.1	11.0
14	0	3	0.4	0	1.0	1.1
15	0	21	1.8	1	2.1	3.9
17	0	6	1.5	1	3.1	4.1
18	0	14	5.5	4.5	12.2	14.0
19	0	20	9.5	8.5	18.1	19.1
20	0	5	1.1	0	3.2	5.0
21	0	18	5.1	4.5	10.4	14.2
22	1	15	4.8	4	9.0	9.3
23	0	4	1.5	1	3.1	4.0
24	0	5	1.3	1	3.0	3.1
25	0	2	0.2	0	1.0	1.1
27	0	34	11.4	9	22.3	25.5
28	1	24	11.6	10	21.0	21.2
30	0	11	5.1	4.5	10.0	10.1
31	1	41	18.6	13.5	38.0	38.2
33	0	34	14.8	14	23.2	25.5
34	0	4	0.9	0	3.0	3.1
35	0	18	3.3	2	6.0	6.6
36	26	140	71.0	65	98.8	107.7
39	2	14	6.4	6	10.2	12.1
41	0	4	1.6	1	4.0	4.0
all fields	0	140	7.0	2	16.0	25.1

Table B.9.1.4.2-2: Granule count data for cultivated headlands (number of granules on the surface/0.25 m^2)

Field number	minimum count	maximum count	mean count	median count	90th percentile	95th percentile
18	0	8	0.6	0	0.4	4.2
21	0	15	5.3	5	14.0	14.1
25	0	2	0.4	0	1.1	2.0
27	0	36	9.4	7	13.6	19.9
34	0	6	0.4	0	1.0	1.3
36	0	110	33.7	28	78.2	98.6
all fields	0	110	8.3	0.5	17.2	50.7

Table B.9.1.4.2-3: Granule count data for uncultivated headlands (number of granules on the surface/0.25 m^2)

Field number	minimum count	maximum count	mean count	median count	90th percentile	95th percentile
1	0	1	0.1	0	0.0	0.1
2	0	2	0.2	0	0.1	1.1
3	0	5	0.8	0.5	1.1	2.2
5	0	16	1.4	0	4.2	6.5
6	0	43	5.8	2	18.5	24.0
7	0	6	0.6	0	2.0	2.2
13	0	1700	90.1[a]	0.5	22.5	119.2
14	0	89	7.5	0	16.5	41.5
15	0	7	1.0	0	4.2	6.1
17	0	47	2.8	0	2.0	4.3
20	0	500	28.8	0	18.0	67.8
22	0	66	8.5	3.5	20.5	27.1
23	0	3	0.25	0	1	1.1
24	0	210	27.7	1	137.0[a]	157.8
28	0	900	55.8	1.5	46.4	178.0
30	0	132	13.3	0	21.5	116.8
31	0	25	3.0	1	7.2	9.7
33	0	59	5.8	1	15.2	19.1
35	0	650	41.9	0	19.8	203.5
39	0	3	0.4	0	1.1	2.1
41	0	140	7.6	0	1.0	14.9
all fields	0	1700	14.5	0	9.3	30.0

[a] Extreme worst-case counts selected for use in refined risk assessment

Table B.9.1.4.2-4: Granule count data for spills (number of granules on the surface/0.25 m^2)

Field number	Number of spills	min size (cm^2)	max size (cm^2)	min count	max count
1	5	280000	280000	0	208
2	1	375	375	-	-
5	1	2000	2000	1000	1000
13	4	160000	160000	800	6000
17	2	-	-	328	926
19	4	2000	80000	900	9000
20	6	10000	80000	150	1000
21	8	5000	15000	108	900
22	4	30000	80000	700	1000
23	1	-	-	1000	1000
27	2	-	-	120	200
28	6	2500	10000	120	900
30	5	250	500	110	370
35	7	2500	120000	270	290
36	5	15000	15000	170	555
39	1	2500	2500	220	220
41	3	2500	2500	160	200

Dissipation of oxamyl from granules

Oxamyl dissipation from granules (studies on 10 sites) ranged from "no dissipation" to a half-life (DT_{50}) of 0.455 hours during the two-day sampling period. DT_{90} values ranged from 1.48 hours to no loss. Rainfall timing and amount appeared to strongly influence the amount of oxamyl remaining in the granules over time. Based upon data from all 10 sites, cumulative rainfall of 0.349 mm was

associated with 50% oxamyl loss and cumulative rainfall of 1.16 mm was associated with 90% loss of oxamyl from granules collected from the soil surface within 48 hrs after application.

Table B.9.1.4.2-5: Kinetic analysis summary

Field	Number of data points	Best fit model[a]	Parameters optimsed[b]	DT_{50} (hours)	DT_{90} (hours)	χ^2 error (%)	r^2
BA (16)	5	DFOS	k_1, k_2, t_b	0.539	1.79	0.86	1.000
BB (17)	4	DFOS	k_2, t_b	2.64	4.70	0.36	1.000
BC (1)	5	SFO	k	96.1	319	2.97	0.903
BD (41)	5	DFOS	k_2, t_b	4.57	7.46	0.14	1.000
BL (6)	5	DFOS	k_1, k_2, t_b	24.8	39.9	0.90	1.000
BM (19)	5	DFOS	k_2, t_b	63.8	203	7.44	0.772
BN (15)	5	DFOS	k_1, k_2, t_b	0.445	1.48	8.65	0.996
BO (18)	5	DFOS	k_1, t_b	20.1	nc[c]	1.88	0.994
BS (23)	5	DFOS	k_2, t_b	1071	3533	4.02	-0.077
BT (25)	5	DFOS	k_2, t_b	37.1	115	6.56	0.925

[a] Double first-order in series (DFOS) is also known as the hockey stick model.
[b] In all cases M0 was fixed to 100% and not allowed to vary in the optimisation. In some cases the rate constants k1 or k2 were fixed to 0 based on preliminary optimisation runs.
[c] nc = not calculated: A DT_{90} value could not be estimated since k2 was fixed to 0 in the optimisation and the DT_{90} was not reached before the breakpoint, t_b.

Conclusion:

A monitoring study was performed on 30 sites in the United Kingdom representative for the potato growing area. Oxamyl 10GR (granules, 10% oxamyl) was broadcast incorporated between half March and half May 2005 at rates between 37-55 kg product/ha (3.7-5.5 kg a.s./ha). Application/incorporation was achieved by a variety of techniques that can be considered representative for normal agricultural practice.

Carcass searched performed on 23 sites 24-48 hours after application did not show any wildlife poisoning related to the use of Oxamyl 10GR.

Bird surveys on 23 sites indicated the most prevalent species on the main field was the pied wagtail, followed by crow and rook, black-headed gull, woodpigeon, pheasant, jackdaw, red-legged partridge, and skylark. Other observed species were seen on at most 2 fields. The most abundant species, in terms of individual numbers, was the black-headed gull, followed by the pied wagtail, rook, crow, linnet, and common gull. Other species were observed at ≤25 individuals. On the field margins, the most prevalent species was the chaffinch, followed by the robin, blackbird, wren, woodpigeon, blue tit, great tit, yellowhammer, greenfinch, pied wagtail, and dunnock. Other observed species were seen on at most 4 fields. The most abundant species was the chaffinch, followed by the fieldfare, woodpigeon, robin, blue tit, and greenfinch. Other species were observed at ≤19 individuals.

Mean surface exposed granule counts (per 0.25 m^2) were 7.0, 14.5, and 8.3 for the main field, uncultivated headlands and cultivated headlands, respectively. All fields median values were 2, 0, and 0.5; 90^{th} percentiles 16, 9.3, and 17.2; and 95^{th} percentiles 25.1, 30.0, and 50.7, respectively. Spills occurred on 17 sites (number of spills between 1 and 8, maximum spill per site 200-9000 granules/0.25 m^2) and were caused at row ends and headlands (due to incomplete incorporation, failure to stop granule flow, or replacement of containers).

Oxamyl dissipation from granules (studies on 10 sites) ranged from "no dissipation" to a half-life of 0.455 hours and was primarily governed by rainfall events immediately after application. It was estimated that a cumulative rainfall of 0.35 mm would result in 50% dissipation and 90% dissipation will be reached after 1.2 mm of rainfall.

It can be concluded that there were no mortalities or sublethal effects on wild birds and mammals observed near and in potato fields during and after commercial applications of Oxamyl 10GR in the United Kingdom.

RMS comments and conclusion

The study DuPont-15823, (2005), as well as its summry, was not submitted for the renewal process.

The study was originally submitted under EU Rev8 Point IIIA 10.1.7 and was summarized and evaluated by the RMS Ireland in the Addendum to Annex B (Ecotoxicology) to the Draft Report and Proposed Decision (May 2010), which was subjected to EU peer review. Since the results of this study (both toxic effects and number of granules on the surface) have been used by the Applicant for the risk assessment, RMS Italy has reported the summary as present in the above cited Addendum (2010). Guidelines were not applicable because there are no specific guidelines for a granule application monitoring study. Birds and mammals surveys were carried out on 23 of the fields during which 1481 individual birds of 57 species were counted on the fields and in the field margins, which would represent a sufficient sample size. No effects on birds or mammals mammals were recorded within 48h after broadcast applications up to 5.5 kg a.s./ha oxamyl 10GR to potatoes in the UK. The RMS notes that the short observation time would have overlook possible effects occurring later in time.

In conclusion, a detailed re-evaluation of the study could not be done in absence of the original study report. The Notifier is asked to submit the study.

Study submitted in the EU Dossier in 2008 and included in the first EU approval review.

B.9.1.1.2/02

Reference: --	**Report:**	Thompson, H.M. (2005); Oxamyl 10G: Field monitoring of granule applications in commercial fields and effects on wildlife in the Netherlands **DuPont Report No.:** DuPont-15827, Revision No. 1 **Guidelines:** Not applicable GLP: No

1. Test material: Oxamyl 10GR
   Lot/Batch #: DPX-D1410-477(granule dissipation study), batch no. not specified for commercial product used in fields
   Purity: 10% w/w nominal

Materials and methods:

Experimental treatments

The effects of the insecticide Oxamyl 10GR on wild birds and mammals in potatoes were assessed in a field trial in 30 potato fields located in The Netherlands (in-life initiated 14-March-2005, completed 31-May-2005). No guidelines are available for this study type. Farmers in the region volunteered to allow their newly planted fields to be monitored immediately after field preparation, Oxamyl 10GR application and potato planting. The locations of the fields represent a cross-section of the major potato growing areas and soil types in which Oxamyl 10GR is used in The Netherlands. Nineteen fields were in-furrow applications and one was broadcast incorporated applications. Applications were made in April 2005 using a range of equipment that can be considered representative for normal agricultural practice. The application rate of the granules was 7-10 kg/ha (the broadcast incorporated application was at 20 kg/ha) except for one site where a 1.4 kg/ha rate was used; 68% of the monitored in-furrow applications were at 10 kg/ha. Only one application used a closed transfer system. The size of the sites varied according to local farming practice (timing of cultivation, application and planting operations) and the field area monitored ranged from 2.66-8.8 ha. Farmers in the region volunteered to allow their newly planted fields to be

monitored immediately after field preparation, application of Oxamyl 10GR, and potato planting.

Carcass Searches

Bird carcass searches were undertaken on 20 fields in the field margins. The main search for carcasses was conducted within a 24 – 48 hour period after application, by 3 field team members. The team searched both the main field and the adjacent hedgerows.
If large numbers of earthworms were observed on the surface of the field, this was also noted

Bird and mammal observations

The purpose of the bird surveys was to identify:

- Species that are seen on newly planted fields and are therefore potentially at highest risk of exposure to pesticides used there.
- Species that use surrounding field margin habitat and have a lower risk of exposure.
- Any evidence of sublethal effects (e.g., birds seen on or near newly planted fields behaving abnormally).

On each survey, the surveyor scanned the field using binoculars noting bird species, number, distance from the edge, and activity. They also conducted a survey of birds along a fixed length of field margin (hedgerow or ditch), again noting species seen or heard and activity.
Two surveys were carried out:

- one during the course of planting (when some bird species are expected to avoid the area, while other such as gulls and corvids may be attracted) and
- one 24-48 hours after completion of cultivation (when species normally disturbed by human presence (e.g. woodpigeons), are expected to be present).

Granule counts

Surface exposed granule counts were made on 20 sites. Monitoring of exposed granules was undertaken on the headlands and main part of the field with 20 counts in each area. On the main field, 20 random counts were made across the diagonal of the field. On the headlands, 20 random counts were made and additional effort was focused on searching for spills in high-risk areas, e.g. row ends, turning areas. The team focused on both random counts and searching for spills along the headlands/row ends. A maximum of 5 spills on each headland and the main field were assessed.

Dissipation of oxamyl from granules

Dissipation of oxamyl from granules was studied at 11 sites, representing a range of soils characteristic of potato growing areas of The Netherlands. All granules were applied to the soil surface at the time that the main application was in progress on the field and in areas representative of the main field, *i.e*. same cultivation. Granules were collected 0, 4, 9, 24 and 48 hrs after application and oxamyl content analysed by HPLC. Additional information such as topsoil characteristics and soil moisture were characterized at each site at each sampling time and a record of rainfall and minimum/maximum air and soil temperatures were recorded during the two-day sampling period. Kinetic analysis of the observed data was performed in order to determine the rate of oxamyl dissipation from the granules.

Monitoring and Statistics

Field monitoring data were summarized as follows:

- Descriptive statistics (granule count data from the database was pasted into MS Excel 2000 spreadsheets for calculation of minimum, maximum, mean, and percentiles values (using the MIN, MAX, AVERAGE, and PERCENTILE statistical functions respectively)

for granule densities per kg product applied/ha, categorized by planting equipment, application rate, or other relevant factors, e.g. soil type

- Descriptive data on occurrence (e.g., x of y fields) and locations of granule spills in fields
- List of species seen on or near fields during and after Oxamyl 10GR application
- Mean number and species of birds seen on newly planted fields and surrounding Habitat Descriptive data on wildlife casualties [species, occurrence (e.g., x of y fields) and locations in fields]. Tabular data summarizing likely cause of death for any carcass collected during or after field applications
- Summarized data on machinery and agronomy associated with Oxamyl 10GR granule application to potato fields in The Netherlands
- Complete data on granule dissipation including active ingredient content, soil moisture, soil and air temperature, and rainfall for kinetic calculations.

Kinetic model selection, optimization, and evaluation were based on the draft guidance of FOCUS (2005). Each field data set was analysed using three kinetic models as briefly described below. Kinetic analyses were performed using the software ModelMaker 4.0. All default software settings were used except for the Marquardt optimization settings where initial lambda was set to 0.01 and the minimum change was set to 1E-05. Excel 2000 was used for calculation of fitting statistics ($\chi 2$, r2), t-test, and residuals.

Findings:

Application methods

The 19 in-furrow applications were all made using applicators mounted on the planters except in one case where a separate tool was used. Applications were made using a range of equipment; 11 (58%) were driven independently of the machine on which they were mounted. In all except one case the width applied in a single pass was 3m. The speed of application varied from 4–7 km/h. The application rate of the granules was 7-10 kg/ha (the broadcast incorporated application was at 20 kg/ha) except for one site where a 1.4 kg/ha rate was used; 68% of the monitored in-furrow applications were at 10 kg/ha with only one application using a closed transfer system.

Granule flow was stopped at row ends by a range of methods. The majority (60%) of the application machinery had a land wheel which stopped when the application machinery was lifted. However, in three cases it was reported not to stop dead on lifting. Other reported methods of stopping granule flow included electric switches in the cab and 45% of the operators reported manually switching off granule flow at row ends.

Incorporation of the granules was undertaken by a disc and press wheel in all cases, apart from the broadcast incorporated application (Site 61) where a harrow was used.

Carcass searches

Carcasses were found on seven fields during the pre-application search (Table B.9.1.4.2-6). There were no mortalities 24 to 48 hrs after application that were attributable to the Oxamyl 10GR application. On Site 46 the wings of a blackbird were recorded on the field margin and on Site 56 the crop of a woodpigeon was reported – both were thought to be the result of predatory bird activity. A squashed small mammal was recorded on Site 54 and a few feathers from a pied wagtail were recorded on Site 57.

Earthworms

No earthworms were found on the surface of any of the monitored fields after Oxamyl 10GR application.

B.9.1.1.2/02-1: Pre-application carcass search results

Site Number	Species	Habitat	Comments
43	frog	grass margin	squashed by tractor, not taken.
50	gull	edge	feather spot, old, not collected
56	woodpigeon	grass	feather spot, older than 1 week, not taken
56	woodpigeon	ditch	feather spot, older than 1 week, not taken
56	woodpigeon	ditch	feather spot, very old, not taken
57	feral pigeon	farm	not taken
60	Gull Sp.	grass margin	feather spot - only small
61	frog	grassland	old, not taken, next to ditch
62	mallard	ditch	old feathers and bones, not taken

Bird and mammal observations

562 individual birds of 51 species were counted on the fields and in the field margins. A hare was also observed on the main field. A total of 271 individuals of 24 species of birds were recorded on or flying over the 20 main fields monitored. Of these the most prevalent, *i.e.*, most recorded species, and the most abundant species was the woodpigeon, which was recorded on 12 visits with total of 57 individuals recorded (Figure B.9.1.4.2-3 and Figure B.9.1.4.2-4).

A total of 291 individuals of 27 species of birds were recorded on the 20 field margins monitored. Of these the most prevalent and the most abundant species was the yellowhammer.

Figure B.9.1.1.2/02-1: Prevalence – Number of fields on which species were recorded on the main field

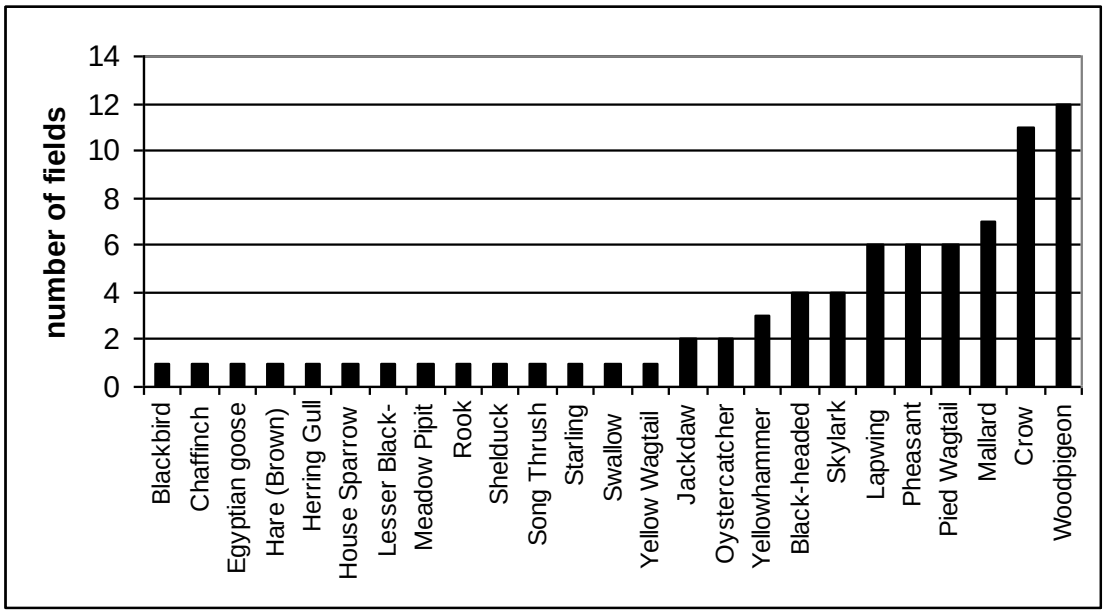
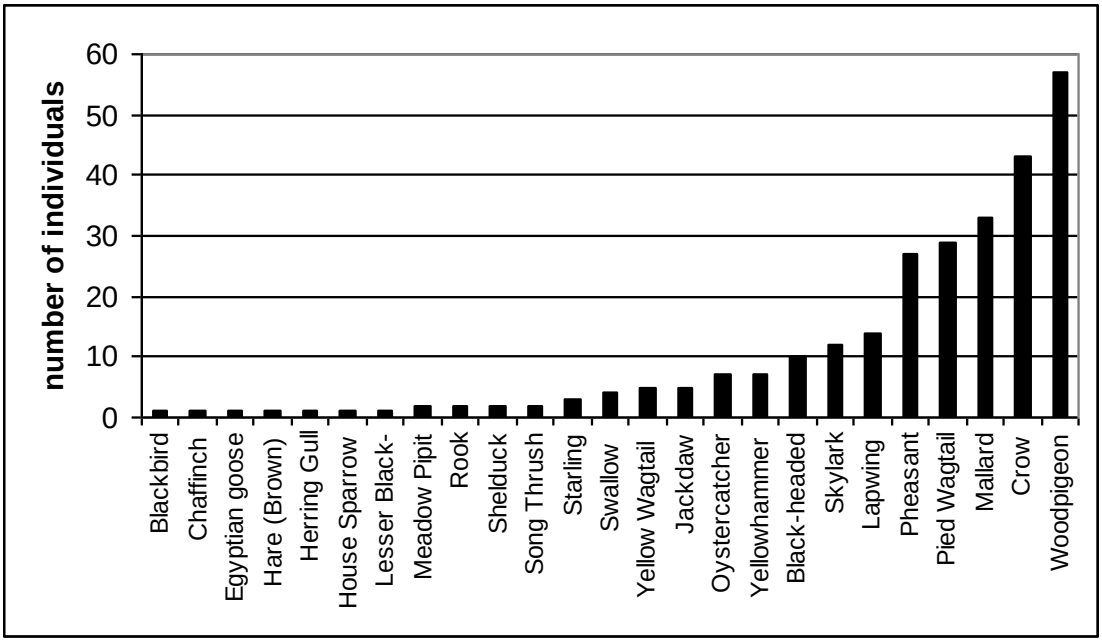


Figure B.9.1.1.2/02-2: Abundance – Number of individuals recorded across all fields on the main field



Granule counts and collections

The granule counts in quadrats across the main field and in the headlands are summarized in Table B.9.1.4.2-7 through Table B.9.1.4.2-9. The granule counts in individual quadrats across the main field ranged from 0-76 granules/0.25m^2 quadrat with a mean value at each site (N = 20 quadrats per site) ranging from 0-3.9 granules/0.25m^2 quadrat (mean all fields 0.4), 90th percentile counts ranging from 0-2.1 granules/0.25m^2 quadrat (all fields 1.0), and 95th percentile counts ranging from 0-4.8 granules/0.25m^2 quadrat (all fields 1.0). There was no apparent effect of soil type or application equipment on the granule counts on uncultivated headlands suggesting that the key in reducing granule counts is the timing of the cessation of granule flow at row ends.

Spills were identified on 17 of the 29 fields monitored (59%) and are summarized in Table B.9.1.4.2-10.

Table B.9.1.1.2/02-2: Granule count data for the main field (number of granules on the surface/0.25 m^2)

Field number	minimum count	maximum count	mean count	median count	90th percentile	95th percentile
43	0	5	0.4	0	1.0	1.2
44	0	0	0.0	0	0.0	0.0
45	0	2	0.4	0	1.1	2.0
46	0	0	0.0	0	0.0	0.0
47	0	0	0.0	0	0.0	0.0
48	0	1	0.1	0	0.0	0.1
49	0	1	0.1	0	0.0	0.1
50	0	76	3.9	0	0.1	4.8
51	0	0	0.0	0	0.0	0.0
52	0	1	0.1	0	0.0	0.1
53	0	1	0.1	0	0.0	0.1
54	0	2	0.2	0	0.1	1.1
55	0	4	0.4	0	1.0	1.2
56	0	2	0.5	0	2.0	2.0
57	0	3	0.4	0	1.1	2.1
58	0	1	0.2	0	1.0	1.0
59	0	4	0.5	0	1.1	2.1
60	0	1	0.2	0	1.0	1.0
61	0	10	0.5	0	0.0	0.5
62	0	5	0.7	0	2.1	3.1
all fields	0	0	0.44	0	0.0	0.0

Table B.9.1.1.2/02-3: Granule count data for cultivated headlands (number of granules on the surface/0.25 m^2)

Field number	minimum count	maximum count	mean count	median count	90th percentile	95th percentile
43	0	13	0.85	0	1	1.6
48	0	2	0.2	0	0.2	1.1
49	0	200	10.1	0	0.2	11.9
50	0	0	0	0	0	0
53	0	1	0.1	0	0.1	1.0
56	0	1	0.1	0	0.1	1
59 (1st)	0	19	1.7	0	3.1	4.75
59 (2nd)	0	7	0.6	0	1.2	3.2
61	0	1	0.05	0	0	0.1
all fields	0	200	1.6	0	1	2

Table B.9.1.1.2/02-4: Granule count data for uncultivated headlands (number of granules on the surface/0.25 m^2)

Field number	minimum count	maximum count	mean count	median count	90th percentile	95th percentile
44	0	0	0.0	0	0.0	0.0
45	0	23	2.0	0	3.2	5.9
46	0	21	1.1	0	0.1	2.0
47	0	23	1.2	0	0.1	2.1
51	0	0	0.0	0	0.0	0.0
52	0	0	0.0	0	0.0	0.0
54	0	0	0.0	0	0.0	0.0
55	0	40	2.1	0	0.2	3.9
60	0	2	0.5	0	1.0	1.1
62	0	245	18.8	0	33.8	85.4
all fields	0	245	2.6	0	1.0	3.1

Table B.9.1.1.2/02-5: Granule count data for spills (number of granules on the surface/0.25 m^2)

Field number	Number of spills	min size (cm^2)	max size (cm^2)	min count	max count
43	9	125	4200	15	500
44	10	150	2500	25	6000
45	9	100	70000	100	750
46	13	400	7500	50	1000
47	12	160	3000	50	2000
48	3	30	75	5	500
49	11	800	3500	200	500
50	11	120	1000	70	2500
51	11	300	160000	40	20000
52	10	100	200000	33	30000
53	11	10	90000	17	4000
54	5	250	1250	300	2000
55	9	625	10000	80	600
56	2	7500	10000	500	3000
57	12	200	640000	150	6000
58	4	1600	2400	300	500
59	13	100	80000	20	8000
60	1	625	625	300	300
62	9	400	5000	100	2000
all fields	9	125	4200	15	500

Dissipation of oxamyl from granules

The DT_{50} of oxamyl loss from granules at each site ranged from 4.1 to 115 hours during the two-day sampling period with DT_{90} values ranging from 4.5 to 382 hours. Rainfall timing and amount appeared to strongly influence the amount of oxamyl remaining in the granules over time. Based upon data from all 11 sites, cumulative rainfall of 0.435 mm was associated with 50% oxamyl loss and cumulative rainfall of 1.44 mm was associated with 90% loss of oxamyl from granules collected from the soil surface.

Table B.9.1.1.2/02-6: Granule count data for spills (number of granules on the surface/0.25 m^2): Kinetic analysis summary

Field	Number of data points	Best fit model[a]	Parameters optimsed[b]	DT_{50} (hours)	DT_{90} (hours)	χ^2 error (%)	r^2
2	5	DFOS	k_2, t_b	12.1	23.2	11.9	0.946
5	5	DFOS	k_2, t_b	25.2	64.4	11.7	0.908
8	5	DFOS	k_2, t_b	25.5	29.5	2.81	0.995
11	5	DFOS	k_2, t_b	6.29	8.74	4.11	0.998
12	5	DFOS	k_2, t_b	7.31	10.6	6.71	0.992
13	5	DFOS	k_1, k_2, t_b	28.8	38.1	7.01	0.980
14	5	SFO	k	115	382	5.29	0.732
15	5	SFO	k	4.42	14.7	27.9	0.835
19	4	DFOS	k_2, t_b	26.1	28.1	2.22	0.998
22	5	DFOS	k_2, t_b	4.11	4.53	0.383	1.000
23	5	DFOS	k_2, t_b	29.3	71.5	3.14	0.990

[a] SFO = single first-order. DFOS = double first-order in series, also known as the hockey stick model.

[b] In all cases M0 was fixed to 100% and not allowed to vary in the optimisation. In some cases the DFOS rate constants k1 was fixed to 0 based on preliminary optimisation runs.

Conclusion:

Twenty potato fields that used Oxamyl 10GR were monitored in The Netherlands in 2005. Nineteen fields were in-furrow applications and one was broadcast incorporated applications. Applications were made between mid-March and mid-April 2005 using a range of equipment. The application rate of the granules was 7-10 kg/ha (the broadcast incorporated application was at 20 kg/ha) except for one site where a 1.4 kg/ha rate was used; 68% of the monitored in-furrow applications were at 10 kg/ha. Only one application used a closed transfer system.

Surveys were carried out on all 20 fields during which 562 individual birds of 51 species were counted on the fields and in the field margins, a hare was also observed on the main field. The most prevalent, *i.e.* most recorded species, and the most abundant species on the main field, was the woodpigeon. The most prevalent and the most abundant species on the field margin was the yellowhammer.

Carcass searches performed on all sites 24-48 hours after application did not show any wildlife poisoning related to the use of Oxamyl 10GR.

Surface exposed granule counts were made on 20 sites in the main field and headlands (row ends, turning areas). The granule counts in individual quadrats across the main field ranged from 0-76 granules/0.25 m^2 quadrat with a mean value at each site (N = 20 quadrats per site) ranging from 0-3.9 granules/0.25 m^2 quadrat (mean all fields 0.4), 90th percentile counts ranging from 0-2.1 granules/0.25 m^2 quadrat (all fields 1.0), and 95th percentile counts ranging from 0-4.8 granules/0.25 m^2 quadrat (all fields 1.0).

The DT_{50} of oxamyl loss from granules at 11 sites ranged from 4.1 to 115 hours during the two-day sampling period with DT_{90} values ranging from 4.5 to 382 hours. Rainfall timing and amount appeared to strongly influence the amount of oxamyl remaining in the granules over time. Based upon data from all 11 sites, cumulative rainfall of 0.435 mm was associated with 50% oxamyl loss and cumulative rainfall of 1.44 mm was associated with 90% loss of oxamyl fom granules collected from the soil surface.

It can be concluded that there were no mortalities or sublethal effects on wild birds and mammals observed near and in potato fields during and after commercial applications of Oxamyl 10GR in The Netherlands.

RMS comments and conclusion

The study DuPont-15827, Revision No. 1, (2005), as well as its summry, was not submitted for the renewal process.

The study was originally submitted under EU Rev8 Point IIIA 10.1.7 and was summarized and evaluated by the RMS Ireland in the Addendum to Annex B (Ecotoxicology) to the Draft Report and Proposed Decision (May 2010), which was subjected to EU peer review. Since the results of this study (both toxic effects and number of granules on the surface) have been used by the Applicant for the risk assessment, RMS Italy has reported the summary as present in the above cited Addendum (2010). Guidelines were not applicable because there are no guidelines for a granule application monitoring study

No acute effects on birds or mammals were recorded within 48h after in-furrow applications of 1.0 kg a.s./ha oxamyl 10GR to potatoes in the NL. The RMS notes that the short observation time would have overlook possible effects occurring later in time.

The RMS cannot find information about the depth of in-furrow application to potato fields. The in-furrow depth application proposed in the renewal submission is 10 cm for potato and 5 cm for tobacco. The study should be submitted.

B.9.1.2 Effects on terrestrial vertebrates other than birds

B.9.1.2.1 Acute oral toxicity to mammals

The acute oral toxicity study with the preparation is summarised in the Oxamyl EU Renewal Dossier, Document M–CP, Section 7, DuPont-40932 EU.

B.9.1.2.2 Higher tier data on mammals

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.

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

Assessments of acute and long-term exposure to oxamyl *via* Oxamyl 10GR in birds and mammals indicated low risk to terrestrial vertebrates. 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

Avian Risk Assessment

Avian toxicity endpoints

A summary of the toxicity endpoints of oxamyl and Oxamyl 10GR to birds is provided in Table 6. Metabolites were not tested with birds, because mammal toxicity data documented low toxicity to terrestrial vertebrates. Details of avian studies with the active substance are provided in Vol 3 B.9 Details of metabolite tests with

mammals are provided in the Oxamyl EU Renewal Dossier, Document M-CA, Section 5, DuPont-40932. EU Endpoints selected for use in the risk assessment are summarised in Table 7.

Table 6 Summary of avian toxicity endpoints for oxamyl and Oxamyl 10GR

Toxicity study (species)	Test substance	LD_{50} or LC_{50} (mg oxamyl/kg bw/day)	Lowest lethal dose (mg oxamyl/kg bw/day)	NOEL or NOEC (mg oxamyl/kg bw/day)	Reference[a]
Acute oral (mallard)	oxamyl	3.16	3.16 mg a.s./kg bw	1.0 mg a.s./kg bw	HLO 89-81
Acute oral (northern bobwhite)	oxamyl	9.5	2.2 mg a.s./kg bw	0.8 mg a.s./kg bw	DuPont-2954
Acute oral (northern bobwhite)	Oxamyl 10GR	12.5	2.0 mg a.s./kg bw	1.0 mg a.s./kg bw	DuPont-2955
Short-term dietary (mallard)	oxamyl	766 mg a.s./kg feed 96.6 mg/kg bw/day	313 mg/a.s/kg feed	<78 mg a.s./kg feed	HLO 48-88
Short-term dietary (northern bobwhite)	oxamyl	340 mg a.s./kg feed 85 mg/kg bw/day	313 mg/a.s/kg feed	39 mg a.s./kg feed	HLO 47-88
Subchronic and reproductive (mallard)	oxamyl	Not applicable	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 applicable	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 are reviewed and summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

Table 7 Avian toxicity endpoints used in risk assessment for oxamyl

Study	Test species	End-points used in risk assessment
Acute toxicity – oxamyl a.s.	Mallard	LD_{50} = 3.16 mg a.s./kg bw/d
	Northern Bobwhite	LD_{50} = 9.5 mg a.s./kg bw/d
	Geomean	LD_{50} = 5.86 mg a.s./kg bw/d
Acute toxicity – Oxamyl 10GR	Northern Bobwhite	LD_{50} = 12.5 mg a.s./kg bw/d
Dietary toxicity (short-term)	Northern Bobwhite	LDD_{50} = 85 mg a.s./kg bw/d
Reproductive toxicity (long-term)	Mallard	$LD_{50}/10$[a] = 0.316 mg a.s./kg bw/d NOEL = 1.5 mg a.s./kg bw/d

[a] According to EFSA guidance, the reproductive toxicity (long-term) evaluation should be based on the $1/10^{th}$ the LD_{50} instead of the chronic NOEL when the NOEL exceeds $1/10^{th}$ of the LD_{50}. The ratio of NOEL to $LD_{50}/10$ is 4.7, hence the LD50/10= 0.316 mg a.s./kg bw/d should be used.

Oxamyl metabolites

Metabolite formation in water, soil, sediment, and rotational crops is summarized in Table 2.

The major metabolic pathways in plants and animals were similar. Oxamyl was rapidly absorbed, extensively metabolised, and excreted in livestock. The major metabolites found in both lactating goats and laying hens were similar. The metabolism of oxamyl proceeded rapidly in livestock animals with the formation of IN−A2213 by

hydrolysis of the carbamate moiety. IN-A2213 (or oxamyl) was converted to IN-N0079, which was then degraded to cyanide. Cyanide was rapidly detoxified by the conversion to thiocyanate.

The soil and water metabolites IN-A2213, IN-D2708, IN-N0079 are major metabolites (>10%) in rodents, livestock (hens, goats), and rotational crops (barley grain, forage, hay, or straw) as summarized in the Oxamyl EU Renewal Dossier, Document M-CA, Section 6, DuPont-40933 EU. It can be assumed that birds have potential dietary exposure to major metabolites. However, these metabolites are not of toxicological concern, because they were found in the mammal and hen metabolism studies at significant levels and have low toxicity to mammals (see the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40932 EU). There is no requirement for a metabolite risk assessment for birds.

Exposure

Application conditions

For field application, Oxamyl 10GR is labelled for single uses on potatoes at-planting at a maximum of 1.0 kg oxamyl/ha in-furrow at-planting or on tobacco at at a maximum of 3.0 kg oxamyl/ha in-furrow at–planting or a maximum of 5.5 kg oxamyl/ha broadcast pre-planting. Good Agricultural Practices are summarised in Table 3.

Exposure scenario

The product will be used outdoors as an in-furrow or as a broadcast application followed by soil incorporation. It is possible that birds may be exposed to granules in different ways: as a source of food, when they eat food contaminated with soil, or when they eat food contaminated with residues resulting from granular applications.

Granule Characterization

The granule properties are summarized in Table 8.

Table 8 Properties of Oxamyl 10GR granules

Granule matrix	Attapulgite clay
Average weight of granule (mg)	0.264
Amount of a.s. in average granule (mg)	0.0264
Size of granules (mm)	97.3% from 0.25–0.85 mm 2.7% <0.25 mm
Shape of granules	Angular, irregular
Color of granules Hue Chroma Value	 Blue-green (Munsell 2.5 BG) Munsell 2 to 4 Mulsell 7 to 8
Odor	Slightly sulphurous
Number of granules/m^2 in 10 to 15 cm soil depth after single application of 55 kg Oxamyl 10GR	20833/m^2

The carrier for Oxamyl 10GR is attapulgite clay. It has no nutritional value and therefore is unlikely to be actively selected as a food source by birds.

Granule size distribution for large and small bird risk assessment

For granule risk assessments according to EFSA (2009), the size range of grit particles (or granules) taken by large birds is >2.0–6.0 mm and by small birds is 0.75–2.0 mm. These size ranges were determined in a published study in which the sizes of the grit particles, granules, or seeds obtained from birds were measured from photographs, rather than measured with sieves.

Bulk density and dry sieve tests were conducted on Oxamyl 10GR in accordance with the guidance provided in the European Union data requirements specified in EU Commission Directive 94/37/EC, Annex II, Section 2.

CIPAC methods were used to measure physical properties. It was not possible to find commercially available 0.75 mm sieves, thus a new study characterized granule size distribution using commercially available sieves of 0.25, 0.71, 0.85, 1.0, 2.0, and 4.0 mm mesh (Robson, 2014; DuPont-39675, summarized in the Oxamyl EU Renewal Dossier, Document M-CA, Section 2, DuPont-40947 EU). The results are summarized in Table 9.

Table 9 Percentage of Oxamyl 10GR granules in sieves

Sieve mesh (mm)	Percentage (%) remaining
0.25	12.4
0.71	12.7
0.85	73.4
1.0	0
2.0	0
4.0	0

As expected by the granule manufacturing specifications, Oxamyl 10GR granules were not retained on 1.0, 2.0, or 4.0 mm sieves. Granules were retained on 0.85, 0.71, and 0.25 mm sieves. A conversion factor was developed to interpolate the estimated percentage of granules that would be retained on a 0.75 mm sieve. This value (69.4% of granules) was selected to represent the size range of granules taken by small birds (0.75–2.0 mm) for use in the bird risk assessment.

Field monitoring of granule applications

Field monitoring studies were conducted to determine the number of granules remaining on the soil surface after broadcast-soil incorporated applications of Oxamyl 10GR to potato fields in the UK in 2005 (Thompson, 2005; DuPont-15823) and after in-furrow applications to potatoes in the Netherlands (Thompson, 2005; DuPont−15827, Revison No. 1). The studies were summarized in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

$G_{surface}$ after broadcast-soil incorporated applications

The numbers of granules on the surface ($G_{surface}$) per 0.25 m^2 were counted in 29 fields after broadcast/incorporation applications of 37 to 55 kg Oxamyl 10GR/ha. Granule counts were normalized to be equivalent to a 55 kg/ha application rate (Table 1). The mean and 90^{th} percentile values for $G_{surface}$ after applications normalized to 55 kg Oxamyl 10GR/ha were 7.2 and 16.4 granules/0.25 m^2. These values were multiplied by 4 to provide an estimate of number of granules/m^2 (28.8 and 65.6 granules/m^2). This refinement will be used in the risk assessment for applications of 1 × 55 kg Oxamyl 10GR/ha in tobacco.

Table 10 Summary of granule count data (number of granules/0.25 m^2) after broadcast-soil incorporation applications of Oxamyl 10GR on the main field, normalized to 55 kg product/ha

Site number	Field name	Application equipment	Appl'n rate (kg/ha)	Normalized mean count	Normalized median count	Normalized 90th percentile	Normalized 95th percentile
1	Field Bottom	Bedformer	55	5.9	6.0	11.3	14.4
2	Flax Field	Ridger	55	0.1	0.0	0.1	1.0
3	Big Glebe	Other	55	2.3	1.0	5.2	7.3
4	Front House	Rotovator/power harrow	40	1.6	0.0	2.9	4.9
5	LF2	Other	55	3.5	2.0	8.2	10.2
6	New Piece	Separate tool	50	7.3	6.1	15.5	16.6
7	Ash Cote	Rotovator/power harrow	40	1.2	0.0	3.0	5.5
13	Back of Garden	Separate tool	52	5.0	3.7	10.7	11.6
14	America Heath	Destoner	45	0.5	0.0	1.2	1.3
15	Rushing Meadow	Bedformer	53	1.9	1.0	2.2	4.0
17	Oaktree Meadow	Bedformer	55	1.5	1.0	3.1	4.1
18	PB11	Rotovator/power harrow	55	5.5	4.5	12.2	14.0
19	Stack Yard	Rotovator/power harrow	55	9.5	8.5	18.1	19.1
20	Field 2	Other	40	1.5	0.0	4.4	6.9
21	P01	Rotovator/power harrow	55	5.1	4.5	10.4	14.2
22	Wainfleet (E)	Rotovator/power harrow	55	4.8	4.0	9.0	9.3
23	R28	Rotovator/power harrow	55	1.5	1.0	3.1	4.0
24	May Farm	Bedformer	55	1.3	1.0	3.0	3.1

Table 10 Summary of granule count data (number of granules/0.25 m2) after broadcast-soil incorporation applications of Oxamyl 10GR on the main field, normalized to 55 kg product/ha (continued)

Site number	Field name	Application equipment	Appl'n rate (kg/ha)	Normalized mean count	Normalized median count	Normalized 90th percentile	Normalized 95th percentile
25	Bungalow	Ridger	55	0.2	0.0	1.0	1.1
27	Laith Close	Rotovator/power harrow	55	11.4	9.0	22.3	25.5
28	LE6	Bedformer	55	11.6	10.0	21.0	21.2
30	Hearts 24	Separate tool	37	7.5	6.7	14.9	14.9
31	Union	Rotovator/power harrow	54	18.5	12.2	38.7	38.9
33	Underwoods Farm	Other	55	14.8	14.0	23.2	25.5
34	Scots	Other	45	1.0	0.0	3.7	3.7
35	Chestnut 27	Other	45	4.0	2.4	7.3	8.1
36	303	Rotovator/power harrow	55	71.5	65.0	98.8	107.7
39	Crossgrains 8	Rotovator/power harrow	55	6.4	6.0	10.2	12.1
41	Keepers Field	Other	40	2.2	1.4	5.5	5.5
-	ALL FIELDS	-		7.2	2.6	16.4	25.1

$G_{surface}$ after in-furrow applications

The numbers of granules on the surface ($G_{surface}$) per 0.25 m^2were counted in 19 fields after in-furrow applications of 1.4 to 10 kg Oxamyl 10GR/ha. Granule counts were normalized to be equivalent to 10 kg/ha application rates (Table 1 through Table). The mean and 90th percentile values for $G_{surface}$ after applications of 10 kg Oxamyl 10GR/ha were 0.4 and 1.0 granules/0.25 m^2. These values were multiplied by 4 to provide an estimate of number of granules/m^2. This is equivalent to mean and 90th percentile values of 1.6 and 4.0 granules/m^2 for $G_{surface}$ after applications of 10 kg Oxamyl 10GR/ha in potatoes and 6.4 and 12.0 granules/m^2 for $G_{surface}$ after applications of 30 kg Oxamyl 10GR/ha in tobacco. These refinements will be used in the risk assessments for applications of 1 × 10 kg Oxamyl 10GR/ha in potatoes and of 1 × 30 kg Oxamyl 10GR/ha in tobacco.

Table 11 Summary of granule count data (number of granules/0.25 m^2) after in-furrow applications of Oxamyl 10GR on the main field, normalized to 10 kg product/ha

Site number	Field name	Application equipment	Appl'n rate (kg/ha)	Normalized mean count	Normalized 90th percentile	Normalized 95th percentile
43	Achter 't huis	Separate tool	10	0.4	1.0	1.2
44	Ter apel 2	On planter	10	0.0	0.0	0.0
45	Naast t kerkhof	On planter	7	0.6	1.57	2.86
46	Bakker	On planter	10	0.0	0.0	0.0
47	Huisplaats	On planter	10	0.0	0.0	0.0
48	Viaduct ERM	On planter	10	0.1	0.0	0.1
49	Mengwoel	On planter	10	0.1	0.0	0.1
50	Dikbos 5	On planter	10	3.9	0.1	4.8
51	Holtslang	On planter	10	0.0	0.0	0.0
52	7	On planter	10	0.1	0.0	0.1
53	Bonnen	On planter	1.4	0.07	0.0	0.07
54	Klein Dijk 1	On planter	10	0.2	0.1	1.1
55	Dommers Kanaal	On planter	10	0.4	1.0	1.2
56	Bij de boorlocatie	On planter	8	0.6	2.5	2.5
57	Smilde	On planter	8	0.5	1.375	2.49
58	Beneden Noord	On planter	8	0.3	1.375	1.25
59	Long narrow	On planter	10	0.5	1.1	2.1
60	Achtert Spoor	On planter	8	0.3	1.25	1.25
62	Menweg 4	On planter	10	0.7	2.1	3.1
-	ALL FIELDS	-		0.4	1	1

Risk Assessment Scenarios

1-Animals ingesting granules as source of food

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

2-Birds ingesting granules with/as grit

Acute risk to birds taking granules as grit

Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. They do not resemble grit, but may be ingested accidentally by birds with grit because of overlap in particle sizes. According to EFSA (2009), small birds take grit that is 0.75–2.0 mm in size and large birds take grit that is >2 mm in size. Less than 70% of Oxamyl 10GR granules (69.4%) fall in size range of granules taken by small birds.

The values provided in the EFSA GD (taken from EPPO 2003) for the daily grit ingestion (DGritI) of 651 (small grit/small birds, 90th %-ile) derive from six granivorous species and is relative to a typical small bird (e.g. finch), whose body weight is assumed to be 25 g.

Realistic granule counts after broadcast-soil incorporated applications to potatoes revealed application-rate normalized number of granules/m^2 on the soil surface (mean and 90th percentile values) were 28.8 and 65.6 respectively (for 55 kg Oxamyl 10GR/ha).

The granule count studies were conducted in 2005 and reflect worst-case agricultural practices with older, less regulated application technology. Modern application equipment is more precise and ensures full coverage of granules by soil, thus precluding exposures.

The 90th percentile acute daily grit dose (DGritD) for small birds consuming small granules is:

$$DGritD_{acute} = 651 \times (G_{density} / (15200 + G_{density})) \times G_{loading}$$

For in-furrow applications to potatoes, the worst-case TER_a exceed the trigger of 10, indicating safe uses to small birds that may take granules as or with grit (Table 12). For in-furrow and broadcast application to tobacco, the worst-case TER_a is below the trigger of 10, indicating a need for refinement.

Table 12 Tier 1 bird TERa values after ingestion of granules as or with grit (revised by the RMS)

Parameter	Endpoint		
Indicator bird (small birds) bw [kg]	0.025		
Daily grit intake (DGI) [number of grit particles/bird/d]	651		
Grit loading ($G_{loading}$) [mg a.s./granule]	0.0264		
% small granules (0.75 – 2.0 mm)	69.4		
Exposure Scenario	**Potato**	**Tobacco in–furrow**	**Tobacco broadcast**
Application rate (kg a.s./ha)	1.0	3.0	5.5
Soil surface granule density ($G_{density}$) [granules/m^2]	4	12	65.6
Soil surface small granule density ($G_{density}$) [granules/m^2] (69.4% of granules)	2.77	8.32	45.52
Daily grit dose ($DGritD_{acute}$)= 651 × ($G_{density}$/ (15200 + $G_{density}$)) × 0.0264	0.0031	0.0094	0.0513
Acute risk			
Toxicity endpoint (mg a.s./kg bw)	3.16		
Toxicity endpoint (mg a.s./small bird)	0.079		
TER_a (= small bird LD_{50}/ $DGritD_{acute}$)	25.5	8.4	1.5
Trigger	10	10	10

A refinement may be made to the toxicity endpoint used in the acute risk assessment accidental ingestion of granules by birds. The acute toxicity of the formulated product to birds is lower than that of the active substance (Table 13).

The acute LD_{50} value of Oxamyl 10GR is 12.5 mg a.s./kg bw/d. For a typical small bird of 25 g bird, it is 0.31mg a.s./small bird.

Table 13 Refined bird TERa values after ingestion of granules as or with grit (tobacco) (revised by the RMS)

Parameter	Endpoint	
Exposure scenario	Tobacco in-furrow	Tobacco broadcast
Toxicity endpoint (mg a.s./kg bw)	12.5	
Toxicity endpoint (mg a.s./small bird)	0.31	
Daily grit dose ($DGritD_{acute}$) = 651 × ($G_{density}$/ (15200 + $G_{density}$) × 0.0264	0.0094	0.0513
TER_a (= small bird LD_{50}/ $DGritD_{acute}$)	33.0	6.0
Trigger	10	10

Based on the endpoint of the formulation the tobacco broadcast TER_a is below the relevant trigger. The Notifier calculated that to pass the acute grit intake risk assessment for the 5.5 kg a.s./ha broadcast-soil incorporation application, a maximum of 7 granules/m^2 (based on LD converted to sparrow weighing 27.7 g as indicator bird and not on the typical small bird of 25g considered in EPPO2013) could remain on the surface as shown in the calculations below. The proposed refinement is reported integrally below:

« $DGritD_{acute} = 651 \times (7/ (15200 + 7)) \times 0.0264$
$DGritD_{acute} = 0.0079$ grit/ m^2

$TER = 0.0875/ 0.0079$
$= 11.6$

The label provides clear stewardship guidelines for mitigating and documenting risk to wildlife and birds. Users are required to cover all granules with soil so they are completely buried and to remove spills. A higher tier field study was conducted to monitor birds in potato fields after broadcast application of 5.5 kg a.s./ha. The study was summarized in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU. Results showed that there were no mortalities or sublethal effects on wild birds and mammals observed near and in commercial fields during and after broadcast application of 5.5 kg a.s./ha, supporting a conclusion of safe use at this worst-case application rate".

RMS comment:

For tobacco in-furrow application at 5cm depth, it is acceptable that the granules density is extrapoled by the density measured in potato fields where granules were applied at 10 cm depth, because the number of granules at the soil surface depends on the application equipment and not on the depth of application.

The Tier 1 acute risk presented above has been revised by the RMS to consider a small bird of 25 g (according to EPPO 2013).

The risk assessment for ingestion of granules as or with grit is based on the number of granules in the main field. Anyhow, the granule density at the row ends is higher. The Applicant should address the risk also at the row ends.

Based on the recalculation by the RMS using the LD50 = 0.079 mg a.s./small bird, a maximum of 7 granules/m2 could remain on the surface in order to obtain an acceptable risk (TER=5.3), as indicated hereunder:

$DGritD_{acute} = 651 \times (7/ (15200 + 7)) \times 0.0264$
$DGritD_{acute}$ = 0.0079 mg a.s./ small bird
TER = 0.079/ 0.0079 =10

The field monitoring study (Thompson, H.M., 2005 –DuPont-15823) mentioned in the acute risk refinement for the scenario "tobacco broadcast" was conducted in UK and evaluated incorporated broadcast granular applications of Oxamyl 10GR at rates between 37-55 kg product/ha (3.7-5.5 kg a.s./ha) in potato fields. This is the same study used to derive exposure data (number of granules remaining on the soil surface). The study was evaluated under the previous EU peer reviewed, but since it was not submitted in the renewal dossier, no detailed re-evaluation was possible here. In order to confirm the conclusion of no acute adverse effects on birds, the Notifier should submit the study. Further, as commented at the end of the robust summary, the observation time for lethal and sublethal effects up to 48 h might have been not sufficient to conclude on adverse effects.

The label should include mitigation phrases such:

SPe5: To proteced birds and wild mammals the product must be entirely incorporated in soil; ensure that the product is also fully incorporated at the end of rows; Spe6: To proteced birds and wild mammals remove spillages. Anyhow, it is debatable if the mitigation phrases would be practically sufficient, considering that acute risk would arise if more than 10 granules/m^2 remain on the surface.

In conclusion, for the tobacco broadcast 5.5 kg a.s./ha, the acute risk to birds taking granules as grit remain to be addressed.

Chronic risk to birds taking granules as grit

According to EFSA (2009), small birds take grit that is 0.75–2.0 mm in size and large birds take grit that is >2 mm in size. Less than 70% of Oxamyl 10GR granules (69.4%) fall in size range of granules taken by small birds.

The values provided in the EFSA GD (taken from EPPO 2003) for the daily grit ingestion (DGritI) of 386 (small grit/small birds, geometric mean) derive from six granivorous species and is relative to a typical small bird (e.g. finch), whose body weight is assumed to be 25 g.

Realistic granule counts after broadcast-soil incorporated applications to potatoes revealed application-rate normalized number of granules/m^2 on the soil surface (mean and 90th percentile values) were 28.8 and 65.6 respectively (for 55 kg Oxamyl 10GR/ha).

The granule count studies were conducted in 2005 and reflect worst-case agricultural practices with older, less regulated application technology. Modern application equipment is more precise and ensures full coverage of granules by soil, thus precluding exposures.

The 90th percentile acute daily grit dose (DGritD) for small birds consuming small granules is:

$$DGritD_{repro} = 386 \times (G_{density}/ (15200 + G_{density})) \times G_{loading}$$

The chronic NOEL has been recalculated by the RMS as LD50/10 = 0.316 mg a.s./kg bw, equivalent to 0.0079 mg a.s./small bird (based on a small bird of 25 g , according to EPPO 2013). The TER_{lt} are calculated as follows:

Table 14 Tier 1 bird TER_{lt} values after ingestion of granules as or with grit (revised by the RMS)

Parameter	**Endpoint**		
Indicator bird (small bird) bw [kg]	0.025		
Daily grit intake (DGI) [number of grit particles/bird/d]	386		
Grit loading ($G_{loading}$) [mg a.s./granule]	$0.0264 \times 0.53 = 0.0140$		
% small granules (0.75–2.0 mm)	69.4		
Exposure Scenario	**Potato**	**Tobacco in-furrow**	**Tobacco broadcast**
Application rate (kg a.s./ha)	1.0	3.0	5.5
Soil surface granule density ($G_{density}$) [granules/m^2]	4	12	65.6
Soil surface small granule density ($G_{density}$) [granules/m^2] (69.4% of granules)	2.76	8.32	45.52
Daily grit dose ($DGritD_{acute}$) $= 386 \times (G_{density}/ (15200 + G_{density}) \times 0.0140$	0.001	0.003	0.0161
Long-term risk			
Toxicity endpoint (mg a.s./kg bw)	0.316		
Toxicity endpoint (mg a.s./small bird)	$0.316 \times 0.025 = 0.0079$		
TER_{lt} (= small bird $LD_{50}/DGritD_{acute}$)	7.9	2.6	0.5
Regulation (EC) 546/2011 Trigger	5	5	5

For in-furrow applications to potatoes, the worst-case TERlt exceed the trigger of 5, indicating safe use to small birds that may take granules as grit after in-furrow applications to potatoes (Table 14). For the other scenarios (in-furrow and broadcast application to tobacco), the worst-case TERlt is below the trigger of 10, indicating a need for refinement.

Since the Applicant had erroneously used the NOEL =1.5 mg a.s./kg bw instead of the LD50/10 = 0.316 mg a.s./kg bw, which provides the lowest value, the need for a refinement arose only for the broadcast-soil incorporation application. The proposal of the Applicant is reported integrally below:

"*To pass the reproduction grit intake risk assessment for the 5.5 kg a.s./ha broadcast-soil incorporation application, a maximum of 23 granules/m^2 could remain on the surface, as shown in the calculation below.*

DGritD = 389 × (23/ (15200 + 23)) × 0.0139
DGritD = 0.0081 grit/ m^2

TER = 0.04/ 0.0081
= 5.1

The label provides clear stewardship guidelines for mitigating and documenting risk to wildlife and birds. Users are required to cover all granules with soil so they are completely buried and to remove spills. A higher tier field study was conducted to monitor birds in potato fields after broadcast application of 5.5 kg a.s./ha. The study was summarized in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU. Results showed that there were no mortalities or sublethal effects on wild birds and mammals observed near and in commercial fields during and after broadcast application of 5.5 kg a.s./ha, supporting a conclusion of safe use at this worst-case application rate. **“**

RMS comment:

For tobacco in-furrow application at 5cm depth, it is acceptable that the granules density is extrapoled by the density measured in potato fields where granules were applied at 10 cm depth, because the number of granules at the soil surface depends on the application equipment and not on the depth of application.

The Tier 1 chronic risk presented above has been revised by the RMS to consider a small bird of 25 g (according to EPPO 2013) and the toxicity endpoint as LD50/10 = 0.316 mg a.s./kg bw.

The risk assessment for ingestion of granules as or with grit is based on the number of granules in the main field. Anyhow, the granule density at the row ends is higher. The Applicant should address the risk also at the row ends.

The chronic risk refinement proposed by the Notifier for the broadcast-soil incorporation application is based on wrong inputs. The recalculation by the RMS indicate that a maximum of 4.3 granules/m2 could remain on the surface in order to obtain an acceptable risk (TER=5.3), as indicated hereunder:

DGritD = 386 * (4.3/ (15200 + 4.3)) * 0.014
DGritD = 0.0015 mg a.s./ small bird max 0.00158
TER= NOEC/ DGritD = 0.0079 / 0.00153 = 5.2

The field monitoring study (Thompson, H.M., 2005 –DuPont-15823) mentioned in the acute risk refinement for the scenario “tobacco broadcast” was conducted in UK and evaluated incorporated broadcast granular applications of Oxamyl 10GR at rates between 37-55 kg product/ha (3.7-5.5 kg a.s./ha) in potato fields. This is the same study used to derive exposure data (number of granules remaining on the soil surface). The study was evaluated under the previous EU peer reviewed, but since it was not submitted in the renewal dossier, no detailed re-evaluation was possible here. In order to confirm the conclusion of no acute adverse effects on birds, the Notifier should submit the study. Further, as commented at the end of the robust summary, the observation time for lethal and sublethal effects up to 48 h might have been not sufficient to conclude on adverse effects in general and definitively not for the chronic ones.

The label should include mitigation phrases such:SPe5: To protect birds and wild mammals the product must be entirely incorporated in soil; ensure that the product is also fully incorporated at the end of rows; Spe6: To protect birds and wild mammals remove spillages. Anyhow, it is debatable if the mitigation phrases would be practically sufficient, considering that chronic risk would arise if more than 4.3 granules/m^2 remain on the surface.

In conclusion, for use in tobacco in furrow 3 kg a.s./ha and tobacco broadcast 5.5 kg a.s./ha, **the chronic risk to birds taking granules as grit remain to be addressed.3-Birds ingesting granules when seeking seeds as food**

Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. They do not resemble seeds and would not be ingested by birds as a source of food. No risk assessment is required.

4-Animals ingesting granules when eating soil-contaminated food

Acute risk assessment

The acute daily dry soil dose for small omnivorous birds is 0.283 × application rate (in kg a.s./ha). TER_a value for application in potatoes is above the trigger of 10, indicating safe use (Table 15). The TER_a values for uses in tobacco are below the trigger of 10, indicating a need for refinement.

Table 15 Tier 1 bird TER_a values after accidental ingestion of granules with soil

Exposure scenario	Potato	Tobacco in-furrow	Tobacco broadcast
Application rate (kg a.s./ha)	1.0	3.0	5.5
– Shortcut	0.283		
Exposure Daily dry soil dose - acute (mg a.s./kg bw/d)	0.283	0.849	1.55
Toxicity endpoint (mg a.s./kg bw)	3.16		
TER_a	11.1	3.7	2.0
Trigger	10	10	10

A refinement may be made to the toxicity endpoint used in the acute risk assessment for accidental ingestion of granules by birds. The acute toxicity of the formulated product to birds is lower than that of the active substance (Table). The refined TER_a value for in-furrow use in tobacco is above the trigger of 10, indicating safe use (Table 16). The TER_a value for broadcast use in tobacco is below the trigger of 10, indicating a need for refinement (Table). A higher tier field study documented safe use after broadcast application of 5.5 kg a.s./ha, supporting a conclusion of safe use at the highest application rate.

Table 16 Refined bird TER_a values after accidental ingestion of granules with soil

Exposure scenario	Tobacco in-furrow	Tobacco broadcast
Application rate (kg a.s./ha)	3.0	5.5
– Shortcut	0.283	
Exposure Daily dry soil dose - acute (mg a.s./kg bw/d)	0.849	1.55
Toxicity endpoint – Oxamyl 10GR (mg a.s./kg bw)	12.5	
TER_a	14.7	8.0
Trigger	10	10

RMS: The short cut = 0.283 used by the Applicant assumes that the compound is equally mixed in a layer of 1 cm soil. For an incorporation of 10 cm as proposed, the shortcut is 0.028 (EFSA guidance, 5.1.6, table 17). Hence for broadcast application it is concluded a safe use at Tier 1.

Chronic risk assessment

The chronic daily dry soil dose for small omnivorous birds is 0.025 × application rate (in kg a.s./ha).

Table 17 Tier 1 bird TER_{lt} values after accidental ingestion of granules with soil (revised by the RMS)

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

RMS: the Applicant used the NOEC=1.5 mg a.s./kg bw/d instead of NOEC = 0.316 mg a.s./kg bw/d (corresponding to the LD50/10) and a shortcut of 0.025. The RMS has recalculated the TER using the correct lower NOEC value and a default twa of 0.53. The short cut = 0.025 x twa assumes that the compound is equally mixed in a layer of 5 cm soil. For an incorporation of 10 cm as proposed, the shortcut is 0.012 x twa (EFSA guidance, 5.1.6, table 17). This was used by the RMS for the tobacco broadcast application. It is concluded a safe use at Tier 1.

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

Herbivorous risk assessment/Residues in seedlings

Acute risk assessment

Pre-cropping weed control with herbicides is a best agricultural practice in commercial potato and tobacco fields to reduce competition between crops and emergent weeds during germination and growth. In addition, the DT50sol of oxamyl is 5.3 days, thus, an exposure of herbivorous birds to oxamyl by emergent weeds is not expected. Potatoes and tobacco are considered to be unpalatable to birds. Thus, the scenario of acute exposure to herbivorous birds immediately after application is considered to be not relevant to the risk assessment.

Chronic risk assessment

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

Residues in worms

Oxamyl 10GR granules could be accidentally ingested if birds consumed soil-contaminated food. Worm-eating birds might be exposed to oxamyl residues if the birds feed on worms occurring in treated fields. Worst-case exposure estimates were determined from a field study that was conducted to quantify residues of oxamyl in worms after an in-furrow application of Oxamyl 10SL at planting of potatoes (Schwarz and Eichler, DuPont-40221, summarized in M-CA, Section 6, Residues Chemistry, DuPont-40933). The study provides the only oxamyl field residue data in worms. It is thought to be relevant to the Oxamyl 10GR exposure scenario in potatoes because Oxamyl 10SL spray was applied to soil in-furrow at the depth of 10–15 cm during potato planting. The application was 20 kg Oxamyl 10GR/ha.

Non-normalized results are summarized in Table 18. Overall residues were very low or not detectable. Oxamyl may have been taken up by worms and later on metabolized. The highest residue (1.544 mg/kg worms) was in the sample taken on Day 0, immediately after application. In order to calculate mean and 90th percentile RUDs, the LOD was replaced by ½ LOD (0.0013 mg/kg) and the LOQ was replaced by ½ LOQ–LOD (0.0037 mg/kg). The non-normalized mean and 90th percentile residues were 0.072 and 0.021 mg a.s./kg worms. After normalization to 1 kg a.s./ha to establish "RUD" values, the mean and 90th percentile residues per unit dose are 0.011 and 0.036 mg a.s./kg worms.

Table 18 Concentration of oxamyl in worms after a 2 kg a.s./ha in-furrow application of oxamyl in potatoes

	Worm residue concentration (mg a.s./kg)		
Day after application	**Plot 1**	**Plot 2**	**Plot 3**
0	<LOQ	0.011	1.544[a]
1	<LOD	<LOQ	0.013
3	<LOQ	0.047	0.019
6	0.021	<LOQ	0.021
9	<LOD	<LOQ	<LOQ
13	0.014	<LOD	<LOD
16	<LOD	<LOD	<LOD
20	<LOD	<LOD	<LOD

LOQ = Limit of Quantification = 0.01 mg oxamyl/kg

LOD = Limit of Detection = 0.0026 mg oxamyl/kg

[a] Residue was confirmed with triplicate analysis

Vermivore risk assessment

Acute risk assessment

The worst case exposure value is 1.544 mg/kg worms after a 2 kg a.s./ha application, which is equivalent to an RUD of 0.772 mg a.s./kg worm after 1 kg a.s./ha application. The Tier 1 acute risk to a small bird (lark) from feeding on earthworms results in TER_a values that are below 10, indicating a need for refinement (Table 19).

Table 19 Tier 1 worst-case bird TER_a for exposure to residues in earthworms (revised by the RMS)

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

The refined Tier 1 assessment considers 90th percentile measured RUD values for the acute exposure assessment (0.036 mg a.s./kg bw). The refined Tier 1 acute risk to a small bird (lark) from feeding on earthworms results in TER_a values that are below 10, indicating a need for refinement (Table 20).

Table 20 Refined Tier 1 bird TER_a for exposure to residues in earthworms (see below the table revised by the RMS)

Parameter	Potatoes (1 × 1000 kg a.s./ha)	Tobacco (1 × 3000 kg a.s./ha)	Tobacco (1 × 5500 kg a.s./ha)
Maximum PEC_{worm} (mg a.s./kg)	0.036	0.108	0.198
Small bird FIR/bw (28.5 g lark; 100% insects)	0.68		
Daily Dietary Dose (mg a.s./bird)	0.0244	0.0734	0.13
LD_{50} for birds (mg a.s./kg bw/d)	3.16		
LD_{50} for lark (mg a.s./kg bw/d)	0.09		
TER_a	3.6	1.2	0.66
Trigger	10	10	10

Higher tier field studies documented safe use after in-furrow application of 2.0 kg a.s./ha and broadcast application of 5.5 kg a.s./ha, supporting a conclusion of safe use at each application rate.

RMS: For the acute risk assessment the Applicant used an LD50 corrected for the weight of the generic focal birds (trush in the worst case first Tier and lark in the refined first Tier). The RMS has used the LD50=3.16 mg a.s./kg bw/d (see Table 21). In addition, in the refined Tier 1, the RMS has used a RUD of 0.26 mg a.s./kg worm calculated as mean value of the three plots at day 0. This is because the acute risk assessment is meant to evaluate the risk short after the exposure to granules possibly adhered to worms. The appropriate species of concern is a 100-g thrush.

Table 21 Refined Tier 1 bird TER_a for exposure to residues in earthworms (see below the table revised by the RMS)

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

The acute risk remains unacceptable for the tobacco scenarios. Higher tier field studies documented lack of acute effects within 48 hours after in-furrow application of 2.0 kg a.s./ha and broadcast application of 5.5 kg a.s./ha, supporting a conclusion of safe use at each application rate.

Chronic risk assessment

The long-term risk to birds from secondary poisoning occurring by feeding on earthworms result in TER_{lt} values that exceed 5, indicating safe use in the worst-case exposure scenario for tobacco after broadcast applications (Table).

Table 22 Tier 1 bird TER_{lt} for exposure to residues in earthworms (see below table revised by the RMS)

Parameter	Potatoes (1 × 1000 kg a.s./ha)	Tobacco (1 × 3000 kg a.s./ha)	Tobacco (1 × 5500 kg a.s./ha)
PEC_{soil} (mg a.s./kg)	0.667	2.228	3.667
BAF	0.03	0.03	0.03
PEC_{worm} (mg a.s./kg bw/d)	0.02	0.06	0.11
Daily dose for birds ($PEC_{worm} \times 0.011$)	0.00022	0.00066	0.00121
NOEL for birds (mg a.s./kg bw/d)	1.5	1.5	1.5
TER_{lt}	6818	2272	1363

RMS comment: the RMS has revised the table as below:

Table 23 revised Tier 1 bird TER_{lt} for exposure to residues in earthworms

Parameter	Potatoes (1 × 1 kg a.s./ha)	Tobacco (1 × 3 kg a.s./ha)	Tobacco (1 × 5.5 kg a.s./ha)
PEC_{soil} (mg a.s./kg)	0.667	4.000	3.667
BAF	0.03	0.03	0.03
PEC_{worm} (mg a.s./kg bw)	0.02	0.12	0.11
Daily dose for birds ($PEC_{worm} \times 1.1$)	0.022	0.132	0.121
NOEL for birds (mg a.s./kg bw/d)	0.316	0.316	0.316
TER_{lt}	14.4	2.4	2.6

The chronic risk to earthworm eating mammals based on initial PECsoil results unacceptable for both the in-furrow and broadcast scenario and remain to be addressed.Exposure *via* Drinking Water

Acute drinking water risk assessment

One scenario was identified as relevant for assessing the risk of granular pesticides *via* drinking water to birds:

- Puddle scenario: Birds taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil.

No specific calculations of exposure and TER are required when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/day) does not exceed 50 in the case of less sorptive substances (K_{oc} <500 L/kg). The K_{foc} of oxamyl is 11.12L/kg. The HQ calculations trigger a drinking water risk assessment (Table).

Table 24 Drinking water risk assessment - ratio of effective application rate to bird acute toxicity endpoints for birds exposed to Oxamyl 10GR in tobacco or potatoes

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

[a] Multiple application factor

[b] Effective application rate

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

[d] Trigger based on a K_{FOC} of 11.12 mL/g (geomean)

PEC_{puddle} (mg a.s./L)= (AR/10)/ (1000 × (w + Koc *x* s)),

Where,

AR = application rate in g/ha
W = 0.02 (pore water term, volume)
S = 0.0015(soil term; volume density, organic carbon content)
Koc = 11.12 L/kg (geomean)

Tobacco PEC_{puddle}, broadcast = (5500/10)/ (1000 × (0.02 + 11.12 × 0.0015)) = 14.99 mg a.s./L

Tobacco PECpuddle, in-furrow = (3000/10)/ (1000 × (0.02 + 11.12 × 0.0015)) = 8.18mg a.s./L

Potato PECpuddle, in-furrow = (1000/10)/ (1000 × (0.02 + 11.12 × 0.0015)) = 2.73 mg a.s./L

The TER_a values are below the Regulation (EC) 546/2011 VI trigger of 10 (Table), indicating a need for refinements for Oxamyl 10GR at all proposed label rates.

Table 25 Tier 1 bird acute drinking water TER_a for Oxamyl 10GR – puddle scenario

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

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

Refinements to the puddle scenario can be made to the exposure part of this scenario by using run-off concentrations directly from relevant FOCUS Step 3 scenarios. The refined TER_a values are above the Regulation (EC) 546/2011 VI trigger of 10, indicating safe uses (table 26).

Table 26 Refined bird acute drinking water TER_a for Oxamyl 10GR – puddle scenario

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

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

Chronic drinking water risk assessment

Table 27 Tier 1 bird chronic drinking water TER_{lt} for Oxamyl 10GR – puddle scenario (revised by the RMS*)

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

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

*The RMS used the LD50/10 instead of the NOEL as done by the Applicant.and Koc =11.12 instead of Koc= 17 .

Refinements to the puddle scenario can be made to the exposure part of this scenario by using run-off concentrations directly from relevant FOCUS Step 3 scenarios. The refined TER_{lt} values are above the Regulation (EC) 546/2011 trigger of 5, indicating safe uses (Table 27)

Table 28 Refined bird chronic drinking water TER_{lt} for Oxamyl 10GR – puddle scenario (revised by the RMS*)

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

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

*The RMS used the LD50/10 instead of the NOEL as done by the Applicant.

Avian risk assessment conclusion

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

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

B.9.2.2 Risk assessment for terrestrial vertebrates other than birds

EU Endpoints: Toxicity of Oxamyl and Oxamyl 10GR to mammals

Study	Test species	Endpoints used in risk assessment
Acute toxicity	Rat	LD_{50} = 2.5 mg a.s./kg bw/d
Acute toxicity 10GR	Rat	LD_{50} = 3.4 mg a.s./kg bw/d
Reproductive toxicity (long-term)	Rat	NOEL = 1.43 mg a.s./kg bw/d

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

Guidelines

The mammalian risk assessment is based on guidance provided in "Guidance of EFSA. Risk Assessment for Birds and Mammals", European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal 2009: 7(12):1438. Input parameters used in the mammal risk assessment are summarised in Table . The reproductive NOAEL for mammals is based on pup number and pup survival and the time-weighted average factor (TWA) is 0.53.

Application conditions

For field application, Oxamyl 10GR is labelled for single uses on potatoes at-planting at a maximum of 1.0 kg oxamyl/ha in-furrow or on tobacco at-planting at a maximum of 3.0 kg oxamyl/ha in-furrow or at a maximum of 5.5 kg oxamyl/ha broadcast pre-planting. Good Agricultural Practices are summarised in Table 3.

Exposure scenario

The product will be used outdoors as an in-furrow or as a broadcast application followed by soil incorporation. It is possible that mammals may be exposed to granules in different ways by ingesting granules as a source of food, mistaken for small seed, when they eat food contaminated with soil, or by consuming food contaminated with residues resulting from granular applications.

Risk Assessment

Mammalian toxicity endpoints

A mammal acute toxicity study with Oxamyl 10GR was conducted for a non-EU country and a summary was included and reviewed in the Oxamyl EU Renewal Dossier, Document M-CP, Section 7 for Oxamyl 10GR, DuPont-40951 EU). A summary of all mammal toxicology endpoints used in the risk assessment is provided in Table .

Table 29 Summary of mammal toxicity endpoints for oxamyl and Oxamyl 10GR

Toxicity study (species)	Test substance	LD_{50} or LC_{50} (mg a.s. or metabolite/kg bw/day)	Lowest lethal dose (mg oxamyl/kg bw/day)	NOEL or NOEC (mg oxamyl/kg bw/day)	Reference[a]
Acute oral (rat)	oxamyl	3.1 (males) 2.5 (females)	2.5	<1.0	DuPont-26931
Acute oral (rat)	Oxamyl 10GR	4.3 (males) 3.4 (females)	3.5	2.2	DuPont-2703[b]
Acute oral (rat)	IN-A2213	ALD = 11000	11000	90	HLR 300-68
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 10GR, DuPont-40951 EU.

Risk Assessment assumptions

1 - Mammals ingesting granules as source of food

Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. The do not look like food and would not be ingested by mammals as a source of food. No risk assessment is required.

2 - Mammals ingesting granules when seeking seeds as food

Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. They do not resemble seeds and would not be ingested by mammals as a source of food. No risk assessment is required.

3 - Mammals ingesting granules when eating soil-contaminated food

Acute risk assessment

The acute daily dry soil dose for small omnivorous mammals is 0.097 × application rate (in kg a.s./ha). TER_a value for application in potatoes and tobacco broadcast is above the trigger of 10, indicating safe use (Table 30). The TER_a values for uses in tobacco in furrow is below the trigger of 10, indicating a need for refinement (Table 30). A refinement may be made to the toxicity endpoint used in the acute risk assessment for accidental ingestion of granules by mammals. The acute toxicity of the formulated product to birds is lower than that of the active substance (Table 30). The refined TER_a value for in-furrow use in tobacco is above the trigger of 10, indicating safe use (Table 30).

Table 30 Tier 1 mammal TER_a values after ingestion of granules with soil-contaminated food (revised by the RMS)

Exposure scenario	Potato	Tobacco in-furrow	Tobacco broadcast
Application rate (kg a.s./ha)	1.0	3.0	5.5
Shortcut value Short cut value at 10 cm depth incorporation*		0.097 0.010	
Exposure Daily dry soil dose - acute (mg a.s./kg bw/d)	0.097	0.291	0.055*
Toxicity endpoint (mg a.s./kg bw)		2.5	
TER_a	25	8.59	45.1
Trigger	10	10	10
Refined toxicity endpoint (mg a.s./kg bw)		3.5	
TER_a		12	
Trigger		10	

Chronic risk assessment

The chronic daily dry soil dose for small omnivorous mammals is 0.005 × application rate (in kg a.s./ha). TER_{lt} values for all scenarios are above the trigger of 10, indicating safe use (Table 31).

Tale 31 Tier 1 mammal TER_{lt} values after accidental ingestion of granules with soil (revised by the RMS)

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

RMS: The Applicant had simply used a short cut value of 0.005. The RMS used 0.004 x default twa 0.53, as indicated in the EFSA guidance (2009).

4 – Mammals consuming other food items with residue from granular applications

Acute herbivore assessment

Pre-cropping weed control with herbicides is a best agricultural practice in commercial potato and tobacco fields to reduce competition between crops and emergent weeds during germination and growth. Potatoes and tobacco are considered to be unpalatable to mammals. Thus, the scenario of acute exposure to herbivorous mammals immediately after application is considered to be not relevant to the risk assessment. In addition the DTsoil of oxanyl is 5.3 days, thus a significant exposure to herbivorous birds to oxamyl by emergent weeds is not expected.

Chronic herbivore assessment

Pre-cropping weed control with herbicides is a best agricultural practice in commercial potato and tobacco fields to reduce competition between crops and emergent weeds during germination and growth. Potatoes and tobacco

are considered to be unpalatable to mammals. Thus, the scenario of chronic exposure to herbivorous mammals after application is considered to be not relevant to the risk assessment.

Vermivore assessment

A study on bioaccumulation of oxamyl in earthworms documented a worst-case BAF = 0.03 (Meinerling, 2014; DuPont-38477). A summary is provided in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, Ecotoxicology, DuPont-40935. The long-term risk to mammals from secondary poisoning by feeding on earthworms results in TER_{lt} value >5, indicating safe use in all exposure scenarios (Table 32).

Table 32 Long-term mammal TER_{lt} for secondary poisoning occurring by feeding on earthworms (see below the revised table by the RMS)

Parameter	Potatoes (1 × 1000 kg a.s./ha)	Tobacco (1 × 3000 kg a.s./ha)	Tobacco (1 × 5500 kg a.s./ha)
PEC_{soil} (mg a.s./kg)	0.667	2.228	3.667
BCF	0.03	0.03	0.03
PEC_{worm} (mg a.s./kg bw/d)	0.02	0.06	0.11
Daily dose for mammals (PEC_{worm} × 1.28)	0.0256	0.0768	0.1408
NOEL for birds (mg a.s./kg bw/d)	1.43	1.43	1.43
TER_{lt}	55.8	18.6	10.1

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

RMS comment: the RMS has revised table 34 as follows:

Table 33 revised Long-term mammal TER_{lt} for secondary poisoning occurring by feeding on earthworms

Parameter	Potatoes (1 × 1 kg a.s./ha)	Tobacco (1 × 3 kg a.s./ha)	Tobacco (1 × 5.5 kg a.s./ha)
PEC_{soil} (mg a.s./kg)*	0.667	4.000	3.667
BAF	0.03	0.03	0.03
PEC_{worm} (mg a.s./kg bw/d)	0.02	0.12	0.11
Daily dose for mammals (PEC_{worm} × 1.28)	0.0256	0.1536	0.1408
NOEL for mammals (mg a.s./kg bw/d)	1.43	1.43	1.43
TER_{lt}	55.8	9.3	10.1

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

The potato and tobacco broadcast scenarios are safe, while the tobacco infurrow scenario results at risk. A refinement should be submitted. The acute risk assessment for the general focal species “shrew” has not been presented and should be submitted.

5 - Drinking Water Risk Assessment

Acute drinking water assessment for mammals (Applicant version, see RMS comment and revision below)

One scenario was identified as relevant for assessing the risk of granular pesticides *via* drinking water to mammals:

- Puddle scenario: Mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil.

No specific calculations of exposure and TER are required when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/day) does not exceed 50 in the case of less sorptive substances (K_{oc} <500 L/kg). The K_{oc} of oxamyl is 17. The acute HQ calculations trigger a drinking water risk assessment.

The adjusted LD_{50} for a 21.7 g mammal is 2.5 mg a.s./kg bw × 0.0217 = 0.054 mg/kg bw. The daily drinking water rate (DWR) for a 21.7 g granivorous mammal is 0.24 L/kg bw/d or 0.005 L/rat/day.

PEC_{puddle} (mg a.s./L)= (AR/10)/ (1000 × (w + K_{oc} × soil))

The TER_a values are below the Regulation (EC) 546/2011 trigger of 10, indicating a need for refinements for Oxamyl 10GR at all proposed label rates.

Table 34 Mammal tier 1 acute drinking water TER_a for Oxamyl 10GR – puddle scenario (Applicant version)

Scenario	Species	LD_{50} (mg/kg bw/day)	DWR[a] in L/kg bw/d	PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous mammal	0.054	0.005	12.08	0.06	0.89	10
Tobacco, 3.0 kg a.s/ha	Granivorous mammal	0.054	0.005	6.59	0.03	1.63	10
Potato, 1.0 kg a.s/ha	Granivorous mammal	0.054	0.005	2.20	0.01	4.90	10

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

RMS comment and revision: for a small granivorous mammal, the daily drinking water rate DWR = 5.1 mL/d, equivalent to 0.24 L/kg bw/d. This value has been used in the revised table below. The LD50 obtained in the laboratory studies does not need to be converted.

PEC_{puddle} (mg a.s./L)= (AR/10)/ (1000 × (w + K_{oc} × soil))

Where,

AR = application rate in g/ha
W = 0.02 (pore water term, volume)
S = 0.0015(soil term; volume density, organic carbon content)
Koc = 11.12 L/kg (geomean)

Tobacco PEC_{puddle}, broadcast = (5500/10)/ (1000 × (0.02 + 11.12 × 0.0015)) = 14.99 mg a.s./L

Tobacco PECpuddle, in-furrow = (3000/10)/ (1000 × (0.02 + 11.12 × 0.0015)) = 8.18 mg a.s./L

Potato PECpuddle, in-furrow = (1000/10)/ (1000 × (0.02 + 11.12 × 0.0015)) = 2.73 mg a.s./L

Table 35 revised Mammal tier 1 acute drinking water TER_a for Oxamyl 10GR – puddle scenario

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

[a] EFSA 2009.

TER_a values did not exceed 10, thus triggering a refined assessment. Refinements to the puddle scenario can be made to the exposure part of this scenario by using run-off concentrations directly from relevant FOCUS Step 3 scenarios. The refined TER_a values are above the Regulation (EC) 546/2011 trigger of 10, indicating safe uses (Table 36).

Table 36 Refined mammal tier 1 acute drinking water TER_a for Oxamyl 10GR – puddle scenario (revised by the RMS)

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

[a] EFSA 2009.

Chronic drinking water assessment for mammals (Applicant version, see RMS comment and revision below)

The HQ values triggered a chronic drinking water risk assessment for mammals.

The adjusted NOEC for a 21.7 g mammal is 1.43 mg a.s./kg bw × 0.0217 = 0.031 mg/mammal. The daily drinking water rate (DWR) for a 21.7 g granivorous mammal is 0.24 L/kg bw/d or 0.005 L/rat/day.

PEC_{puddle} (mg a.s./L)= (AR/10)/ (1000 × (w + Koc × soil)),

The TER_{lt} values are below the Regulation (EC) 546/2011 trigger of 10, indicating a need for refinements for Oxamyl 10GR at all proposed label rates.

Table 37 Tier 1 mammal chronic drinking water TER_a for Oxamyl 10GR – puddle scenario (Applicant version)

Scenario	Species	NOEL (mg/kg bw/day)	DWR[a] in L/kg bw/d	PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous mammal	0.031	0.005	12.08	0.06	0.51	5
Tobacco, 3.0 kg a.s/ha	Granivorous mammal	0.031	0.005	6.59	0.03	1.03	5
Potato, 1.0 kg a.s/ha	Granivorous mammal	0.031	0.005	2.20	0.01	0.01	5

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

RMS comment and revision: for a small granivorous mammal, the DWR = 5.1 mL/d, equivalent to 0.24 L/kg bw/d. This value has been used in the revised table below. The NOEL obtained in the laboratory studies does not need to be converted.

PECpuddle (mg a.s./L)= (AR/10)/ (1000 □ (w + Koc □ soil))
Where,
AR = application rate in g/ha
W = 0.02 (pore water term, volume)
S = 0.0015(soil term; volume density, organic carbon content)
Koc = 11.12 L/kg (geomean)

Tobacco PECpuddle, broadcast = (5500/10)/ (1000 □ (0.02 + 11.12 □ 0.0015)) = 14.99 mg a.s./L
Tobacco PECpuddle, in-furrow = (3000/10)/ (1000 □ (0.02 + 11.12 □ 0.0015)) = 8.18 mg a.s./L
Potato PECpuddle, in-furrow = (1000/10)/ (1000 □ (0.02 + 11.12 □ 0.0015)) = 2.73 mg a.s./L

Table 38 Tier 1 mammal chronic drinking water TER_a for Oxamyl 10GR – puddle scenario

Scenario	Species	NOEL (mg/kg bw/day)	DWR[a] in L/kg bw/d	PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous mammal	1.43	0.24	14.99	3.6	0.40	5
Tobacco, 3.0 kg a.s/ha	Granivorous mammal	1.43	0.24	8.18	1.96	0.73	5
Potato, 1.0 kg a.s/ha	Granivorous mammal	1.43	0.24	2.73	0.65	2.2	5

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

TER_a values did not exceed 10, thus triggering a refined assessment. Refinements to the puddle scenario can be made to the exposure part of this scenario by using run-off concentrations directly from relevant FOCUS Step 3 scenarios. The refined TER_{lt} values are above the Regulation (EC) 546/2011 trigger of 5, indicating safe uses (Table 39).

Table 39 Refined mammal tier 1 chronic drinking water TER_{lt} for Oxamyl 10GR – puddle scenario (revised by the RMS)

Scenario	Species	NOEC (mg/kg bw/day)	DWR[a] in L/kg bw/d	FOCUS Step 3a PEC_{pool}/ PEC_{puddle} (mg a.s./L)	DDD	TER_{lt}	Trigger
Tobacco, 5.5 kg a.s/ha	Granivorous mammal	1.43	0.24	0.028	0.00672	213	5
Tobacco, 3.0 kg a.s/ha	Granivorous mammal	1.43	0.24	0.015	0.0036	397	5
Potato, 1.0 kg a.s/ha	Granivorous mammal	1.43	0.24	0.048	0.01152	124	5

[a] EFSA 2009.

Mammal risk assessment conclusion

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

B.9.3 Effects on aquatic organisms

Fish acute toxicity

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.3.1/01

Reference: --	**Report**	[redacted]. (2000b); Oxamyl 10G: Static, acute, 96-hour, (LC_{50}) test to rainbow trout, *Oncorhynchus mykiss* **DuPont Report No.:** DuPont-2912 **Guidelines:** EEC Method C.1. (1992), U.S. EPA 72-1 (1988), OECD 203 (1992)

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s/kg by analysis

Materials and methods:

Fish were purchased from [redacted] and acclimated for 26 d at 12±2°C. The acute toxicity of Oxamyl 10 GR to unfed fingerling rainbow trout, *Oncorhynchus mykiss*, was determined in an unaerated, static, 96-hour test. Fish were unfed for 2 days before testing and during the test. Treatments consisted of a dilution water control, and nominal concentrations of 7.8, 13, 22, 36, and 60 mg Oxamyl 10 GR/L. Two replicates containing 5 fish were exposed to each treatment concentration and control. Glass aquaria (40 l × 20 w × 25 h cm) holding approx 10 L of test solution (13 cm liquid depth). Test solutions were maintained between 12.2 and 12.7°C. Dilution water originated as deionized water prepared at [redacted] and met OECD and ASTM dilution water criteria and specifications. A photoperiod of 16 hours light (approximately 560 lux) and 8 hours darkness was employed which included 15 minutes of transitional light preceding and following the 16-hour light interval.

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

Analysis of test solutions were made by HPLC equipped with UV. The Binomial method was used to calculate 48 hour LC50s and 95% confidence limits, and the probit method was used to calculate the 72 and 96 hour LC50s and 95% confidence limits.

Findings:

During the test, water temperature was in the range 12.2 – 12.7°C, dissolved oxygen ranged from 7.6 to 9.9 mg/l (mean=9.4 mg/l) and pH was between 7.1 and 7.7. Total alkalinity and EDTA hardness of the dilution water control and the 9.54 mg/L Oxamyl test solution at test start were 25 and 24 mg/L CaCO3, and 40 mg/L CaCO3, respectively.

At test conclusion, fish from the water control ranged from 3.30 to 3.72cm in total length (mean 3.5 cm), and 0.29 to 0.41 g in wet weight, blotted dry (mean 0.34 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 0.17 g/L at test conclusion.

A summary of cumulative mortality and sublethal effects is presented in Table . Mean, measured concentrations were 0.715, 1.29, 2.19, 3.72, and 6.11 mg a.s./L and ranged from 92 to 103% of nominal concentrations. Since at the end of test the concentrations were maintained within 20% of the nominals, nominal concentrations were used for all calculations. There were no mortality or sublethal effects below 13 mg Oxamyl 10 GR/L. The highest concentration causing no mortality was 13 mg Oxamyl 10 GR/L and the lowest concentration causing 100% mortality was 60 mg/L. Several fish exposed to 13, 22, 36, and 60 mg Oxamyl 10 GR/L exhibited a loss of equilibrium, erratic swimming, change in coloration and/or immobilisation at 24, 48, 72, and 96 hours. No other sublethal effects were observed at any tested concentration during the definitive toxicity test. Time to first observed mortality was 24 hours.

Table 40 Summary of mortality and sublethal effects of Oxamyl 10 GR on Rainbow Trout, *Oncorhynchus mykiss*, exposed for 96 hours in an unaerated, static, acute test.

Nominal concentration of Oxamyl 10GR (mg/L)	Cumulative mortality (No. dead / No. at test start)[a]				Sublethal effects (No. affected / No. at test start)[a]			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h

Water Control	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
7.8	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
13	0/10	0/10	0/10	0/10	0/10	0/10	$1^{b,d,f}$/10	$1^{d,f}$/10
22	0/10	0/10	0/10	1/10	3^{c}/10	$9^{b,d,f}$/10	$9^{b,d,f}$/10	$9^{b,c,d,f}$/10
36	0/10	1/10	3/10	4/10	9^{b}/10	$9^{b,f}$/10	$7^{b,f}$/10	$6^{b,e,f}$/10
60	1/10	9/10	9/10	10/10	$9^{b,e,f}$/10	$1^{b,f}$/10	$1^{b,f}$/10	L

a Ten fish per test concentration at test start
b Loss of equilibrium
c Erratic swimming
d Change in coloration
e Immobilization
f Lethargy
L Total mortality

Conclusion:

The 96-hour LC50 for Oxamyl 10 GR to the rainbow trout was 36 mg/L (c.i., 29-44 mg/L) equivalent to 3.6 mg a.s./L, based on nominal total formulation.

RMS comments and conclusion

Additional details were added by the RMS to the study summary.

The acute toxicity to fish study DuPont-2912, originally submitted under EU Rev8 Point IIA 10.2.1 and conducted with test material Oxamyl 10GR, was conducted under guidelines EEC Method C.1. (1992), U.S. EPA 72-1 (1988), and OECD 203 (1992). A review of this study against the current OECD 203 (1992) indicates that the validity criteria regarding control mortality, constant conditions, DO concentration were fulfilled. Since the concentrations of the test substance in the test solutions were satisfactorily maintained, the results are based on nominal concentrations.

The following deviations from OECD 203 (1992) are noted:

Temperature range was 12.2 – 12.7°C , i.e. slightly lower then the recommended 13-17°C;
The fish total length was 3.30 to 3.72 cm in total length (mean 3.5 cm), i.e. shorter than the recommended 5.0 ±1.0 cm.
Fish were starved for 2 d prior the test instead of 1d.

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

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.3.1/02

Reference: --	**Report**	[redacted] (2000c); Oxamyl 10G: Static-renewal, acute, 96-hour, (LC_{50}) test to bluegill sunfish, *Lepomis macrochirus* **DuPont Report No.:** DuPont-2913

		Guidelines: OECD 203 (1992), EEC Method C.1. (1992), U.S. EPA 72-1 (1988)

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s/kg

Materials and methods:

Bluegill sunfish, *Lepomis macrochirus*, were purchased from [redacted] and acclimated for 96d at at 22±2°C. Fish were unfed for 2 days before testing and during the test. Fish in the water control ranged from 3.10 to 3.97cm in total length (mean 3.41 cm), and 0.33 to 0.68 g in wet weight, blotted dry (mean 0.47 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 0.24 g/L at test conclusion.

The acute toxicity of Oxamyl 10 GR to unfed juvenile bluegill sunfish, *Lepomis macrochirus*, was determined in an unaerated, static-renewal, 96-hour test. Treatments consisted of a dilution water control, and nominal concentrations of 13, 22, 36, 60, and 100 mg Oxamyl 10 GR/L. Two replicates containing 5 fish were exposed to each treatment concentration and control. Test solutions were maintained between 21.1 and 22.3 °C.

Glass aquaria (40 l × 20 w × 25 h cm) holding approx 10 L of test solution (13 cm liquid depth). Test solutions were maintained between 12.2 and 12.7°C. Dilution water originated as deionized water prepared at [redacted] and met OECD and ASTM dilution water criteria and specifications. A photoperiod of 16 hours light (approximately 560 lux) and 8 hours darkness was employed which included 15 minutes of transitional light preceding and following the 16-hour light interval.
Mortality and behavioural observations were made every 24 hours. Dead fish were removed from the test chambers when observed. Analysis of test solutions were made by HPLC equipped with UV. The probit method was used to calculate the LC50s and 95% confidence limits.

Findings:

During the test, water temperature was in the range 21.1 – 22.3°C (mean 21.8°C), dissolved oxygen ranged from 7.0 to 9.0 mg/l (mean=8.4 mg/l) and pH was between 7.2 and 7.7. Total alkalinity and EDTA hardness of the dilution water control and the 9.54 mg/L Oxamyl test solution at test start were 25 and 24 mg/L CaCO3, and 40 mg/L CaCO3, respectively. Conductivity ranged from 120 to 130 mhos/cm (mean = 120 mhos/cm) during the test.

.A summary of cumulative mortality and sublethal effects is presented in Table . Mean, measured concentrations were 1.27, 2.11, 3.52, 5.82, and 9.54 mg a.s./L and ranged from 95 to 98% of nominal concentrations. Since at the end of test the concentrations were maintained within 20% of the nominals, nominal concentrations were used for all calculations. There were no mortality or sublethal effects below 36 mg Oxamyl 10 GR/L. The highest concentration causing no mortality was 22 mg/L and the lowest concentration causing 100% mortality was 100 mg Oxamyl 10 GR/L. Several fish exposed to 60 and 100 mg/L exhibited signs of lethargy at 24, 48, 72, and 96 hours. No other sublethal effects were observed at any tested concentration during the definitive toxicity test. Time to first observed mortality was 24 hours.

Table 41 Summary of mortality and sublethal effects of Oxamyl 10 GR on bluegill sunfish, *Lepomis macrochirus*, exposed for 96 hours in an unaerated, static- renewal, acute test

Nominal concentration of Oxamyl 10GR (mg/L)	Cumulative mortality (No. dead / No. at test start)[a]				Sublethal effects (No. affected / No. at test start)[a]			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
Water Control	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
13	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
22	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
36	1/10	1/10	2/10	3/10	0/10	0/10	0/10	0/10
60	2/10	4/10	7/10	7/10	0/10	6[b]/ 10	3[b]/10	3[b]/10
100	5/10	10/10	10/10	10/10	5[b]/10	L	L	L

a Ten fish per test concentration at test start

b Lethargic

L Total mortality

Conclusion:

The 96-hour LC50 in the bluegill sunfish was 47 mg Oxamyl 10 GR/L (c.i. 37-58 mg Oxamyl 10 GR/L) equivalent to 4.7 mg a.s./L based on nominal total formulation.

RMS comments and conclusion

Additional details were added by the RMS to the study summary.

The acute toxicity to fish study DuPont-2912, originally submitted under EU Rev8 Point IIA 10.2.1 and conducted with test material Oxamyl 10GR, was conducted under guidelines EEC Method C.1. (1992), U.S. EPA 72-1 (1988), and OECD 203 (1992). A review of this study against the current OECD 203 (1992) indicates that the validity criteria regarding control mortality, constant conditions, DO concentration were fulfilled. Since the concentrations of the test substance in the test solutions were satisfactorily maintained, the results are based on nominal concentrations.

The following deviations from OECD 203 (1992) are noted:

The fish total length was 3.10 to 3.97cm in total length (mean 3.41 cm), i.e. higher than the recommended 2.0 ±1.0 cm.
Fish were starved for 2 d prior the test instead of 1d.

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

***Daphnia* acute toxicity**

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.3.1/03

Reference: --	**Report**	Ward, T.J., Magazu, J. P., Boeri, R.L. (2000a); Oxamyl 10G: Acute, 48-hour EC_{50} to *Daphnia magna* **DuPont Report No.:** DuPont-2555 **Guidelines:** OECD 202 (1984), EEC Method C.2. (1992), U.S. EPA 72-2 (1988)

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s/kg

Materials and methods:

The acute toxicity of Oxamyl 10 GR to unfed *Daphnia magna* neonates (<24-hour old collected 12 days after the first appearance of neonates in the parent culture) was determined in an unaerated, static-renewal, 48-hour test. Treatments consisted of a dilution water control, and nominal concentrations of 1.3, 2.2, 3.6, 6.0, and 10 mg Oxamyl 10 GR/L. Test media was renewed at 24 hours. Daphnids were transferred to test vessels containing freshly prepared solutions.The dilution water control met OECD and ASTM dilution water criteria and specifications and contained no solvent. Ten daphnids were used per replicate with two replicates per test concentration and control. Glass beakers (300-mL) containing 200 mL of test solution were used as test chambers (two replicate chambers per concentration). A photoperiod of 16 hours light (approximately 490 LUX) and 8 hours darkness was employed which included approximately 15 minutes of transitional light preceding and following the 16-hour light interval. 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.. Daphnia were assessed for effects in terms of signs of toxicity and immobility at 0, 24 and 48 hours. Water temperature, pH and dissolved oxygen were monitored as required during the test.

The binomial method was used to calculate 24 hour EC50 and 95% confidence limits,

Findings:

During the 48h test, the test solution concentrations were maintained within 20% of nominals.The mean, measured concentrations were 0.123, 0.211, 0.346, 0.576, and 0.946 mg Oxamyl/L. Mean calculated concentrations ranged from 95 to 96% of the nominal concentrations. All chemical and physical parameters were within acceptable ranges. Temperature in the test chambers ranged between 19.6 and 20.6°C (mean = 20.1) The temperature, which was continuously recorded throughout the test, was not always 20□1□C.; pH ranged between 7.6 and 8.0; dissolved oxygen concentrations were between 8.6 and 9.0 mg/l (mean = 8.9 mg/l). The conductivity of the test solutions, including the control solution ranged from 550 – 560 µmshos/cm (mean = 550 µmhos/cm). Nominal concentrations were used for all calculations.

The highest concentration causing no immobility was 2.2 mg Oxamyl 10 GR/L and the lowest concentration causing 100% immobility was 6.0 mg Oxamyl 10 GR/L. Immobile *Daphnia magna* were observed in test vessels containing 3.6, 6.0, and 10 mg Oxamyl 10 GR/L at 24 and 48 hours. There were no sublethal effects other than immobility observed at any time.

Immobility and Sublethal Effects in *Daphnia magna* at 24 and 48 Hours in an Unaerated Static Renewal, Acute Toxicity (EC_{50}) Test with Oxamyl 10G

Nominal Oxamyl 10G Concentration (mg/L)	Immobility (%)[a,b] 0 Hours	24 Hours	48 Hours
Water Control A[†]	0	0	0
Water Control B[†]	0	0	0
1.3 A[†]	0	0	0
1.3 B[†]	0	0	0
2.2 A[†]	0	0	0
2.2 B[†]	0	0	0
3.6 A[†]	0	20	80
3.6 B[†]	0	30	50
6.0 A[†]	0	100	100
6.0 B[†]	0	100	100
10 A[†]	0	100	100
10 B[†]	0	100	100

[†] A and B represent replicates; each replicate contained 10 daphnids (total 20 daphnids per test concentration) at test start.
[a] There were no sublethal effects other than immobility observed at any time.
[b] Immobility is defined as the inability of a daphnid to swim within 15 seconds of gentle agitation of the test vessel.

A summary of the findings is presented in Table 42.

Table 42 Summary of observed immobility and sublethal effects of unfed *Daphnia magna* exposed to Oxamyl 10 GR for 48 hours in an unaerated, static- renewal, acute test

Test substance	Oxamyl 10GR
Test object	*Daphnia magna*
Exposure	48 h, static
24 EC_{50} mg formulation./l	4.1 (3.6 – 6.0)
48 EC_{50} mg formulation/l	3.3 (2.2 – 6.0)
Lowest observed effect concentration (LOEC) mg formulation/l	3.6
Highest tested conc. without toxic effect (NOEC) mg formulation/l	2.2

Conclusion:

The 48-hour EC50 in Daphnia magna was 3.3 mg Oxamyl 10 GR/L (0.33 mg a.s./L) based on nominal total formulation, with a 95% confidence limit of 2.2 to 6.0 mg/L.

RMS comments and conclusion

The acute toxicity to aquatic invertebrates study, DuPont-2555, originally submitted under EU Rev8 Point IIA 10.2.1. and conducted with test material Oxamyl 10GR, 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 meets the** current guideline (OECD 202, April 2004.
The validity criteria are met:
- No more than 10% immobilisation or other sign of disease/stress in the control (actual 0%);
- DO at the end of test ≥ 3 mg/L in the control and test vessels (actual 8..7 in all test vessels after 48 h or at test termination).

The temperature in the test chambers was maintained within the prescribed limit but the study report mentions that "The temperature, which was continuously recorded throughout the test, was not always 20 ± 1°C", without further details. The RMS guess that this referes to the ambient temperature.

Conclusion: the study is acceptable and relied upon.

Algal growth and growth rate

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.3.1/04

Reference: --	**Report**	Boeri, R.L., Ward, T.J. (2000); Oxamyl 10G: Influence on growth and growth rate of the alga, *Selenastrum capricornutum* **DuPont Report No.:** DuPont-3914 **Guidelines:** OECD 201 (1984)

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s/kg

Materials and methods:

The test was concudcted at T.R. Wilbury Laboratories, Inc., in Marblehead, Massachusetts.The effect of Oxamyl 10 GR on *Selenastrum capricornutum* was determined using algal cultures with AAP nutrient medium. Three replicates at nominal total formulation concentrations of 3.8, 7.5, 15, 30, and 60 mg Oxamyl 10 GR/L, were incubated for 72 hours and cell counts were taken at 24-hour intervals. Six replicates were set for the control. The test was performed in 250 mL glass Erlenmeyer flasks (typically approximately 80 mm bottom diameter x 130 mm height) that contained 100 mL of test solution arranged in a rotary shaker adjusted to 100 rpm. An incubator was used and its temperature was recorded daily (ranged from 23.4 to 24.2°C). A photoperiod of 24 hours light, measured as approximately 6,400 to 6,900 lux, and 0 hours darkness was employed. Initial measured concentrations of the active ingredient, Oxamyl, were 0.400, 0.811, 1.60, 3.13, and 6.29 mg/L. The occurrence of cell size differences, unusual cell shapes, colours, flocculations, adherence of cells to test containers or aggregation of cells was determined. Recovery within 96 hours after exposure was assessed for algae exposed to 60 mg/L, the maximally inhibited test concentration.

Actual concentrations of Oxamyl were determined by chemical analysis at 0 and after 72 hours in control and test solutions using a Hewlett Packard Series 1100 HPLC equipped with a UV detector. Algal cell numbers were determined visually by means of direct microscopic examination with a haemacytometer at 24, 48, 72, 96 and 120 hours. Temperature and pH were determined at the beginning and at the end of the test.

Findings:

pH in the control vessels was 7.4 at 0h and 10.3-10.4 at 72h.

Initial, measured concentrations were <LOQ (test media control), 0.400, 0.811, 1.60, 3.13, and 6.29 mg Oxamyl/L,Final measured concentrations were <LOQ (limit of quantitation of 0.0115 mg/L; test media control), <LOQ, <LOQ, <LOQ, 1.36, and 3.11 mg Oxamyl/L. Nominal concentrations were used for all calculations. No visible insoluble material was noted during the definitive toxicity test, however solutions in test vessels with a nominal concentration of 30 mg/L were cloudy at the start of the test and solutions with a nominal concentration of 60 mg/L were cloudy throughout the test.

Measured Concentrations of Oxamyl in Test Solution Samples

Nominal Concentration (mg/L)	Corrected Nominal Concentration[a] (mg/L)	Measured Oxamyl Concentration (mg/L) 0 Hour	72 Hours	0 Hour Percent Recovery (%)
Test Media				
Water Control	Water Control	<LOQ[b]	<LOQ	---
3.8	0.38	0.400	<LOQ	105
7.5	0.75	0.811	<LOQ	108
15	1.5	1.60	<LOQ	107
30	3.0	3.13	1.36	104
60	6.0	6.29	3.11	105
Laboratory Control Sample				
15	1.5	1.61	1.61	107
Matrix Spike Sample				
15	1.5	--	<LOQ	---
		--	<LOQ	---
Blank				
0	0	<LOQ	<LOQ	---

[a] Nominal concentrations corrected for Oxamyl 10G purity of 10.00% Oxamyl.
[b] LOQ denotes the limit of quantitation was 0.0115 mg/L.

Aggregations of algal cells were observed in all noncontrol test vessels at 48 and 72 hours, however these aggregations dissipated upon vigorous swirling of the test vessels prior to the determination of cell counts and the collection of analytical samples. The effects of Oxamyl 10 GR on the growth of *Selenastrum capricornutum* are shown in

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

Nominal Total Formulation Concentration of Oxamyl 10G (mg/L)	Average Specific Growth Rate		
	24 hour	48 hour	72 hour
0 (control)	0.074	0.079	0.078
3.8	0.075	0.071	0.071
7.5	0.068	0.067	0.071
15	0.066	0.062	0.060
30	0.046	0.036	0.040
60	0.014	0.000	0.015
Nominal Total Formulation Concentration of Oxamyl 10G (mg/L)	Percent of Control		
	24 hour	48 hour	72 hour
0 (control)	--	--	--
3.8	101	90	91
7.5	92	85	91
15	89	78	77
30	62	46	51
60	19	0	19

Table . No effects (size differences, flocculations, unusual cell shapes, colours, adherence of cells to test containers or aggregation of cells) were observed during the test. Recovery was observed as an increase in cell number from a calculated cell count of 440 cells/ml to 304,000 cells/ml in the highest concentration tested (60 mg/l) indicated that oxamyl was algistatic rather than algicidal. Algae grew exponentially in the recovery phase, demonstrating that Oxamyl 10 GR is algistatic.

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

Nominal Total Formulation Concentration of Oxamyl 10G (mg/L)	Average Specific Growth Rate		
	24 hour	48 hour	72 hour
0 (control)	0.074	0.079	0.078
3.8	0.075	0.071	0.071
7.5	0.068	0.067	0.071
15	0.066	0.062	0.060
30	0.046	0.036	0.040
60	0.014	0.000	0.015
Nominal Total Formulation Concentration of Oxamyl 10G (mg/L)	Percent of Control		
	24 hour	48 hour	72 hour
0 (control)	--	--	--
3.8	101	90	91
7.5	92	85	91
15	89	78	77
30	62	46	51
60	19	0	19

Table 43 Summary of algal growth inhibition following exposure of *Selenastrum capricornutum* to Oxamyl 10 GR for 72 hours

Dose (mg/L)	Mean cell density (cells/mL)	% Inhibition		
		Cell density	Growth rate	Area under the growth curve
Water control	2.7×10^6	—	—	—
3.8	1.6×10^6	41*	9*	38*
7.5	1.7×10^6	38*	9*	39*
15	2.0×10^5	73*	23*	68*
30	1.8×10^5	93*	49*	92*
60	2.9×10^4	99*	81*	>99*

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

Conclusion:

Growth inhibition data obtained with Oxamyl 10 GR on *Selenastrum capricornutum* were as follows:

Parameter	Endpoint (mg Oxamyl 10GR/l)	
	72h EC_{50}	72h Calculated NOEC
Cell Density	8.6	<3.8
Area under the growth curve	9.8	<3.8
Growth Rate	31	<3.8

The effects of Oxamyl 10 GR on *Selenastrum capricornutum* are expected to be reversible at the maximally inhibited Oxamyl 10 GR concentration, 60 mg/L. Oxamyl 10 GR is considered to be algistatic.

A review of this study indicates that it fully meets the current guideline OECD 201 (2011),.

RMS comments and conclusion

Details and tables were added by the RMS to the summary.

This study, originally submitted under EU Rev8 Point IIA 10.2.1 and conducted with test material Oxamyl 10GR, was conducted under guideline OECD 201 (1984). A review of this study according to the current guideline OECD 201 (2011) was made.

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 273). 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 10.0%). 3) The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was < 7% (actual 5.3%).

The following deviations were noted.

pH increased by 2.9-3.0 units in the controls instead of the recommended maximum 1.5 units.

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.

Conclusion: the study fulfils the validity criteria but the results are not reliable.

Non-target aquatic plants

This is not an EU data requirement.

Aquatic field testing

No aquatic field testing was required.

B.9.3.1 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 since the potential for bioconcentration is low (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).

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). No fish lifecycle studies were required or conducted with either oxamyl technical or 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 the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU). 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 the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU). No chronic aquatic insect studies were conducted with the formulated product.

Chronic toxicity for a representative species of aquatic gastropod molluscs

Oxamyl 10GR is not intended to be used as an insecticide or insect growth regulator or directly applied to water. The chronic toxicity of Oxamyl 10GR to aquatic gastropod species was not determined since continuous or repeated exposure is not likely. Oxamyl 10GR is applied less than 3 times a season and the DT_{50} in water is <2 days.

B.9.3.2 Further testing on aquatic organisms

There is no need for further testing.

B.9.4 Risk assessment for aquatic organisms

Aquatic application conditions, exposure scenario, and risk assessment assumptions

The aquatic risk assessment will consider each exposure scenario of Oxamyl 10GR applied at planting. Oxamyl 10GR is applied to soil at planting of potatoes or tobacco by tractor mounted application equipment. Oxamyl 10GR will not be applied directly to bodies of surface water, and therefore, the primary potential route of exposure to aquatic organisms considered in this aquatic risk assessment is *via* dust drift and run-off as a result of normal agricultural applications. Aquatic organisms may be exposed to oxamyl as a consequence of the accidental entry of the compound into the environmental compartments occupied by organisms or as a consequence of run-off events. Details of the predicted environmental concentrations for oxamyl in surface water, arising as a consequence of dust drift and run-off, are provided in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10GR, DuPont-40934 EU. Good Agricultural Practices are summarised in the Oxamyl EU Renewal Dossier, Document D, Part 1, DuPont-40925 EU.

The formulated product, Oxamyl 10GR, and its active substance, oxamyl, were tested on a range of aquatic species in accordance with established test guidelines (B.9.3 in this document and the Oxamyl dRAR Vol 3 a.s. B). Effect levels were analytically determined in all studies except where exposure concentrations were below the limit of quantification. Testing for effects on sediment dwelling organisms was not carried out because effects were not observed in invertebrate species at the exposure levels likely to arise following dust drift or run-off - direct application to water bodies is not proposed. A bioconcentration test was not carried out because Log P_{ow} value for oxamyl is <3, the trigger value used to determine when such testing is required, and because repeated exposure does not occur.

The major metabolites of oxamyl that are of ecotoxicological relevance and their environmental compartments are summarised in Table 2. The ecotoxicological 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.

Aquatic toxicity endpoints

Summaries of the acute and chronic aquatic toxicity profiles of oxamyl active substance, metabolites and Oxamyl 10GR are provided in Table 44 to Table 45.

Table 44 Oxamyl acute and chronic 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	data gap			DuPont-2909
Lemna gibba	chronic (7 d)	EC_{50} E_rC_{50}	1.670 3.30	DuPont-34272
Chironomus tentans	acute (48 h)	EC_{50}	0.350	DuPont-37400
Chimarra atterima	acute (48 h)	EC_{50}	0.096	DuPont-37402
Centroptilum triangulifer	acute (48 h)	EC_{50}	0.067	DuPont-37401
Hyalella azteca	acute (48 h)	EC_{50}	0.320	DuPont-37397
Daphnia pulex	acute (48 h) Not valid			DuPont-37398
Ceriodaphnia dubia	acute (48 h)	EC_{50}	0.094	DuPont-37399
Americamysis bahia	acute (48 h)	EC_{50}	0.0465	DuPont-34271
Crassostrea virginica	Acute (96 h)	EC_{50}	27.5	DuPont-34273
Fathead minnow	Early life stage (28 d) Supportive information	NOEC	0.500 Supportive information	HLR 877-81
Rainbow trout	early life stage (90 d) Not valid			HLR 468-88
Sheepshead minnow *Cyprinodon variegatus*	early life stage (29 d)	NOEC	0.356	DuPont-34270
Daphnia magna	chronic (21 d)	NOEC	0.0268	DuPont-2554
Americamysis bahia	chronic (28 d)	NOEC	0.0189	DuPont-34269

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

Table 45 Acute and chronic toxicity of Oxamyl 10GR to aquatic organisms

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

[a] M = Measured concentration; N = Nominal concentration (analytically confirmed)

[b] Biomass is lowest value

[c] Study summarised in this document

Table 46 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) Supportive information	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	acute (72 h)	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 cited in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU

Exposure assessment (predicted environmental concentrations [PEC])

Predicted environmental concentrations were generated to simulate applications of oxamyl to potatoes or tobacco in the EU. The predicted surface water (PEC_{sw}) and sediment (PEC_{sed}) concentrations of oxamyl and relevant soil and aquatic metabolites IN-A2213, IN-D2708, IN-N0079, and IN-T2921 were determined following recommendations of the FOCUS surface water workgroup in a stepwise approach.

The application framework for Oxamyl 10GR included in-furrow application to potatoes at 1 × 1000 g a.s./ha, in-furrow application to tobacco at 1 × 3000 g a.s./ha, and broadcast application to tobacco at 1 × 5500 g a.s./ha.

FOCUS Step-1 and Step 2:

The calculations started at Steps 1 and 2 for oxamyl and its metabolites IN-A2213, IN-D2708, IN-N0079, and IN-T2921. The endpoints chosen for these calculations were based on the recommendations of the FOCUS workgroup. Geometric mean $DegT_{50}$ derived from the laboratory aerobic degradation studies and geometric mean of OC-normalised sorption coefficients were taken forward where possible.

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

The assumptions at Step 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-2 calculation of PEC surface water (PEC_{sw}), and PEC sediment (PEC_{sed}) are presented in DuPont-40859 EU, summarized in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10GR, DuPont-40953 EU.

A summary of the FOCUS Steps 1 and 2 predicted environmental concentrations for Oxamyl 10GR and metabolites for the purposes of calculating toxicity exposure ratios for aquatic species is provided in Table 47.

Table 47 Worst-case Step 1 and 2 calculations for oxamyl and its metabolites for field use in tobacco (1 × 5500 g a.s./ha).

	Step 1		Step 2 Southern Europe Mar-May	
Compound	**PEC_{sw} (µg/L)**	**PEC_{sed} (µg/kg)**	**PEC_{sw} (µg/L)**	**PEC_{sed} (µg/kg)**
Oxamyl	1860.000	200.888	444.792	48.848
IN-A2213	722.816	44.537	72.358	4.285
IN-D2708	782.017	71.326	207.819	18.953
IN-N0079	95.341	4.428	12.264	0.464
IN-T2921[a]	112.256	-	26.845	-

[a] The results represent predicted concentrations of IN-T2921 after formation in the water body. The PEC_{sw} were calculated from the maximum PEC_{sw} of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

FOCUS Step-3:

The calculations were further refined at Steps 3 and 4 for the parent compound only.

At Step 3a, all proposed oxamyl uses were considered in simulations employing conservative parameterisation. For open field uses, dust drift was considered based on the worst-case estimates provided in EFSA (2004). A conservative parameterisation of the "application method", CAM and DEPI parameters was taken forward in modelling.

At Step 3b, further refinements were considered for the open field uses. The drift entries into surface water were refined based on the evidence from the field studies. The simulations were performed for the in-furrow applications to potatoes and tobacco.

At Step 3c, a further refinement was introduced for the oxamyl application to potato to reflect a more realistic distribution of the parent compound in soil. Step 3b parameterisation with the CAM value of 5 was employed in simulations. Only R scenarios were considered in simulations.

At Step 4a, a vegetation filter strip (VFS) of 10 m was introduced to the potato R3 stream scenario. The simulation was based on Step 3c results.

At Step 4b, no-spray zones (NSZ) were introduced to estimate oxamyl concentrations following application to tobacco at 1 × 5500 g a.s./ha. The simulations were based on Step 3a results. The reduction of drift loadings with distance was assumed to be the same as that of spray application. NSZ of 10, 20, and 25 m were simulated.

Results of Steps 3 to Step 4 for oxamyl applications to potatoes and tobacco are presented in Table 48 to Table 50.

Table 48 Summary of maximum Step 3a, Step 3b, Step 3c, and Step 4a PEC_{sw} and PEC_{sed} values for oxamyl following application to potatoes at 1 × 1000 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sw} Caused by	Maximum PEC_{sed} (µg/kg ds)
Step 3a			
D3, ditch	4.895	Drift	0.404
D4, pond	0.151	Drift	0.068
D4, stream	4.390	Drift	0.293
D6, ditch	4.851	Drift	0.333
D6, ditch	4.944	Drift	0.544
R1, pond	0.150	Drift	0.035
R1, stream	3.623	Drift	0.287
R2, stream	4.797	Drift	0.309
R3, stream	48.786	Run-off	2.761
Step 3b			
D3, ditch	0.001	Drainage	0.001
D4, pond	0.121	Drainage	0.053
D4, stream	0.737	Drainage	0.289
D6, ditch	2.080	Drainage	0.306
D6, ditch	0.707	Drainage	0.128
R1, pond	0.020	Run-off	0.004
R1, stream	3.601	Run-off	0.273
R2, stream	3.096	Run-off	0.300
R3, stream	48.786	Run-off	2.714
Step 3c			
R1, pond	0.001	Run-off	<0.001
R1, stream	0.263	Run-off	0.021
R2, stream	0.201	Run-off	0.021
R3, stream	3.120	Run-off	0.184
Step 4a, 10 m VFS			
R3, stream	1.425	Run-off	0.087

Table 49 Summary of maximum Step 3b PEC_{sw} and PEC_{sed} values for oxamyl following application to tobacco at 1 × 3000 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sw} Caused by	Maximum PEC_{sed} (µg/kg ds)
Step 3a			
R3, stream	15.376	Drift	0.853
Step 3b			
R3, stream	1.941	Run-off	0.200

Table 50 Summary of maximum Step 3a and Step 4b PEC_{sw} and PEC_{sed} values for oxamyl following application to tobacco at 1 × 5500 g a.s./ha

Scenarios	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sw} Caused by	Maximum PEC_{sed} (µg/kg ds)
Step 3a			
R3, stream	28.189	Drift	1.543
Step 4b, 10 m NSZ			
R3, stream	5.459	Drift	0.310
Step 4b, 20 m NSZ			
R3, stream	2.838	Drift	0.210
Step 4b, 25 m NSZ			
R3, stream	2.291	Drift	0.207

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 51). At FOCUS Step 2, the TER_a value for Oxamyl 10GR is below the Regulation (EC) 546/2011 trigger level of 100 for acute exposure indicating a need for further refinement. At FOCUS Step 2, the TER_a value for the metabolites IN-A2213, IN-D2708, and IN-N0079 are above the Regulation (EC) 546/2011 trigger level of 100 for acute exposure indicating safe use.

At FOCUS Step 3a for acute exposure in tobacco, the TER_a values for Oxamyl 10GR are above the Regulation (EC) 546/2011 VI trigger level of 100, indicating safe use (Table 52). At FOCUS Step 3a for acute exposure in potatoes, the TER_a values are above the Regulation (EC) 546/2011 trigger level of 100 for all scenarios except R3 stream, indicating a need for further refinement (Table 53). At FOCUS Step 4a for acute exposure in potatoes, the TER_a value is above the Regulation (EC) 546/2011 VI trigger level of 100 for the R3 stream, indicating safe use with the mitigation of a 10 m vegetative filter strip It can be concluded that the proposed applications of Oxamyl 10GR pose low acute risks to fish.

Table 51 Worst-case fish acute toxicity exposure ratios (TER_a) for Oxamyl 10GR and its major metabolites based on initial PECs from applications to tobacco (FOCUS step 2 modelling)

Compound	Maximum PEC_{sw} (µg/L)	Fish LC_{50} (µg/L)	Fish acute TER	Trigger
Tobacco, 5500 g a.s./ha				
Oxamyl	444.792	3130	7.54	100
IN-A2213	72.358	>132000	1824	100
IN-D2708	207.819	93800 (supportive information)	451	100
IN-N0079	12.264	22400	1826	100
IN-T2921	26.845	>127000	4731	100

Table 52 Refined fish acute toxicity exposure ratios (TER_a) for Oxamyl 10GR based on initial PECs from applications to tobacco (FOCUS step 3a modelling)

Scenario	Maximum PEC_{sw} (µg/L)	Fish LC_{50} (µg/L)	Fish acute TER	Trigger
Tobacco, 1 × 3000 g a.s./ha				
R3, stream	15.376	3130	206	100
Tobacco, 1 × 5500 g a.s./ha				
R3, stream	28.189	3130	112	100

Table 53 Refined fish acute toxicity exposure ratios (TER_a) for Oxamyl 10GR based on initial PECs from applications to potatoes (FOCUS step 3a modelling)

Scenario	Maximum PEC_{sw} (µg/L)	Fish LC_{50} (µg/L)	Fish acute TER	Trigger
Potatoes, 1 × 1000 g a.s./ha				
D3, ditch	4.895	3130	646	100
D4, pond	0.151		20927	100
D4, stream	4.390		720	100
D6, ditch	4.851		651	100
D6, ditch	4.944		639	100
R1, pond	0.150		21067	100
R1, stream	3.623		872	100
R2, stream	4.797		659	100
R3, stream	48.786		65	100

RMS: For the acute risk to fish, the applicant has not used the PEC at FOCUS step 3c to refine the risk and calculated the mitigation measure directly with the FOCUS Step 4a modelling, The RMS, consistently with what was done for other organisms, used the PEC calculated at FOCUS step 3c, which resulted wel above the trigger.

Table 54 Refined fish acute toxicity exposure ratios (TER_a) for Oxamyl 10GR based on PECs from applications to potatoes (FOCUS Step 3c modelling)

Scenario	PEC_{sw} (µg/L) FOCUS Step 3c	Fish LC_{50} (µg/L)	Fish acute TER	Trigger
Potatoes 1 × 1000 g a.s./ha				
R3 Stream	3.120	3130	997	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). At FOCUS Step 2, the TER_{lt} value does not exceed the Regulation (EC) 546/2011 trigger level of 10 for long-term exposure indicating a need for further refinements. At FOCUS Step 3a for chronic exposure after application to tobacco, the TER_a values for Oxamyl 10GR are above the Regulation (EC) 546/2011 VI trigger level of 10, indicating safe use (Table). For potato, the scenario

R3 stream requires refinement. It can be concluded that the proposed applications of oxamyl 10GR pose low chronic risks to fish.

Table 55 Worst-case fish chronic toxicity exposure ratios (TER_{lt}) for Oxamyl 10GR based on initial PECs from applications to tobacco (FOCUS step 2 modelling)

Compound	PEC_{sw} (µg/L)	Fish NOEC (µg/L)	Fish chronic TER	Trigger
Tobacco, 1 × 5500 g a.s./ha				
Oxamyl	444.792	356	0.8	10

Table 56 Refined fish chronic toxicity exposure ratios (TER_a) for Oxamyl 10GR based on initial PECs from applications to potatoes (FOCUS Step 3a modelling)

Scenario	Maximum PEC_{sw} (µg/L)	Fish NOEC (µg/L)	Fish acute TER	Trigger
Potatoes, 1 × 1000 g a.s./ha				
D3, ditch	4.895	356	73	10
D4, pond	0.151		2357	10
D4, stream	4.390		81	10
D6, ditch	4.851		73	10
D6, ditch	4.944		72	10
R1, pond	0.150		2373	10
R1, stream	3.623		98	10
R2, stream	4.797		74	10
R3, stream	48.786		7.3	10
Tobacco, 1 × 3000 g a.s./ha				
R3 Stream	15.376	356	23	10
Tobacco, 1 × 5500 g a.s./ha				
R3 Stream	28.189	356	13	10

Table 57 Refined fish chronic toxicity exposure ratios (TER_a) for Oxamyl 10GR based on initial PECs from applications to potatoes (FOCUS Step 3c modelling)

Scenario	PEC_{sw} (µg/L)	Fish NOEC (µg/L)	Fish chronic TER	Trigger
Potatoes 1 × 1000 g a.s./ha				
R3 Stream	3.120	356	114	10

RMS conclusion for fish: for all the uses proposed the acute and chronic toxicity to fish are acceptable.

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 (58). The Tier 1 regulatory acceptable concentration (RAC_{sw}) for aquatic invertebrates is 3.19 µg a.s./L. The FOCUS Step 2 PEC_{sw} value for Oxamyl 10GR is above the RAC_{sw} for acute exposure indicating a need for refinement.

The FOCUS Step 2 TER_a values for the water metabolites IN-A2213, IN-D2708, IN-N0079, and IN-T2921 are above the Regulation (EC) 546/2011 trigger level of 100 for acute exposure indicating safe use.

Table 58 Worst-case *Daphnia* acute toxicity exposure ratios (TER_a) for Oxamyl 10GR and its major metabolites based on Initial PECs from applications to tobacco or potatoes (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	*Daphnia* EC_{50} (µg a.s./L)	*Daphnia* acute TER	Trigger
Tobacco 1× 5500 g a.s./ha				
Oxamyl	444.792	319	0.72	100
IN-A2213	72.358	>125000	1728	100
IN-D2708	207.819	>134000	645	100
IN-N0079	12.264	>128000	10437	100
IN-T2921	26.845	>123000	4582	100

The Tier 2 refinements may be introduced on the basis of additional laboratory toxicity tests.

At Tier 2a, a geomean assessment factor approach may be implemented. The geomean EC_{50} value of 8 aquatic invertebrate endpoints summarized in Table is 115.6 µg as./L. The Tier 2a assessment factor is 100, thus the Tier 2a RAC_{sw} is 1.15 µg a.s./L, which is lower than the Tier 1 RAC_{sw} and does not reflect the increased certainty associated with a larger data set to characterize effects to aquatic invertebrates.

Table 59 Oxamyl aquatic toxicity endpoint values

Species	Test/duration	Measurement endpoint	Endpoint value (µg a.s./L)	Reference[a]
Chironomus tentans	acute (48 h)	EC_{50}	350	DuPont-37400
Hyalella azteca	acute (48 h)	EC_{50}	320	DuPont-37397
Daphnia magna	acute (48 h)	EC_{50}	319	DuPont-2553
Chimarra atterima	acute (48 h)	EC_{50}	96	DuPont-37402
Ceriodaphnia dubia	acute (48 h)	EC_{50}	94	DuPont-37399
Daphnia pulex	acute (48 h)	Not valid		DuPont-37398
Centroptilum triangulifer	acute (48 h)	EC_{50}	67	DuPont-37401
Americamysis bahia	acute (48 h)	EC_{50}	46.5	DuPont-34271

[a] All studies cited and summarized in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

At Tier 2b, a species sensitivity distribution approach may be implemented with the data in Table .

RMS: The Applicant has applied the SSD methodology, using 48 EC50 data (including the Daphnia pulex) and calculated a HC_5 =33.0 µg a.s./L with a lower confidence bound of 1.0 µg a.s./L and an upper confidence bound of 60.0 µg a.s./L.

The SSD approach is not acceptable because valid acute acute toxicity data are available only for 7 invertebrate species, hence the refined risk assessment proposed by the applicant is not reported here. In addition, based on several considerations for selection of an assessment factor, the Applicant proposed an AF=3, which is not agreed by the RMS, but not reported here because the SSD was not accepted.

Reliable acute toxicity data are available for 7 invertebrate species (the Daphnia pulex test is not valid), hence the SSD approach is not considered appropriate. Considering that data for 3 insect species and 4 crustacean species are available, the RMS calculated the geomean for this two groups, which resulted in 131.0 µg a.s./L and 145.3 µg a.s./L, for insect and crustacean, respectively. According to EFSA 2013 guidance, the lower geomean value should be taken together with an AF of 100. In the present case, the geomeans are lower then the EC 50 for *Daphnia magna* (319 µg a.s./L) as expected by the higher acute toxicity of the additional species tested, hence

using the EC 50 for Daphnia magna with an AF of 100 is considered adequate to cover the more sensitive species (7.5 is the ratio between lower and higher EC50 value).

The risk assessment carried out by the RMS and the refinement using the Step 3a-c and Step 4 PECsw are reported in the tables below.

It is concluded that the uses of Oxamyl 10GR in Potatoes 1 × 1000 g a.s./ha and Tobacco, 1 × 3000 g a.s./ha are safe upon acute exposure without the implementation of mitigation measures, while use in Tobacco broadcast at 1 × 5500 g a.s./ha requires the application of a 20m NSZ in order to achieve an acceptable risk.

Table 607 Refined *Daphnia* acute risk assessment for Oxamyl 10GR based on initial PECs from applications to tobacco or potatoes (FOCUS step 3a modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	EC 50 *Daphnia magna* (µg a.s./L)	Assessment Factor	Regulatory Acceptable Concentration (µg a.s./L)
Tobacco, 1 × 3000 g a.s./ha				
R3 stream	15.376	319	100	3.19
Tobacco 1 × 5500 g a.s./ha				
R3 stream	28.189	319	100	3.19
Potatoes 1 × 1000 g a.s./ha				
D3, ditch	4.895	319	100	3.19
D4, pond	0.151	319	100	3.19
D4, stream	4.390	319	100	3.19
D6, ditch	4.851	319	100	3.19
D6, ditch	4.944	319	100	3.19
R1, pond	0.150	319	100	3.19
R1, stream	3.623	319	100	3.19
R2, stream	4.797	319	100	3.19
R3, stream	48.786	319	100	3.19

Table 61 Refined *Daphnia* acute toxicity risk assessment for Oxamyl 10GR based on initial PECs from applications to tobacco or potatoes (FOCUS step 3b modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	*EC 50 Daphnia magna* (µg a.s./L)	Assessment Factor	Regulatory Acceptable Concentration (µg a.s./L)
Tobacco, 1 × 3000 g a.s./ha				
R3 stream	1.941	319	100	3.19
Potatoes 1 × 1000 g a.s./ha				
D3, ditch	0.001	319	100	3.19
D4, stream	0.737	319	100	3.19
D6, ditch	2.080	319	100	3.19
D6, ditch	0.707	319	100	3.19
R1, stream	**3.601**	**319**	**100**	**3.19**
R2, stream	3.096	319	100	3.19
R3, stream	**48.786**	**319**	**100**	**3.19**

Table 62 Refined *Daphnia* acute risk assessment for Oxamyl 10GR based on initial PECs from applications to potatoes (FOCUS step 3c modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	EC 50 *Daphnia magna* (µg a.s./L)	Assessment Factor	Regulatory Acceptable Concentration (µg a.s./L)
Potatoes 1 × 1000 g a.s./ha				
R1, stream	0.263	319	100	3.19
R3, stream	3.120	319	100	3.19

Table 63 Refined *Daphnia* acute risk assessment (RAC_{sw}) for Oxamyl 10GR based on initial PECs from applications to tobacco 1 × 5500 g a.s./ha (FOCUS step 4b modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	EC 50 *Daphnia magna* (µg a.s./L)	Assessment Factor	Regulatory Acceptable Concentration (µg a.s./L)
Tobacco 1 × 5500 g a.s./ha				
R3, stream, 20 m NSZ	2.838	319	100	3.19

TER_{lt} for *Daphnia*

On the basis of the worst-case toxicity values and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for long-term exposure of aquatic invertebrates *(Daphnia magna)* oxamyl or IN-D2708 were calculated (Table). The TER_{lt} value for oxamyl is below the Regulation (EC) 546/2011 trigger level of 10 for long-term exposure indicating a need for refinements, which are presented in Table 65 through Table 9.

It can be concluded that the proposed applications of Oxamyl 10GR pose low chronic risks to *Daphnia* provided that a 25 m NSZ is implemented .

Table 64 Worst-case *Daphnia* chronic aquatic toxicity exposure ratios (TERs) for Oxamyl 10GR and its residual major metabolite based on initial PECs from applications to tobacco (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
Tobacco 1 × 5500 g a.s./ha				
Oxamyl	444.792	26.8	0.06	10
IN-D2708	207.819	66100	318.07	10

Table 65 Refined *Daphnia* chronic toxicity exposure ratios (TER_{lt}) for Oxamyl 10GR based on initial PECs from applications to tobacco or potatoes (FOCUS Step 3a modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	*Daphnia* NOEC (µg a.s./L)	*Daphnia* chronic TER	Trigger
Tobacco, 1 × 3000 g a.s./ha				
R3, stream	15.376	26.8	**2**	10
Tobacco 1× 5500 g a.s./ha				
R3, stream	28.189	26.8	**0.9**	10
Potatoes 1 × 1000 g a.s./ha				
D3, ditch	4.895	26.8	**5**	10
D4, pond	0.151		177	10
D4, stream	4.390		**6**	10
D6, ditch	4.851		**6**	10
D6, ditch	4.944		**5**	10
R1, pond	0.150		179	10
R1, stream	3.623		**7**	10
R2, stream	4.797		**6**	10
R3, stream	48.786		**1**	10

Table 66 Refined *Daphnia* chronic toxicity exposure ratios (TER_a) for Oxamyl 10GR based on initial PECs from applications to tobacco or potatoes (FOCUS step 3b modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	*Daphnia* NOEC (µg a.s./L)	*Daphnia* chronic TER	Trigger
Tobacco, 1 × 3000 g a.s./ha				
R3 stream	1.941	26.8	14	10
Potatoes 1 × 1000 g a.s./ha				
D3, ditch	0.001	26.8	26800	10
D4, stream	0.737	26.8	36	10
D6, ditch	2.08	26.8	13	10
D6, ditch	0.707	26.8	38	10
R1, stream	3.601	26.8	**7**	10
R2, stream	3.096	26.8	**9**	10
R3, stream	48.786	26.8	**1**	10

Table 67 Refined *Daphnia* chronic toxicity exposure ratios (TER_a) for Oxamyl 10GR based on initial PECs from applications to potatoes (FOCUS step 3c modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	*Daphnia* NOEC (µg a.s./L)	*Daphnia* chronic TER	Trigger
Potatoes 1 x 1000 g a.s./ha				
R1, stream	0.263	26.8	101	10
R2, stream	0.201	26.8	133	10
R3, stream	3.12	26.8	**8.5**	10

Table 68 Refined *Daphnia* chronic toxicity exposure ratios (TER_a) for Oxamyl 10GR based on initial PECs from applications to potatoes (FOCUS step 4a modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	*Daphnia* NOEC (µg a.s./L)	*Daphnia* chronic TER	Trigger
Potatoes 1 × 1000 g a.s./ha				
R3, stream, 10 m NSZ	1.425	26.8	19	10

Table 69 Refined *Daphnia* chronic toxicity exposure ratios (TER_a) for Oxamyl 10GR based on initial PECs from applications to Tobacco, 1 × 5500 g a.s./ha (FOCUS Step 4b)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	*Daphnia* NOEC (µg a.s./L)	*Daphnia* chronic TER	Trigger
Tobacco, 1 × 5500 g a.s./ha				
R3, stream, 25 m NSZ	2.291	26.8	12	10

TER_a for an aquatic insect species

Oxamyl 10GR is a nematicide and is not a growth regulator. The acute toxicity of oxamyl a.s. to aquatic insect species was determined in multiple species; studies are summarized in the Oxamyl dRAR a.s. Vol 3 B). It can be concluded that the proposed applications of Oxamyl 10GR 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 2 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-CA, Section 7, DuPont-40934 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 10GR 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 worst-case toxicity value and the relevant worst-case PEC_{sw} values, toxicity exposure ratios for acute exposure of aquatic invertebrates *(Daphnia magna)* were calculated (Table). The TER_a value for oxamyl is below the Regulation (EC) 546/2011 trigger level of 100 for acute exposure indicating a need for refinements, which are presented in the section above for *Daphnia* higher tier refinements. It can be concluded that the proposed applications of Oxamyl 10GR pose low acute risk to aquatic crustaceans. For use in tobacco broadcast 1 x 5500 g a.s./ha mitigation measures should be implemented.

Table 70 Worst-case aquatic crustacean acute toxicity exposure ratios (TERs) for Oxamyl 10GR based on initial PECs from applications to tobacco (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	Mysid EC_{50} (µg a.s./L)	Mysid acute TER	Trigger
Tobacco, 1 × 5500 g a.s./ha				
Oxamyl	444.792	46.5	0.1	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 10GR poses low acute risk to aquatic invertebrates. In addition, this data point is not relevant since Oxamyl 10GR is not intended for use directly on surface waters. It can be concluded that the proposed applications of Oxamyl 10GR 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 10GR poses low chronic risk to aquatic invertebrates. In addition, this data point is not relevant since Oxamyl 10GR is not intended for use directly on surface waters. It can be concluded that the proposed applications of Oxamyl 10GR pose low chronic risk to aquatic gastropods.

TER_{lt} for algae

RMS: After reevaluation of the algae studies by the RMS according to current OECD guideline, reliable data for both the active substance oxamyl and for Oxamul 10GR are not available and a data gap has been identified. For the metabolites, only for IN-T2921 reliable data are available, for IN-A2213 the study provided supportive information. For the metabolites IN-D2708 and IN-N0079, a data gap has been concluded.

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 for these two metabolites (Table 71). The FOCUS Step 2 TER_a values for the water metabolites IN-A2213, and IN-T2921 are above the Regulation (EC) 546/2011 trigger level of 10 indicating safe use.

For oxamyl and metabolites IN-D2708 and IN-N0079, a data gap is concluded, hence the risk assessment proposed by the Applicant has not been presented here.

Table 71 Worst-case algae chronic toxicity exposure ratios (TERs) for Oxamyl 10GR and its major metabolites based on initial PECs from applications to tobacco (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	Algae EC_{50} (µg a.s./L)	Algae TER_{lt}	Trigger
Tobacco, 1 × 5500 g a.s./ha				
Oxamyl	444.792	Data gap		10
Oxamyl 10GR		Data gap		
IN-A2213	72.358	>122000 Supportive information	1686	10
IN-D2708	207.819	Data gap		10
IN-N0079	12.264	Data gap		10
IN-T2921	26.845	>113000	4209	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).

Table 72 Worst-case *Lemna* toxicity exposure ratios (TERs) for Oxamyl 10GR and its major metabolites based on initial PECs from applications to tobacco (FOCUS step 2 modelling)

Compound	Initial PEC_{sw} (µg a.s./L)	*Lemna* EC_{50} (µg a.s./L)	*Lemna gibba* TER	Trigger
Tobacco, 1 × 3000 g a.s./ha (in furrow)				
Oxamyl	242.61	3300	13.6	10
Tobacco 1× 5500 g a.s./ha (broadcast)				
	444.79	3300	**7.4**	10
Potatoes 1 × 1000 g a.s./ha				
	80.87	3300	40.8	10

The calculated TER values indicate an acceptable risk for use in tobacco, 1 × 3000 g a.s./ha (in furrow) and potatoes 1 x 1000 g a.s./ha, while a potential risks arise for *Lemna gibba* upon use in Tobacco 1× 5500 g a.s./ha (broadcast). As a result, for the latter use, PEC_{sw} values for oxamyl a.s. were further refined using FOCUS Step-3 modelling. These results are shown in Table 73. The calculated Step-3 PEC_{sw} values resulted in acceptable TER values for Oxamyl 10GR for *Lemna*. The TER values for Oxamyl 10GR exceed the Regulation (EC) 546/2011 trigger levels of 10 for long-term exposure indicating that the proposed applications of Oxamyl 10GR pose low risk to macrophytes for all the proposed uses.

Table 73 Refined *Lemna* chronic toxicity exposure ratios (TERs) for Oxamyl 10GR based on initial PECs from applications to tobacco or potatoes (FOCUS step 3a modelling)

FOCUS Scenario	Initial PEC_{sw} (µg a.s./L)	*Lemna* EC_{50} (µg a.s./L)	*Lemna* chronic TER	Trigger
Tobacco 1× 5500 g a.s./ha				
R3, stream	28.189	3300	117	10

RMS conclusion for the aquatic organisms Fish: for all the proposed uses the acute and chronic risk is acceptable based on the refined PEC values calculated at FOCUS step a-c

Invertebrates:

Acute risk - based on the *Daphnia magna* EC50 = 319 µg a.s./L, it is concluded that the uses of Oxamyl 10GR in Potatoes 1 x 1000 g a.s./ha and Tobacco, 1 x 3000 g a.s./ha are safe upon acute exposure without the implementation of mitigation measures, while use in Tobacco broadcast at 1 x 5500 g a.s./ha requires the application of a 20m NSZ in order to achieve an acceptable acute risk.

The acute riskt o *Daphnia magna* is considered to cover also the risk to the other (most sensitive) invertebrate species for which data are available.

Chronic risk - The chronic risk *Daphnia magna* is acceptable for use in Tobacco, 1 x 3000 g a.s./ha g a.s./ha. For use in Potatoes 1 x 1000 g a.s./ha, a NSZ of 10 m should be implemented. For use in Tobacco broadcast 1 x 5500 g a.s./ha, a NSZ of 25 m is needed to achieve an acceptable chronic risk.

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

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

B.9.5 Effects on arthropods

B.9.5.1 Effects on bees

Toxicity endpoints

Summaries of the acute and chronic toxicity endpoints of the active substance oxamyl and Oxamyl 10GR are provided in Table 74 and Table 75, respectively.

Table 74 Toxicity endpoint values for honeybees (*Apis mellifera*) and bumblebees (*Bombus terrestris*) exposed to oxamyl (technical)

Species/life stage	Test/duration	Measurement endpoint	Endpoint value	Reference[a]
Honeybees, adult	Oral 48 h	LD_{50}	0.38 µg a.s./bee	DuPont-2740
	Contact 48 h	LD_{50}	0.47 µg a.s./bee	
Bumblebees, adult	Oral 48 h	LD_{50}	0.36 µg a.s./bee	DuPont-39670
	Contact 48 h	LD_{50}	39.3 µg a.s./bee	
Honeybees, adult	Oral 10 days	LDD_{50}	0.14 µg a.s./bee/day	DuPont-39665
Honeybees, larva	Larval stage, 7 days	LD_{50}	0.81 µg/larva	DuPont-39678

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

Table 75 Toxicity endpoint values for honeybees (*Apis mellifera*) and bumblebees (*Bombus terrestris*) exposed to Oxamyl 10GR

Species/life stage	Test/duration	Measurement endpoint	Endpoint value	Reference[a]
Apis mellifera colony	Semi-field 30 days exposed to treated *Phacelia tanacetifolia* **Not reliable**			DuPont-39667
Bombus terrestris colony	Semi-field 30 days exposed to treated *Solanum tuberosum* **Valid only for residues**			DuPont-39666

[a] Studies summarised in this document

Hazard quotients for bees and bumblebess

The decision making criterion oral and contact hazard quotient, Q_{HC} and Q_{HO}, were calculated as

Q_{HO} = application rate/oral LD_{50}.
Q_{HC} = application rate/Contact LD_{50}.

Oral exposure Q_{HO}

The hazard quotient for oral exposure of honeybees and bumblebees based on the maximum recommended field use rate and acute oral toxicity is presented in Table 76.

Table 76 Oral toxicity of Oxamyl 10GR to honeybees (*Apis mellifera*) and bumblebees (*Bombus terrestris*)

Species	Exposure route	Application rate (g a.s./ha)	LD_{50} (µg a.s./bee)	Hazard quotient (Q_{HO})
Honeybees	Oral	5500	0.38	**14500**
Bumblebees			0.36	**15300**

Values in bold are above the relevant trigger.

Contact exposure Q_{HC}

The hazard quotient for contact exposure of honeybees and bumblebees based on the maximum recommended field use rate and acute contact toxicity is presented in Table 877.

Table 8 Contact toxicity of Oxamyl 10GR to honeybees (*Apis mellifera*) and bumblebees (*Bombus terrestris*)

Species	Exposure route	Application rate (g a.s./ha)	LD_{50} (µg a.s./bee)	Hazard quotient (Q_{HC})
Honeybees	Contact	5500	0.47	**11700**
Bumblebees			39.3	**140**

Values in bold are above the relevant trigger.

The hazard quotients, Q_{HC} and Q_{HO}, for Oxamyl 10GR were each above the decision-making criterion of 50, and therefore risk of Oxamyl 10GR is to be assessed based on a realistic to worst-case exposure.

Exposure

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

According to the **EPPO 2010 scheme**[1]**,** the main route of exposure to soil treatments is oral through the consumption of contaminated pollen and nectar. Therefore, potential exposure of bees may either occur through residues in pollen and nectar of plants growing in the field after soil application or *via* residues on plants in the field margin contaminated by dust drift during application.

A worst-case of potential exposure *via* residues in pollen and nectar of plants in soil treated fields can be estimated based on the default worst-case value of 1 mg a.s./kg (see EPPO 2010 scheme, Note 6), based on a database of measured values from aerial plant parts as a surrogate for nectar and pollen. The default residues can then be combined with a measure of consumption in order to estimate the exposure to adult and larval pollinators. Worst-case data from EFSA opinion (2012)[2] have been used estimating maximum food consumption of bumblebees at 149 mg per bumblebee per day. Worst-case data from Rortais *et al.*, 2005 have been used as proposed in the EPPO scheme estimating the consumption of honeybee larvae and adults at 98.2 mg sugar/larva/developmental period and 128 mg nectar/adult honeybee/day. The results of oral in-field exposure are presented in Table 78.

1 EPPO/OEPP (2010) Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(3)). Bulletin OEPP/EPPO Bulletin 40: 323-331.

2 EFSA (2012) Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp., and solitary bees). EFSA Journal 10(5): 2668.

Table 78 Oral exposure of Oxamyl 10GR to honeybees (*Apis mellifera*) and bumblebees (*Bombus terrestris*) in soil treated fields

Species	Application rate (kg a.s./ha)	Generic RUD[a] (mg a.s./kg plant matrix)	Residue levels in pollen and nectar (µg a.s./mg)	Food consumption	Exposure
Honeybees, adult	5.5	1.0	0.0055	128 mg/bee/day[b]	0.704 µg a.s./bee/day
Honeybees, larva				98.2 g/larva/dev.[b]	0.540 µg a.s./larva/dev.
Bumblebees, adult				149 mg/bee/day[c]	0.820 µg a.s./bee/day

[a] at soil treatment rate of 1 kg a.s./ha (EPPO 2010)

[b] estimated from EPPO (2010) Rortais *et al.* (2005)

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

The amount of dust-drift reaching the off-crop habitat is calculated using dust drift values provided by EFSA (2004)[3], in accordance with PEC_{sw} calculations (see the Oxamyl 10GR dRAR Vol 3 B8.). For broadcast granular application, a maximum of 1.49% of the application rate was assumed to reach off-crop areas at 1 m from the edge of the crop (worst-case scenario). In-furrow application to potato and tobacco is performed during transplanting and dust development is not expected to occur for this application method as demonstrated by a field study (DuPont–38691 EU, summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 6, DuPont-40933 EU). Contact exposure is considered to occur directly to dust particles. Oral exposure is considered to occur by consumption of contaminated pollen and nectar in the off-crop and can be estimated by the combination of off-field PER and food consumption by the pollinators using the figures described above. The results of off-field exposure are presented in Table 79 and Table 80.

Table 79 Drift of Oxamyl 10GR into field margins

Application rate (g a.s./ha)	Drift rate (%/100)	Off-field PER (g a.s./ha)
5 500	0.0149	81.95

Table 80 Oral exposure of Oxamyl 10GR to honeybees (*Apis mellifera*) and bumblebees (*Bombus terrestris*) in field margins after dust drift

Species	Off-field PER (kg a.s./ha)	Generic RUD[a] (mg a.s./kg plant matrix)	Residue levels in pollen and nectar (µg a.s./mg)	Food consumption	Exposure
Honeybees, adult	0.08195	1.0	0.00008195	128 mg/bee/day[b]	0.0105 µg a.s./bee/day
Honeybees, larva				98.2 mg/larva/dev.[b]	0.00805 µg a.s./larva/dev.
Bumblebees, adult				149 mg/bee/day[c]	0.0122 µg a.s./bee/day

[a] residue unit dose at soil treatment rate of 1 kg a.s./ha (EPPO 2010)

[b] estimated from EPPO (2010) Rortais *et al.* (2005)

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

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

Risk assessment

The EPPO 2010 scheme proposes a trigger of 10 for assessment of the acute risk to bees and a trigger of 1 for the assessment of chronic risk to bees. Resulting TER values are presented in the Table 81.

Table 81 TER for soil treatment of Oxamyl 10GR

Species	Exposure scenario	Exposure route	Endpoint	Exposure	TER	EPPO trigger
Honeybees, adult	Plants in soil treated field	Oral acute	0.38 µg a.s./bee	0.704 µg a.s./bee/day	**0.54**	≥10
Honeybees, adult		Oral chronic	0.14 µg a.s./bee/day	0.704 µg a.s./bee/day	**0.20**	≥1
Honeybees, larva		Oral chronic	0.81 µg/larva	0.540 µg a.s./larva/dev.	1.5	≥1
Bumblebees, adult		Oral acute	0.36 µg a.s./bee	0.820 µg a.s./bee/day	**0.44**	≥10
Honeybees, adult	Dust drift in field margin	Oral acute	0.38 µg a.s./bee	0.0105 µg a.s./bee/day	36	≥10
Honeybees, adult		Oral chronic	0.14 µg a.s./bee/day	0.0105 µg a.s./bee/day	13	≥1
Honeybees, larva		Oral chronic	0.81 µg/larva	0.00805 µg a.s./larva/dev.	101	≥1
Bumblebees, adult		Oral acute	0.36 µg a.s./bee	0.0122 µg a.s./bee/day	29	≥10

Values in bold are below the relevant trigger.

The TER values for risk in the field margin are above the relevant trigger of 10 (acute) and 1 (chronic), respectively, indicating acceptable risk during application. However, the TER values for plants in soil treated field are below the relevant trigger for adult honeybees and bumblebees indicating potential acute and chronic risk to bees foraging on crops in soil-treated fields. A risk refinement for the in-field scenario is given below.

Refinement (proposed by the Applicant, see comment of the RMS below)

Honeybees and bumblebees were investigated in tunnel tests for effects of Oxamyl 10GR according to OECD guidance document No. 75 (2007) (studies DuPont-39667 and DuPont-39666, summarised in this document). The following conclusions were drawn based on the findings of these studies:

- No negative effect on honeybees of in-furrow (3 kg oxamyl a.s./ha, equivalent to 8.625 kg a.s./ha within the furrows with an inter-row space of 18 cm)) or broadcast applications (5.5 kg oxamyl a.s./ha) of Oxamyl 10GR as a granular application during the seeding of *Phacelia tanacetifolia* on mortality, flight intensity, behaviour, colony size, or colony condition. The termination rates, brood indices, and compensation indices of the individually marked cells in the Oxamyl 10GR treatments were on the same level as the control (DuPont-39667).

- In the *Phacelia tanacetifolia* nectar samples taken from the forager honeybees, a maximum value of 0.082 mg oxamyl/kg was found after in-furrow application of 8.625 kg a.s./ha. A maximum value of 0.049 mg oxamyl/kg could be found in the pollen samples taken from the forager honeybees after in-furrow application, whereas a maximum value of 0.505 mg oxamyl/kg could be found in the *Phacelia tanacetifolia* flower samples after broadcast application of 5.5 kg a.s./ha (DuPont-39667).

- No negative effect on bumblebees was observed on mortality, flight intensity, condition of colonies, and behaviour compared to the control when Oxamyl 10GR was applied once during planting of *Solanum tuberosum* up to an application rate of 3.5 kg oxamyl a.s./ha (DuPont-39666).

- In the *Solanum tuberosum* pollen samples taken from the forager bumblebees, a maximum value of 0.008 mg oxamyl/kg was found; and in the flower samples, a maximum value of 0.019 mg oxamyl/kg could be found in the treatment group of 3.5 kg oxamyl a.s./ha (DuPont-39666).

Thus, these two tunnel tests indicate no unacceptable risk to honeybees and bumblebees after oral exposure to Oxamyl 10GR according to the proposed use pattern of in-furrow applications during planting and transplanting at 3 kg a.s./ha (equivalent to 8.625 kg a.s./ha within the furrows).

With respect to the pre-planting broadcast application at 5.5 kg a.s./ha in tobacco, only the tunnel test with honeybees on *Phacelia tanacetifolia* sufficiently demonstrate a low risk to forager bees in soil-treated field (DuPont-39667). However, this study revealed a maximum residue level of 0.505 mg a.s./kg plant matrix (= 0.000505 µg a.s./mg plant matrix) in the flower samples. This substance-specific figure can be used to replace the generic RUD and allows a refined exposure realistic to worst-case in combination with feed consumption estimate of the bumblebees. The resulting TER value for bumblebees is presented in Table 82.

Table 82 Refined oral exposure of Oxamyl 10GR to bumblebees (*Bombus terrestris*) in soil-treated field.

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

Values in bold are below the relevant trigger

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

The TER value of 4.8 is still below the relevant trigger of 10 indicating a potential risk to bumblebees. Nevertheless, acute oral toxicity suggests that bumblebees are similarly sensitive to oxamyl as honeybees with acute oral LD_{50} values of 0.36 µg a.s./bumblebee and 0.38 µg a.s./honeybee, respectively. The tunnel test DuPont-39667 with honeybees exposed to residues after pre-planting broadcast application further demonstrates a low risk not only to honeybees but also to all other bees (including bumblebees) with a similar sensitivity to oxamyl. Based on these assumptions, a low risk can be concluded for honeybees and bumblebees according to the proposed use pattern of broadcast application in tobacco.

An additional margin of safety can be reached by the usual agricultural practice for tobacco where flower buds are removed or crops are harvested before flowering. Broadcast application in tobacco may be limited to uses considering this practice as risk mitigation measure.

Conclusion:

Considering a risk assessment using acute and chronic data of honeybees and bumblebees, Oxamyl 10GR poses no unacceptable risk to bees.

RMS comments and conclusion

Contact exposure: The refinement of risk assessment upon contact exposure to dust drift should be presented by the Applicant.

Dust drift: it is noted that for the risk assessement at field margin, the EFSA Guidance on risk assessment on bees (Appendix H, 2013) indicates a default dust deposition from granules of 3.2% for the assessment of the concentrations in nectar and pollen entering the hive and of 9.6% for the contact exposure assessment (subject to confirmation). These values are based on the same document cited by the Applicant (EFSA, 2004) but here the use of 1.49% drift for oral risk assessment was used in accordance with the assumption made in the PECsw calculation. The RMS highlights that using a dust drift of 3.2% instead of 1.5% would not change the conclusion of acceptable risk for field margin (see Table 81).

Food consumption:

According to EFSA (2013), the food consumption of honey bees larva is 149 mg/bee/day (sugar) + 30.3 mg/bee/day (pollen) and for adult bumble bees is 59.4 mg/larva/5 days (sugar) + 2 mg/larva/5 days (pollen). These values should be used in Tables 78 and 80.

Risk to boney bees:

-For dust drift in field margin, using the inputs indicated by the RMS above would not change the conclusion, which would remain acceptable (table 81).

-For plants in soil-treated field, the revised inputs indicated by the RSM would confirm unacceptable risk for oral acute and chronic exposure to adults and will show risk also for oral chronic exposure to larvae.

Refinement of risk in soil-treated field -

The semi-field study with honey bees exposed to *Phacelia tanacetifolia* treated with Oxamyl 10GR DuPont-39667) is judged not reliable (see RMS comments of the study summary). In addition, semi-field studies are considered of limited use against the protection goals identified in EFSA (2013), due to the limited size of colonies (overwintering information not recorded) and short duration (two brood cycles not covered).

Risk to bumble bees:

-For dust drift in field margin, using the inputs indicated above by the RMS would not change the conclusion, which would remain acceptable (table 81).

-For plants in soil-treated field, the use of the revised inputs indicated above by the RSM would be confirm the unacceptable risk for oral acute exposure to bumblebees (table 81).

Refinement of risk in soil treated field:

In-furrow application - The semi-field study with bumblebees (DuPont-39666) was judged not acceptable for the biological results. In addition, semi-field studies are considered of limited use against the protection goals identified in EFSA (2013), due to the limited size of colonies (overwintering information not recorded) and short duration (two brood cycles not covered). Anyhow data on residues from this study could be used for the risk refinement.

Broadcast application - The extrapolation of the results of the field test with honey bees to bumblebees, based on a similar acute sensitivity to oxamyl, is not straightforward because of the higher food consumption of bumble bees. The low risk to bumble bees is not demonstrated.

Following broadcast application in tobacco, mitigation measures such as those proposed by the Applicant should be implemented.**Conclusion: Although it is acknowledged that the EFSA Bee Guidance Document (2013) is not yet in force, it was agreed at the Pesticides Peer Review Expert Meeting 133 (September, 2015) that it should be used at least for the first tier scheme and the general principles for the higher tier.**

For both honey and bumble bees an acceptable risk is concluded for the scenario "dust drift in field margin" (TER to be recalculated). For the scenario "plants in soil-treated field" the risk to honey bees is unacceptable for oral acute and chronic exposure to adults and for oral chronic exposure to larvae, and the risk to bumblebees is unacceptable upon oral acute exposure. The refinements proposed by the Applicant are not acceptable.

For all the proposed uses, the Applicant should submit a revised risk assessment according to the EFSA Bee Guidance Document (2013) (for the first tier), taking into account the comments above.

B.9.5.1.1 Acute toxicity to bees

B.9.5.1.1.1 Acute oral toxicity to bees

A laboratory oral and contact toxicity test with oxamyl technical on honey bees and bumblebee was conducted. Summaries of these studies are given in the Oxamyl dRAR a.s. Vol 3 B9.

Study submitted in the EU Dossier in 2001 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)

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

Materials and methods:

Acute oral and contact toxicity of Oxamyl 10 SL to honey bees (*Apis mellifera* L.) were tested in a laboratory study conducted under EPPO Guideline No. 170. These tests were conducted with five test substance treatment rates (Oral & Contact: 0.1; 0.2; 0.4; 0.8 and 1.6 µg a.s./bee) plus a control (50% sucrose solution) and 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); five replicates per treatment and 10 Honey bees per replicate. Dimethoate ("Perfekthion", 395.7 g dimethoate/L) 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. . In the contact test bees were dosed with Oxamyl 10SL by topical application to the ventral thorax of each bee.

Following exposure to test substance, bees were provided with an aqueous 50% sucrose solution in both the oral and contact studiesBees were observed 2, 4, 24, and 48 hours after treatment for mortality and sublethal effects. Temperature and relative humidity were measured during the test.

Findings:

Actual test substance intake in the oral test and mortality results for both tests at 24 and 48 hours are reported in Table 83 and Table 84. Temperature during the study ranged between 26 – 28 °C and relative humidity between 49 – 66%. Treated bees did not differ from the control bees in behaviour at any time. 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.

Table 83 Acute oral toxicity of Oxamyl 10 SL to Honey bees

Treatment[a]		Test Substance Intake[b]		Cumulative Mortality (%)[c]	
µg Oxamyl a.s./bee	µg Oxamyl 10 SL /bee	µg Oxamyl a.s./bee	µg Oxamyl 10 SL /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 84 Acute contact toxicity of Oxamyl 10 SL to Honey Bees

Treatment[a]		Cumulative Mortality (%)	
µg Oxamyl a.s./bee	µg Oxamyl 10 SL /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.

Table 85 Summary of acute oral and contact toxicity of Oxamyl 10 SL to Honey Bees

Acute Endpoint	µg Oxamyl a.s./bee	µg Oxamyl 10 SL/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

Conclusion:

The 48 hour oral LD50 of Oxamyl 10 SL was 0.26 µg a.s./bee (2.60 µg Oxamyl 10 SL) with 95% confidence limits of 0.23 to 0.29 µg a.s./bee. The NOEL was 0.09 µg a.s./bee (0.90 µg Oxamyl 10 SL/bee). In the contact

study the 48 hour LD50 was 0.23 µg a.s./bee (2.30 µg Oxamyl 10 SL/bee) with 95% confidence limits of 0.04 to 0.70 µg a.s./bee. The NOEL was 0.10 µg a.s./bee (1.00 µg Oxamyl 10 SL/bee).

RMS comments and conclusion

This study ha been already summarized and commented in Oxanyl 10SL dRAR Vol 3 B9.

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 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

Acute oral and contact toxicity testing for bees is conducted in the same study. A summary of this study is given in the Oxamyl EU Renewal Dossier, Document M-CP, Section 10 for Oxamyl 10SL, DuPont-42130 EU.

Study submitted in the EU Dossier in 2001 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

RMS comments and conclusion

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).

See summary and RMS evaluation in B.9.56.1.1.1/01 above.

B.9.5.1.2 Chronic toxicity to bees

A laboratory study was conducted to assess the chronic effects of oxamyl technical on bees. A summary of this study is given in the Oxamyl dRAR a.s Vol 3 B9).

B.9.5.1.3 Effects on honey bee development and other honey bee life stages

On the basis of the risk assessment, Oxamyl 10GR will pose a low risk to honey bees (Point B.9.5.1 in this document). No further testing is needed. It can be concluded that Oxamyl 10GR will be safe to honey bees when used according to Good Agricultural Practice.

B.9.5.1.4 Sub-lethal effects

Larval toxicity

A laboratory study was conducted to assess the effects on honey bee larvae (DuPont-39678). A summary of this study is given in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

Long residual tests

On the basis of the risk assessment, Oxamyl 10GR will pose a low risk to honey bees (Point B.9.5.1 in this document). No further testing is needed. It can be concluded that Oxamyl 10GR will be safe to honey bees when used according to Good Agricultural Practice.

Disorienting effects on bees

On the basis of the risk assessment, Oxamyl 10GR will pose a low risk to honey bees (Point B.9.5.1 in this document). No further testing is needed. It can be concluded that Oxamyl 10GR will be safe to honey bees when used according to Good Agricultural Practice.

B.9.5.1.5 Cage and tunnel tests

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

B.9.5.1.5/01

Reference: CP 10.3.1.5/01	**Report**	Berg, C. (2015a); Oxamyl (DPX-D1410) 10GR [100 g/kg (w/w)]: A semi-field study to evaluate effects on the bumble bee (*Bombus terrestris* L; Hymenoptera, Apidae) in *Solanum tuberosum* in Germany in 2014 **DuPont Report No.:** DuPont-39666

		Guidelines: No specific guideline available **Deviations:** None **Testing Facility:** Eurofins Agroscience Services EcoChem GmbH, Niefern-Öschelbronn, Germany **Testing Facility Report No.:** S14-03501 **GLP:** Yes **Certifying Authority:** Landesanstalt Fur Umwelt, Messungen Und Naturschutz Baden-Wurttemberg

Executive summary

The objective of the study was to determine the effects of the insecticide Oxamyl 10GR applied in-furrow during planting of *Solanum tuberosum* (potato) on the bumble bee *Bombus terrestris* L. under semi-field conditions in Germany. There are no specific guidelines available. The study conduct is based on general SETAC/ESCORT recommendations (BARRETT *et al*. 1994) and OEPP/EPPO Guideline No. 170 (4), (2010). Additionally, guttation water, pollen from forager bumble bees, and flowers were taken for residue analysis.

Four replicate tunnels per test item treatment T1, test item treatment T2, and control treatment C with one bumble bee hive each for biological assessment were set up with a tunnel size of 60 m². Additionally, one replicate tunnel of 200 m² for each treatment group with three bumble bee hives were used for residue sampling. The bumble bee colonies in the residue tunnels were used for residue sampling only.

Oxamyl 10GR was applied in-furrow as granules during planting. Three field plots of sufficient size to include all tunnel tents per treatment group were planted with potatoes. One plot received an application made during planting with Oxamyl 10GR at a target application rate of 1.0 kg a.s./ha (T1), one plot received an application made during planting with Oxamyl 10GR at a target application rate of 3.5 kg a.s./ha (equivalent to 8.625 kg a.s./ha within the furrows) (T2), and one plot received no application of Oxamyl 10GR (C). The field plots were marked. Before full flowering, four 60-m² tunnels per treatment group were set up on the accordingly marked field plots. Additionally, one 200-m² tunnel per treatment group T1, T2, and C was installed on the same plots for residue sampling.

After the initial brood assessment, the bumble bee colonies were set up in the tunnels. The bumble bee colonies were exposed to the treated potato plants for 30 days in the tunnel tents. The colonies were assessed for mortality, flight intensity, and behaviour. For each treatment group, four replicate tunnels were set up with one bumble bee colony each. The study was located in Southern Germany near Vaihingen an der Enz.

The influence of the test item Oxamyl 10GR was evaluated by comparing the results of the test item to the data in the control treatment regarding the following observations.

- Bumble bee mortality (larvae and adults)
- Flight intensity within the crop
- Development of the bumble bee colonies (measured by colony weight before and after the tunnel period)
- Condition of the colonies and development of bumble bee brood (measured before and after the tunnel period)
- Photographic documentation of brood stages and brood development (measured before and after the tunnel period)
- Residue levels of the different analysed matrices

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-563
   Content of a.s., nominal: 10% (w/w) oxamyl
   Description: blue green granules
   CAS#: None for the formulation
   23135-22-0 for oxamyl active substance
2. Test organism
   Species: *Bombus terrestris* L.
   Age at dosing: Adults, indirect exposure of all stages of development. Young normal queen right colonies each with at least 53 worker bumble bees.
   Source: Koppert Biological Systems, Postbus 155, 2650 AD Berkel en Rodenrijs. Ordered *via* Hummelvertrieb Sven Behr, Moorweg 18, D-21261 Welle/Kampen.
   Diet: Supplied with auxiliary food (sugar solution) during the tunnel period, additionally supplied with pollen inside the colony before and after the tunnel period
   Test design: Four replicates (tunnel tents) per treatment T1, T2, and C with one bumble bee hive each for biological assessment. The tunnel size was approximately 60 m².
   Additionally, one replicate (tunnel tent) per treatment T1, T2, and C with three bumble bee hives per tunnel for residue sampling. The tunnel size was approximately 200 m².
   Test age: Indirect exposure of all stages of development
3. Environmental conditions during exposure of the bumble bees in the tunnel period (0DAS to 29DAS)
   Temperature (min/max): 6.5–33.6°C
   Relative humidity: 26.7–100.0 %

B. STUDY DESIGN AND METHODS

1. In-life intitiated/completed

   08-May-2014 to 27-November-2014

2. Experimental treatments

   Four replicate tunnels per test item treatment T1, test item treatment T2, and control treatment C with one bumble bee hive each for biological assessment were set up with a tunnel size of 60 m². Additionally, one replicate tunnel of 200 m² for each treatment group with three bumble bee hives were used for residue sampling. The bumble bee colonies in the residue tunnels were used for residue sampling only.

3. Observations

   The influence of the test item Oxamyl 10GR was evaluated by comparing the results of the test item to the data in the control treatment regarding the following observations.

   - Bumble bee mortality (larvae, pupae and adults)
   - Flight intensity within the crop
   - Behaviour of the bumble bees
   - Development of the bumble bee colonies (measured by colony weight before and after the tunnel period)

- Condition of the colonies and development of bumble bee brood (evaluated before and after the tunnel period)
- Photographic documentation of brood stages and brood development (taken before and after the tunnel period)
- Residue levels of the different analysed matrices

Statistics: The statistical software program SAS version 9.3 was used for the statistical analysis of mortality and flight data. For all tests, the significance level was selected as $\alpha = 0.05$. Tests were conducted one-sided. Data of the test item treatments T1, T2 and the control were checked for normality using Shapiro-Wilks test. If the distribution of the data fitted the normal distribution very well (Shapiro-Wilks test, $p \geq 0.2$) then Bartlett's test was used to check for homogeneity of the variances, in the other cases Levene's test was used. Logarithmic transformed values were used for mortality when these data were normal and homogeneous whereas the original values were not normal and/or not homogenous. For data that were normal and homogeneous, Dunnett's t-test was used to test for possible differences of mortality or flight intensity in T1 and T2 compared to the control. For data which were normal but not homogeneous, the Welch test with Bonferroni-Holms correction was used. For data which were not normal, the Bonferroni U-test Exact was used. For the evaluations of mortality, the numbers of dead bumble bees including adult workers, queens, pupae and larvae as well as only the numbers of dead larvae were used.

4. Contact toxicity test

Additionally, the sensitivity of the bumble bees used in the tunnel study was tested by means of a contact test in the labouratory. Therefore, one single 2-µL droplet of the application solution was applied to the dorsal thorax of each bumble bee. Three different concentrations (5.0, 10.0, and 20.0 µg a.s. dimethoate/bumble bee) were used and the LD_{50} value was determined.

II. RESULTS AND DISCUSSION

A. FINDINGS

1. Mortality

The mortality of bumble bees was statistically significantly higher compared to the control in the treatment group T1 at 6, 12, and 18 DAS and in the treatment group T2 at 12, 16, 18 DAS and for T2 also the mean over the period from 0 to 29 DAS (Dunnett's t-test, $p \leq 0.05$) compared to the control. Although statistically significantly higher, the mortality at these days is comparable to other days during this study. The increased mortality during these days could also result from higher numbers of forager bumble bees which were left in the hive, because flight intensity was also higher in the treatment groups T1 and T2. Overall, there was no effect of Oxamyl 10GR on mortality.

In general, the mortality of bumble bee larvae was relatively high in all groups from 4 to 12 DAS. In this period, the mortality of the larvae in the treatment group T1 was significantly higher than in the control at 6 DAS (Dunnett's t-test, $p \leq 0.05$). No other significant differences in the larval mortality could be observed during the exposure period in the tunnel tents and afterwards. The influence of the external factors like weather, pollen, and nectar supply in the tents seemed to be high and drastic. From the period of the increased larval mortality onward, there was no recovering of the colonies in any replicate of the treatment groups C, T1, and T2.

The queens of all replicates in the treatment groups C, T1, and T2 began dying before the final colony assessment at 22-August-2014. The first dead queen of the four replicates was found in the control on 12-July-2014, in the test item treatment group T1 on 12-July-2014 as well and in the test item treatment group T2 on 5-July-2014.

Overall, the mortality in the treatment groups T1 and T2 was comparable to the control over the entire observation period.

Table 86 Mean number of dead bumble bees, larvae, and pupae per treatment group

Date	DAS[a]	Mean number of dead bumble bees, larvae, and pupae (sum of hive and linen sheets)		
		C	T1	T2
25-June-2014	0 DAS	1.3	1.8	1.3
26-June-2014	1 DAS	6.3	3.5	4.3
27-June-2014	2 DAS	2.5	1.3	1.5
28-June-2014	3 DAS	0.8	1.3	2.3
29-June-2014	4 DAS	5.0	7.0	4.3
30-June-2014	5 DAS	4.5	6.0	8.0
01-July-2014	6 DAS	7.0	19.3[b]	6.8
02-July-2014	7 DAS	4.8	11.3	15.5
03-July-2014	8 DAS	12.5	17.5	20.3
04-July-2014	9 DAS	20.5	19.5	20.0
05-July-2014	10 DAS	6.0	4.3	4.8
06-July-2014	11 DAS	3.0	4.0	6.8
07-July-2014	12 DAS	2.8	7.3[b]	9.3[b]
08-July-2014	13 DAS	2.5	1.8	5.0
09-July-2014	14 DAS	0.3	0.3	2.5
10-July-2014	15 DAS	0.3	0.5	2.0
11-July-2014	16 DAS	0.3	2.8	4.3[b]
12-July-2014	17 DAS	3.5	5.8	11.0
13-July-2014	18 DAS	0.8	3.5[b]	4.5[b]
14-July-2014	19 DAS	2.0	2.0	3.0
15-July-2014	20 DAS	2.5	1.8	5.0
16-July-2014	21 DAS	3.0	4.0	6.0
17-July-2014	22 DAS	3.8	5.3	4.0
18-July-2014	23 DAS	0.5	1.3	4.3
19-July-2014	24 DAS	1.5	1.5	1.8
20-July-2014	25 DAS	1.3	3.0	1.8
21-July-2014	26 DAS	0.5	1.8	1.8
22-July-2014	27 DAS	1.0	1.0	3.0
23-July-2014	28 DAS	1.5	0.5	1.3
24-July-2014	29 DAS	1.0	1.0	1.8
Mean 0 to 29 DAS		**3.4**	**4.7**	**5.6[b]**
STD[c]		0.9	0.7	2.2
31-July-2014	36 DAA	13.3	16.0	23.8
08-August-2014	44 DAA	1.0	1.5	4.3
15-August-2014	51 DAA	4.0	3.3	11.8
16-August-2014	58 DAA	1.0	1.3	2.3
Mean 36 to 58 DAS[d]		**4.8**	**5.5**	**10.5**
STD		1.7	1.4	2.5

[a] DAS: Days after setup of the hives

[b] Statistically significantly different compared to the control (Dunnett's t-Test or Bonferroni U-Test Exact, p≤0.05)

[c] STD: Standard deviation

[d] Mean and STD were calculated by using the values of each assessment day

2. Flight intensity

The flight intensity was low during the first 2 days after the set up in the tunnel tents, because the bumble bees went through a typical period of adaptation to the confined situation in the tunnel tents. The mean flight intensity on 0 DAS was 0.8 bumble bees/tunnel in C, 1.3 bumble bees/tunnel in T1, and 2.8 bumble bees/tunnel in T2. On 3 DAS, the flight intensity reached its maximum mean value in C, counting 10.5 bumble bees/tunnel. In the treatment group T1, the maximum mean value of

15.0 bumble bees/tunnel was detected on 10 DAS. In T2, the maximum mean value was 14.8 bumble bees/tunnel on 4 DAS. After 11 DAS, it began to rain for the next several days resulting in low flight values in all treatment groups. In the observation period after 12 DAS, the flight intensity was lower compared to the flight intensity in the period from 2 to 11 DAS. This may be related to the high number of dead bumble bees found. The mean flight intensity from 0 to 29 DAS was 3.1 bumble bees/tunnel in the control, 5.5 bumble bees/tunnel in T1, and 6.0 bumble bees/tunnel in T2.

There were no statistically significant results between the treatment groups in the complete period from 0 to 29 DAS.

Overall, the application of Oxamyl 10GR had no effect on the flight intensity of the bumble bees.

Table 87 Flight intensity per treatment group

		Flight intensity (mean number of foraging bumble bees/tunnel)		
Date	**DAS[a]**	**C**	**T1**	**T2**
25-June-2014	0 DAS	0.8	1.3	2.8
26-June-2014	1 DAS	3.8	6.5	6.5
27-June-2014	2 DAS	6.8	8.0	10.8
28-June-2014	3 DAS	10.5	13.0	9.0
29-June-2014	4 DAS	8.8	12.3	14.8
30-June-2014	5 DAS	4.3	11.0	9.5
01-July-2014	6 DAS	9.0	12.8	11.3
02-July-2014	7 DAS	8.0	12.3	12.8
03-July-2014	8 DAS	7.5	11.8	12.8
04-July-2014	9 DAS	8.0	10.3	9.3
05-July-2014	10 DAS	9.5	15.0	13.8
06-July-2014	11 DAS	5.5	11.8	12.5
07-July-2014	12 DAS	0.5	2.5	2.5
08-July-2014	13 DAS	0.0	0.3	0.8
09-July-2014	14 DAS	0.0	0.0	0.0
10-July-2014	15 DAS	0.0	0.8	2.5
11-July-2014	16 DAS	0.0	0.8	2.0
12-July-2014	17 DAS	0.5	1.3	5.5
13-July-2014	18 DAS	1.8	3.8	2.8
14-July-2014	19 DAS	0.5	2.3	2.3
15-July-2014	20 DAS	0.5	4.8	7.0
16-July-2014	21 DAS	3.0	4.8	6.8
17-July-2014	22 DAS	1.3	2.8	4.8
18-July-2014	23 DAS	0.5	3.5	4.8
19-July-2014	24 DAS	0.8	3.0	5.8
20-July-2014	25 DAS	1.0	2.8	5.0
21-July-2014	26 DAS	0.0	0.0	0.3
22-July-2014	27 DAS	0.0	0.0	0.3
23-July-2014	28 DAS	0.0	2.3	1.8
24-July-2014	29 DAS	0.8	2.5	1.0
Mean 0 to 29 DAS		**3.1**	**5.5**	**6.0**
STD[b]		0.7	1.9	4.4

[a] DAS: Days after the start of exposure

[b] STD: Standard deviation

3. Condition of the colonies and development of bumble bee brood

The initial brood assessment revealed that all bumble bee hives were queenright and in good condition. In the control group, a mean of 89.0 worker bumble bees, in T1, a mean of 122.5 worker bumble bees,

and in T2, a mean of 108.5 worker bumble bees were present. Additionally, the number of living brood stages (eggs, larvae, and pupae) was similar in all three treatment groups at the initial brood assessment.

Table 88 Initial and final brood assessments per treatment group

Initial brood assessment: 23-June-2014						
Treatment group	**C**		**T1**		**T2**	
	Mean	**STD[a]**	**Mean**	**STD**	**Mean**	**STD**
Living queen	**Yes**	—	**Yes**	—	**Yes**	—
Number of alive worker bees	**89.0**	25.9	**122.5**	15.9	**108.5**	9.7
Number of brood cells with eggs	**13.8**	1.9	**18.5**	6.4	**15.3**	4.5
Number of brood cells with larvae	**117.5**	34.1	**128.0**	16.9	**146.5**	16.5
Number of alive pupae	**70.0**	14.3	**54.3**	10.6	**79.3**	7.3
Number of filled nectar cells	**35.3**	7.8	**26.3**	10.4	**29.0**	18.9
Weight of hive (without hive box) [g]	**628.3**	20.7	**621.8**	16.3	**615.5**	24.7
Final brood assessment: 22-August-2014						
Treatment group	**C**		**T1**		**T2**	
	Mean	**STD**	**Mean**	**STD**	**Mean**	**STD**
Living queen	**No**	—	**No**	—	**No**	—
Number of alive workers	**0.5**	0.6	**1.8**	3.5	**1.5**	1.0
Number of brood cells with eggs	**1.3**	1.9.	**0.8**	3.5	**1.0**	1.2
Number of brood cells with larvae (workers/males)	**6.3**	3.9	**8.0**	6.7	**3.8**	3.0
Number of pupae	**0.5**	1.0	**1.0**	2.0	**2.3**	2.6
Number of filled nectar cells	**18.0**	12.0	**15.5**	6.8	**21.5**	8.6
Number of filled pollen cells	**0.3**	0.5	**3.3**	2.4	**2.0**	1.4
Weight of hive (without hive box) [g]	**563.5**	16.0	**575.0**	19.0	**591.0**	27.5

[a] STD: Standard deviation

At the final brood assessment on 58 DAS, all queens were dead, and no young queens were present. In addition, the mean number of living worker bumble bees was 0.5 in the control, 0.0 in the test item treatment group T1, and 1.5 in the test item treatment group T2.

Nectar cells were present in all hives. There were very low numbers of pollen cells in the treatment groups.

The weight of the hives was decreasing from the first to the final brood assessment. In C, the weight was decreasing from 628.3 to 563.5 g, in T1, from 621.5 to 575.0 g, and in T2, from 615.5 to 591.0 g.

The final brood assessment shows that the control and treatment colonies were in similar condition and did not recover from the period in the tunnel tents. It can be concluded that the application of Oxamyl 10GR had no effect on the condition of the bumble bee colonies.

4. Behaviour of the bumble bees

From 0 to 4 DAS, no individual bumble bee showed unusual behaviour in any of the treatment groups. In this period, some colonies in the control and treatment tunnels showed aggressive behaviour towards the observer, especially when opening the hive to count the dead bees. This is not unusual because bumble bees intensively try to defend their colonies from threats. After this period, aggressive behaviour was recorded only in very few assessments.

The behaviour of the individual bumble bees was also normal in the period from 5 to 29 DAS, only very few bumble bees showed unusual behaviour. In the complete period, there were 18 bumble bees (including one queen) showing locomotion problem in the control. There were 14 bumble bees showing

locomotion problems, four cramping bumble bees, five inactive bumble bees, and two intensively cleaning bumble bees in T1, and there were 56 bumble bees showing locomotion problems, nine inactive bumble bees, and one intensively cleaning bumble bee. Individual bumble bees that showed unusual behaviour have been recorded on many successive behaviour assessments (especially the bumble bees with malformations in the replicate T2b), since these bumble bees usually stay inside the hive and have a long life-span nonetheless.

In the period on the monitoring site, only one bumble bee showed locomotion problems in the control, two bumble bees showed locomotion problems in T1, and 1 bumble bee showed locomotion problems in T2. During this period, there were few bumble bees left in the colonies.

Overall, the application of Oxamyl 10GR had no effect on behaviour of the bumble bees.

5. Photographic documentation of brood stages and brood development

Photographs were taken once before the set-up of the bumble bees in the tunnel tents and once at the end of the study at the monitoring site, 58 days after the set-up of the colonies in the tunnel tents. In all colonies, the picture at the initial brood assessment shows a healthy colony with brood cells of all stages, whereas the picture of the final brood assessment shows an abandoned and decayed colony. There do not seem to be any differences in the appearance of the colonies between the treatment groups T1 and T2 and the control.

6. Toxic reference contact test

The mortality data showed a high sensitivity of bumble bee workers for the exposure of the reference item Perfekthion. Forty-eight hours after application of Perfekthion the corrected mortality was 66.7% with 20.0 µg a.s./bee.

No bumble bees died in the control group.

Table 89 Bumble bee mortality

Treatment (µg a.s./bee)	Introduced (number)	Survived (% survival)	Dead (% mortality)
Blank control	30	100% (30)[a]	0% (0)
5.0	30	96.7% (29)	0.03% (1)
10.0	30	66.7 (20)	33.3% (10)
20.0	30	33.3 (10)	66.7 (20)

[a] (): Total number of bumble bees out of a total of 30 bumble bees per treatment group

The dimethoate LD_{50} value was 12.66 µg a.s./bumble bee after 48 hours.

7. Residue analysis

Guttation water specimens

Residues of oxamyl in treated guttation water specimens from treatment group T1 were in the range of 0.001 to 14.7 mg/kg and from treatment group T2 in the range of 0.161 to 130 mg/kg. No residues of oxamyl were detected at or above the limit of detection (LOD = 0.0003 mg/kg) in untreated guttation water samples.

Table 90 Residues in guttation water specimens

Eurofins sample code	Treatment	Timing	Residue[a] (mg/kg)
L14-03501-01-025A	Ce[b]	1 DAE[c]	n.d.[d]
L14-03501-01-026A	Ce	4 DAE	n.d.
L14-03501-01-027A	Ce	10 DAE	n.d.
L14-03501-01-028A	Ce	18 DAE	n.d.
L14-03501-01-001A	T1e[e]	0 DAE	14.7
L14-03501-01-003A	T1e	1 DAE	10.4
L14-03501-01-005A	T1e	2 DAE	3.95
L14-03501-01-007A	T1e	3 DAE	3.76
L14-03501-01-009A	T1e	4 DAE	10.4
L14-03501-01-011A	T1e	6 DAE	8.97
L14-03501-01-013A	T1e	8 DAE	7.07
L14-03501-01-015A	T1e	10 DAE	2.92
L14-03501-01-017R1	T1e	12 DAE	1.16
L14-03501-01-019A	T1e	14 DAE	0.416
L14-03501-01-021A	T1e	18 DAE	0.001
L14-03501-01-023A	T1e	22 DAE	No sample available
L14-03501-01-002A	T2e[e]	0 DAE	16.4
L14-03501-01-004A	T2e	1 DAE	48.9
L14-03501-01-006A	T2e	2 DAE	28.9
L14-03501-01-008A	T2e	3 DAE	45.9
L14-03501-01-010A	T2e	4 DAE	89.3
L14-03501-01-012A	T2e	6 DAE	130
L14-03501-01-014A	T2e	8 DAE	53.4
L14-03501-01-016A	T2e	10 DAE	23.0
L14-03501-01-018A	T2e	12 DAE	9.07
L14-03501-01-020A	T2e	14 DAE	6.64
L14-03501-01-022A	T2e	18 DAE	0.161
L14-03501-01-024A	T2e	22 DAE	No sample available

[a] LOQ: 0.001 mg/kg

[b] Ce: Control specimens

[c] DAE: Days after emergence of 50% of the potato plants

[d] n.d.: Not detectable (<LOD = 0.0003 mg/kg)

[e] T1/T2: Treated specimens.

Pollen specimens

Residues of oxamyl in treated pollen specimens from treatment group T1 were detected below the LOQ (<LOQ [0.001 mg/kg]) or below the LOD (<LOD [0.0003 mg/kg]) and from treatment group T2 in the range of 0.001 to 0.008 mg/kg. No residues of oxamyl were detected at or above the limit of detection (LOD = 0.0003 mg/kg) in untreated pollen samples.

Table 91 Residues in pollen specimens

Eurofins sample code	Treatment	Timing	Residue[a] (mg/kg)
L14-03501-01-030A	Ce[b]	1 DAS[c]	n.d.[d]
L14-03501-01-036A	Ce	9 DAS	n.d.
L14-03501-01-042A	Ce	16 DAS	n.d.
L14-03501-01-048A	Ce	21 DAS	No sample available
L14-03501-01-054A	Ce	28 DAS	No sample available
L14-03501-01-028A	T1e[e]	1 DAS	<LOQ (0.0004)
L14-03501-01-034A	T1e	9 DAS	<LOQ (0.0004)
L14-03501-01-040A	T1e	16 DAS	n.d.
L14-03501-01-046A	T1e	21 DAS	n.d.
L14-03501-01-052A	T1e	28 DAS	No sample available
L14-03501-01-029A	T2e[e]	1 DAS	0.008
L14-03501-01-035A	T2e	9 DAS	0.001
L14-03501-01-041A	T2e	16 DAS	0.003
L14-03501-01-047A	T2e	21 DAS	No sample available
L14-03501-01-053A	T2e	28 DAS	No sample available

[a] LOQ: 0.001 mg/kg

[b] Ce: Control specimens

[c] DAS: Days after set-up of the hives in the tunnel tents (0 DAS = first day of exposure of the bumble bees)

[d] n.d.: Not detectable (<LOD = 0.0003 mg/kg)

[e] T1/T2: Treated specimens.

Flowers specimens

No residues of oxamyl were detected at or above the limit of detection (LOD = 0.0003 mg/kg) in treated flowers specimens from *Solanum tuberosum* plants from treatment group T1. From treatment group T2, residues of oxamyl were in the range of below the LOD (<LOD [0.0003 mg/kg]) to 0.019 mg/kg. No residues of oxamyl were detected at or above the limit of detection (LOD = 0.0003 mg/kg) in the untreated flower samples.

Table 92 Residues in flower specimens

Eurofins sample code	Treatment	Timing	Residue[a] (mg/kg)
L14-03501-01-027A	Ce[b]	1 DAS[c]	n.d.[d]
L14-03501-01-033A	Ce	9 DAS	n.d.
L14-03501-01-039A	Ce	16 DAS	n.d.
L14-03501-01-045A	Ce	21 DAS	n.d.
L14-03501-01-051A	Ce	28 DAS	n.d.
L14-03501-01-025A	T1e[e]	1 DAS	n.d.
L14-03501-01-031A	T1e	9 DAS	n.d.
L14-03501-01-037A	T1e	16 DAS	n.d.
L14-03501-01-043A	T1e	21 DAS	n.d.
L14-03501-01-049A	T1e	28 DAS	n.d.
L14-03501-01-026A	T2e[e]	1 DAS	0.019
L14-03501-01-032A	T2e	9 DAS	<LOQ (0.0007)
L14-03501-01-038A	T2e	16 DAS	n.d.
L14-03501-01-044A	T2e	21 DAS	n.d.
L14-03501-01-050A	T2e	28 DAS	n.d.

[a] LOQ: 0.001 mg/kg

[b] Ce: Control specimens

[c] DAS: Days after set-up of the hives in the tunnel tents (0 DAS = first day of exposure of the bumble bees)

[d] n.d.: Not detectable (<LOD = 0.0003 mg/kg)

[e] T1/T2: Treated specimens.

III. CONCLUSIONS

Oxamyl 10GR applied once during planting of *Solanum tuberosum* at an application rate of 1.0 kg oxamyl a.s./ha (T1) or 3.5 kg oxamyl a.s./ha (equivalent to 8.625 kg a.s./ha within the furrows) (T2) did not have any effects on mortality, flight intensity, condition of colonies, and behaviour compared to the control.

The colonies were suffering under the confined situation in the tunnels with *Solanum tuberosum*. Many dead larvae could be found in the hives, and the queens died during or shortly after the tunnel period. At the final brood assessment, only very few bumble bees were left in the colonies. The bumble bee colonies developed weakly probably due to insufficient and restricted food supply in the tunnels (pollen of potato flowers only) and did not enter the reproduction phase.

Overall, Oxamyl 10GR applied once during planting of *Solanum tuberosum* at an application rate of 1.0 kg oxamyl a.s./ha (T1) or 3.5 kg oxamyl a.s./ha (equivalent to 8.625 kg a.s./ha within the furrows) (T2) did not have any effects on mortality, flight intensity, condition of colonies, and behaviour compared to the control.

In the guttation samples, a maximum value of 130 mg oxamyl/kg could be found in the treatment group T2, 6 days after emergence of 50% of the plants. In the pollen samples taken from the forager bumble bees, a maximum value of 0.008 mg oxamyl/kg was found in the treatment group T2. In the flower samples, a maximum value of 0.019 mg oxamyl/kg could be found in the treatment group T2.

(Berg, C., 2015a)

RMS comment and conclusion

Due to the poor condition of the control colonies at the end of the study (low number of adult and larvae, no queen) as described above, the conclusion of no stastistical difference between the control and the treated groups is not meaningful. In addition, the food provided may mask the toxic effects. Also, rainfall occurring during the exposure period (after 11 DAS up to the next several days) resulted in low flight intensity in all treatment groups.

Conclusion: the biological results are not acceptable. The information on residues can be considered reliable.

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

B.9.6.1.5/02

Reference: CP 10.3.1.5/02	**Report**	Berg, C. (2015b); Oxamyl (DPX-D1410) 10GR [100 g/kg]: A semi-field study to evaluate effects on the brood of honey bees (*Apis mellifera*; Hymenoptera, Apidae) in *Phacelia tanacetifolia* in Germany 2014 **DuPont Report No.:** DuPont-39667 **Guidelines:** OECD 75 (2007) and partial integration of recommendations by EFSA (2013) **Deviations:** None **Testing Facility:** Eurofins Agroscience Services EcoChem GmbH, Niefern-Öschelbronn, Germany **Testing Facility Report No.:** S14-03580 **GLP:** Yes **Certifying Authority:** Landesanstalt Fur Umwelt, Messungen Und Naturschutz Baden-Wurttemberg

Executive summary

The effects of Oxamyl 10GR were tested on the honey bee (*Apis mellifera* L.) under semi-field conditions following the OECD guidance document No. 75 (2007) and partial integration of recommendations by EFSA (2013). This study was conducted near Pforzheim in Southern Germany (region: Baden-Württemberg) from June to August 2014 and included a total of four treatment groups:

- Oxamyl 10GR treatment group T1 with one granular application of the test item as an in-furrow application during the seeding of *Phacelia tanacetifolia* at a target rate of 8.625 kg oxamyl a.s./ha.
- Oxamyl 10GR treatment group T2 with one granular application of the test item as a broadcast application during the seeding of *Phacelia tanacetifolia* at a target rate of 5.5 kg oxamyl a.s./ha.
- Reference item group R with one application of Insegar during flowering of *P. tanacetifolia* (BBCH 63–65) and bee-flight, 3 days after the set-up of the colonies in the tunnel tents. The application was carried out as a spray application at a target rate of 300 g a.s. fenoxycarb/ha with a spray volume of 400 L water/ha.
- Untreated control group C with no application during seeding or flowering of *P. tanacetifolia*.

The applications in the test item treatment groups T1 and T2 were carried out on 03-June-2014. The effects of the test item treatment were examined on small honey bee colonies in tunnel tents (5.0 m × 16.0 m and a height of 3.5 m in the centre) placed over the plots of *P. tanacetifolia.* The exposure of the honey bees started on 28-July-2014. The application of the reference item was carried out on 31-July-2014 (3 days after installation of the hives in the tunnels). The colonies were removed from the tunnels in the evening on 07-August-2014. The semi-field test comprised four replicate tunnel tents in each of the treatment groups plus one replicate tunnel used for residue sampling in the treatment groups C, T1, and T2.

The influence of the applications of Oxamyl 10GR was evaluated by comparing the results in the treatment groups to the data in the control treatment as well as in the reference item treatment regarding the following observations:

- Mortality: number of dead honey bees in the crop area (linen sheets), in the dead bee traps, and in the bottom drawers
- Flight intensity in the crop (number of forager honey bees/m²/10–15 seconds, *P. tanacetifolia*)
- Condition of the colonies and development of the brood
- Detailed observation of the brood development in ≥200 selected cells
- Behaviour of the honey bees in the crop area and around the hives
- Level of residues in the samples of hive products and nectar stomach contents and pollen loads from forager bees

I. MATERIAL AND METHODS

A. MATERIALS:

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-563
   Content of a.s., nominal: 10% (w/w) Oxamyl
   Description: Blue green granules
   CAS#: None for the formulation
   23135-22-0 for oxamyl active substance
   Reference item: Insegar 25WG (fenoxycarb)
   Lot/Batch: SMO3E0003
   Content of a.s., nominal: 25.0% (w/w)
   Description: Grey to brown solid
   CAS#: 72490-01-8
   Stability in solution: Not available
2. Vehicle and/or control: Tap water for spray application of the reference item, none for the test item (applied as granules)
3. Test organism
   Species: *Apis mellifera* L.
   Age at dosing: Direct exposure of adult honey bees; indirect exposure of all stages of development
   Source: Eurofins Agroscience Services EcoChem GmbH, D-75223 Niefern-Öschelbronn, Germany
   Diet: Nectar and pollen of flowering *Phacelia tanacetifolia.*
   Tunnel tents (exposure): On the plots with (T1 and T2) or without (C and R) granular application, small plots (each 5.0 m × 16.0 m) were marked and paths (0.5 m) were made in each plot by removing the plants and smoothing the ground. Before set-up of the bee colonies, tunnel tents (5.0 m × 16.0 m and a height of 3.5 m in the centre) were installed over the marked plots. The tent frames were covered with light plastic gauze. The paths (approx. 14.9 m^2) were covered with linen sheets for the assessment of dead bees in the crop area. The crop area per tent was approx. 65.1 m^2.
4. Environmental conditions during the exposure period (28-July-2014 to 07-August-2014):
   Temperature (min/max): 12.0–27.8°C
   Relative humidity: 35.7–91.6%
   Photoperiod (exposure): Natural light conditions

B. STUDY DESIGN AND METHODS

1. In-life initiated/completed

03-June-2014 to 20-November-2014

The semi-field test was located in Neulingen-Nussbaum near Pforzheim, region: Baden-Württemberg, Germany. The hives were set up in the tunnels on the same date for all treatments groups during flowering. They were kept in the tunnels for 10 days.After the exposure period in the tunnels, the hives were installed at a monitoring site and kept for 20 days.

2. Experimental treatments

- Oxamyl 10GR treatment group T1 with one granular application of the test item as an in-furrow application during the seeding of *Phacelia tanacetifolia* at a target rate of 8.625 kg oxamyl a.s./ha (equivalent to 86.25 kg Oxamyl 10GR formulated product per ha with an inter-row distance of 18.75 cm, based on nominal concentration and density which corresponds to a row-based application rate of 32.34 kg/ha with an inter-row spacing of 50 cm). The application was done as an in-furrow- application with the same machine which was used for the seeding of P tanacetifolia. Therefore, the granules were applied in rows with an inter-row distance of 18.75 cm) and incorporated into the soil to a depth of 10 cm, shortly before the Phacelia seeds were seeded in the same row with an inter-row distance of 18.75 cm as accurately as possible.
- Oxamyl 10GR treatment group T2 with one granular application of the test item as a broadcast application during the seeding of *Phacelia tanacetifolia* at a target rate of 5.5 kg oxamyl a.s./ha. The granules were evenly distributed on the plot (broadcasted) and incorporated into the soil to a depth of 10 cm before the seeding of P. tanacetifolia.
- Reference item group R with one application of Insegar during flowering of *P. tanacetifolia* (BBCH 63–65) and bee-flight, 3 days after the set-up of the colonies in the tunnel tents. The application was carried out as a spray application at a target rate of 300 g a.s. fenoxycarb/ha with a spray volume of 400 L water/ha.
- Untreated control group C with no application during seeding or flowering of *P. tanacetifolia*.

3. Observations

The influence of the applications of Oxamyl 10GR was evaluated by comparing the results in the treatment groups to the data in the control treatment as well as in the reference item treatment regarding the following observations:

- Mortality: number of dead honey bees in the crop area (linen sheets), in the dead bee traps, and in the bottom drawers. Mortality in dead bee traps and bottom drawers observed over 4 days before installation of the hives in the tunnels (pre-exposure period at the monitoring site). Mortality in dead bee traps, bottom drawers and on linen sheets, after installation of the hives in the tunnels over 10 days until the removal of the hives from the tunnels. Mortality in the dead bee traps after removal of the colonies out of the tunnels until 27 days after marking of cells for assessment of brood development (=BFD0) (post-exposure period at the monitoring site).
- Flight intensity in the crop (number of forager honey bees/m²/10–15 seconds, *P. tanacetifolia*) observed after installation of the hives in the tunnels over 10 days until the removal of the hives from the tunnels, and behaviour.
- Condition of the colonies and development of the brood. Observation made once shortly before installation of the bee hives in the tunnel tents and six times afterwards: at the same time as BFD0 (3 days after the installation of the hives in the tunnels), 6 days after BFD0, 11 days after BFD0, 15 days after BFD0, 21 days after BFD0 and 27 days after BFD0.

- Detailed observation of the brood development in ≥200 selected cells
- Behaviour of the honey bees in the crop area and around the hives, observed after installation of the hives in the tunnels over 10 days until the removal of the hives from the tunnels and behaviour.
- Level of residues in the samples of hive products and nectar stomach contents and pollen loads from forager bees

II. RESULTS AND DISCUSSION

A. MORTALITY

Daily mean mortality per treatment group at the monitoring site before the installation of the hives in the tunnel (4 to 1 DBE) was in the range from 44.5 to 73.8 dead honey bees/day in the control, from 15.0 to 76.3 dead honey bees/day in the test item treatment T1, from 12.3 to 68.8 in the test item treatment T2, and from 16.5 to 87.8 dead honey bees/day in the reference item treatment R. The mean daily mortality was 63.2 in C, 42.8 in T1, 29.9 in T2, and 42.2 in R. None of these differences was statistically significant (Tukey-Test, $p \leq 0.05$).

In all treatments, the total number of dead pupae and young bees was low during the pre-application period (eight dead pupae in C, seven dead pupae in T1, twelve dead pupae in T2, and two dead pupae in R).

Table 93 Mean number of dead honey bees, larvae, and pupae/day per treatment group

Date	DBE[a]/ DAE[b]	Mean number of dead honey bees, larvae, and pupae/day per treatment group				
		C		T1	T2	R
		For T1 and T2	For R			
24-July-2014	4 DBE	73.8		76.3	68.8	87.8
25-July-2014	3 DBE	63.5		38.8	24.3	46.3
26-July-2014	2 DBE	71.0		41.3	14.0	16.5
27-July-2014	1 DBE	44.5		15.0	12.3	18.3
Mean 4 to 1 DBE[c]		**63.2**		**42.8**	**29.9**	**42.2**
STD[d]		58.3		14.4	4.1	27.3
28-July-2014	0 DAE	18.3		16.0	14.3	13.0
29-July-2014	1 DAE	87.0		14.8	28.3	23.5
30-July-2014	2 DAE	254.0		65.5	161.0	97.8
31-July-2014	3 DAEba[e]	—	167.8	—	—	87.0
Mean 0 to 3 DAEba		—	**131.8**	—	—	**55.4**
STD		—	52.9	—	—	34.9
31-July-2014	3 DAE	242.0	—	151.3	247.8	—
31-July-2014	3 DAEaa[f]	—	74.3	—	—	21.5
01-August-2014	4 DAE	17.8		10.0	19.5	11.8
02-August-2014	5 DAE	86.0		31.8	73.8	33.5
03-August-2014	6 DAE	80.5		25.3	40.8	29.3
04-August-2014	7 DAE	63.3		30.3	43.5	24.3
05-August-2014	8 DAE	101.0		43.5	74.5	41.3
06-August-2014	9 DAE	90.8		48.8	90.8	44.5
07-August-2014	10 DAE	124.8		51.0	83.0	56.0
Mean 0 to 10 DAE[g]		**106.0**	—	**44.4**	**79.7**	—
STD		23.9	—	20.7	46.1	—
Mean 3 DAEaa to 10 DAE		—	**79.8**	—	—	**32.8**
STD		—	7.8	—	—	7.0

Table 93 Mean number of dead honey bees, larvae, and pupae/day per treatment group (continued)

Date	DBE[a]/ DAE[b]	Mean number of dead honey bees, larvae, and pupae/day per treatment group			
		C	T1	T2	R
08-August-2014	11 DAE	8.3	6.0	8.8	6.0
09-August-2014	12 DAE	5.5	8.0	9.8	6.0
10-August-2014	13 DAE	10.5	7.3	20.8	20.8
11-August-2014	14 DAE	14.8	8.5	16.3	23.5
12-August-2014	15 DAE	27.5	15.3	25.0	46.0[h]
13-August-2014	16 DAE	33.0	11.3	26.0	66.3
14-August-2014	17 DAE	23.8	11.0	20.0	82.0[h]
15-August-2014	18 DAE	23.8	9.5	21.3	70.3[h]
16-August-2014	19 DAE	38.0	18.3	27.5	57.0
17-August-2014	20 DAE	28.8	12.3	19.0	42.5
18-August-2014	21 DAE	27.0	7.8	18.5	44.8
19-August-2014	22 DAE	18.5	9.0	11.5	27.0
20-August-2014	23 DAE	25.0	11.8	24.3	36.5
21-August-2014	24 DAE	19.0	6.8	16.3	33.0
22-August-2014	25 DAE	35.5	24.0	37.5	50.3
23-August-2014	26 DAE	29.3	12.0	24.5	37.3
24-August-2014	27 DAE	16.3	5.3	9.5	15.8
25-August-2014	28 DAE	16.8	8.0	15.0	15.3
26-August-2014	29 DAE	17.3	27.8	34.0	13.5
27-August-2014	30 DAE	15.8	5.3	77.0	19.8
Mean 11 to 30 DAE[i]		**21.7**	**11.3**	**23.1**	**35.7**
STD		8.9	5.8	17.0	13.5

[a] DBE: Days before the start of the exposure
[b] DAE: Days after the start of the exposure
[c] 4 to 1 DBE: Dead bees from dead bee traps and bottom drawer (monitoring period)
[d] STD: Standard deviation
[e] ba: Before application
[f] aa: After application
[g] 0 to 10 DAE: Dead bees from linen sheets, dead bee trap and bottom drawer (exposure period inside tunnel)
[h] Significantly different from the control (one-sided pooled t-test, $p \leq 0.05$)
[i] 11 to 30 DAE: Dead bees from dead bee traps and bottom drawer (monitoring period)

1. Comparison between the control and the test item treatment groups

During the exposure period in the tunnels from 0 to 10 DAE, the daily mortality was in the range from 17.8 to 254.0 dead honey bees/day in C, from 10.0 to 151.3 dead honey bees/day in T1, and from 14.3 to 247.8 dead honey bees/day in T2. The mean daily mortality was 106.0 dead honey bees/day in C, 44.4 dead honey bees/day in T1, and 79.7 dead honey bees/day in T2. The increased mortality, particularly present in the control group, resulted mainly from dead bees that were found on the linen sheets (*i.e.*, the number of dead bees in traps or bottom drawers did not increase). The highest values occurred during 2 and 3 DAE. After 3 DAE, daily mortality slightly decreased in all treatment groups, showing that the bees started to get used to the confinement in the tunnels. There were no statistically significant differences during this period (Dunnett's t-Test, $p \leq 0.05$).

After the exposure period inside the tunnels, the colonies were relocated to a monitoring site, where the dead bees in the dead bee traps and in the bottom drawers were counted. During this period from 11 to 30 DAE, the mean daily mortality was in the range from 5.5 to 38.0 in C, from 5.3 to 27.8 in T1, and from 8.8 to 77.0 in T2. There were no statistically significant differences during this period (Dunnett's t-Test, $p \leq 0.05$).

2. Comparison between the control and the reference item group

At the beginning of the period inside the tunnels after the installation of the hives until the application of the reference item (0 DAE to 3 DAEba), the mean daily mortality was in the range from 18.3 to 254.0 dead honey bees/day in the control and from 13.0 to 97.8 dead honey bees/day in the reference item treatment R. The mean daily mortality during this period was 131.8 in C and 55.4 in R.

After the application of the reference item on 3 DAE, the mean daily mortality values were increasing slightly in both the control and the reference item group until the end of the tunnel period on 10 DAE. This results from the increasing numbers of dead bees which were found on the linen sheets. The mean daily mortality was in the range from 17.8 to 124.8 dead honey bees/day in C and from 11.8 to 56.0 dead honey bees/day in R. The mean daily mortality was 79.8 in C and 32.8 in R. The differences during that period were not statistically significant (pooled t-Test, $p \leq 0.05$).

After the exposure period inside the tunnels until the last assessment of mortality (11 to 30 DAE), the mean daily mortality was in the range from 5.5 to 38.0 dead honey bees/day in C and from 6.0 to 82.0 dead honey bees/day in R. The mean daily mortality was statistically significantly different on 15, 17, and 18 DAE (pooled t-Test, $p \leq 0.05$). The increased mortality in R on these days results from the large numbers of dead pupae. Over the period from 11 to 30 DAE, a total of 1970 dead pupae were found in the four replicates of R, showing a clear effect of the application of the reference item on the colonies.

Overall, there was no increased mortality in the two the Oxamyl 10GR test item groups T1 and T2 after the start of the exposure phase.

B. FLIGHT INTENSITY

1. Comparison between the control and the test item treatment groups

The mean daily flight intensity after the installation of the colonies in the tunnels until the end of the exposure period in the tunnels (0 to 10 DAE) was in the range from 0.3 to 26.3 honey bees/m² in C, from 0.0 to 28.4 honey bees/m² in T1, and from 0.0 to 30.3 honey bees/m² in T2. The mean daily flight intensity was 14.4 honey bees/m² in C, 16.3 honey bees/m² in T1, and 15.4 honey bees/m² in T2. The flight intensity in T2 on 0 DAE was statistically significantly lower compared to the control (Dunnett's t-Test, $p \leq 0.05$).

2. Comparison between the control and the reference item group

The mean daily flight intensity after the installation of the colonies in the tunnels (0 DAE) until the assessment before the application of the reference item (3 DAEba) was in the range from 0.3 to 25.5 forager bees/m² in C and from 0.0 to 22.6 forager bees/m² in R. The mean daily flight intensity in this period was 12.1 in C and 10.3 in R. There were no statistically significant differences during that period (pooled t-Test or Satterthwaite t-Test, $p \leq 0.05$).

After the application of the reference item, the mean daily flight intensity was in the range from 5.4 to 26.3 in C and from 5.0 to 22.2 in R. On 3 DAEaa, after the application of the reference item, the flight intensity of R was statistically significantly lower compared to the control (pooled t-Test, $p \leq 0.05$).

Table 94 Flight intensity per treatment group

Date	DAE[a]	Flight intensity (mean number of forager bees/m²)				
		C		T1	T2	R
		for T1 and T2	for R			
28-July-2014	0	16.4		12.7	10.8[b]	13.1
29-July-2014	1	6.1		5.0	7.9	5.3
30-July-2014	2	0.3		0.0	0.0	0.0
31-July-2014	3ba[c]	—	25.5	25.2	26.3	22.6
Mean 0 DAE to 3 DAEba		—	**12.1**	—	—	**10.3**
STD[d]		—	1.3	—	—	3.0
31-July-2014	3aa[e]+1 h	19.8		22.5	18.4	15.2
31-July-2014	3aa+2 h	27.0		24.8	25.9	18.0
31-July-2014	3aa+4 h	23.6		21.5	23.5	13.6
31-July-2014	3aa+6 h	18.0		18.1	19.3	13.5
Mean 3 DAE		**22.8**	—	**22.4**	**22.7**	—
STD		0.7	—	2.2	3.4	—
Mean 3 DAEaa		—	**22.1**	—	—	**15.1[b]**
STD		—	1.5	—	—	3.2
01-August-2014	4	24.5		25.5	24.9	22.2
02-August-2014	5	26.3		23.0	22.1	19.3
03-August-2014	6	5.4		10.4	8.9	5.9
04-August-2014	7	16.7		25.3	18.5	14.0
05-August-2014	8	6.5		10.8	7.7	5.0
06-August-2014	9	21.1		28.4	30.3	21.4
07-August-2014	10	12.0		16.0	15.0	8.9
Mean 0 to 10 DAE		**14.4**	—	**16.3**	**15.4**	—
STD		1.6	—	1.1	1.3	—
Mean 3 DAEaa to 10 DAE		—	**16.9**	—	—	**14.0**
STD		—	2.0	—	—	2.5

[a] DAE: Days after the start of exposure

[b] Significantly lower than the control (Dunnett's t-Test or pooled t-test, $p \leq 0.05$)

[c] ba: Before application

[d] STD: Standard deviation

[e] aa: After application

Overall, flight intensity in the Oxamyl 10GR treatments was comparable to the control.

C. BEHAVIOUR

Before the start of the exposure phase on the monitoring site, very few bees were cramping, had locomotion problems, or were inactive. There were no considerable differences between the treatment groups.

After the start of the exposure phase in the tunnels (0 to 10 DAE), there were very few bees that showed unusual behaviour at each assessment. There were 14 cramping bees, 8 trembling bees, 62 bees that showed locomotion problems, 10 inactive bees, and 1 intensively cleaning bee in C. In T1, 14 cramping bees, 16 bees with locomotion problems, 12 inactive bees, and 1 intensively cleaning bee could be observed. In T2, there were 53 cramping bees, 3 trembling bees, 17 bees with locomotion problems, 14 inactive bees, and 6 hanging bees. Of the 53 cramping bees that could be detected in T2, 42 were found on 3 DAE. On the other days, a maximum of 3 cramping bees could be detected in the treatment group, so the effect does not seem to be test item-related.

During the period at the monitoring site, there were very few bees that showed unusual behaviour at each assessment. During the complete period from 11 to 30 DAE, there were 9 cramping bees, 48 bees that

showed locomotion problems, and 33 inactive bees in C. In T1, there were 3 cramping bees, 29 bees with locomotion problems, and 43 inactive bees. In T2, there were 10 cramping bees, 54 bees with locomotion problems, and 76 inactive bees.

In the reference item treatment R, there were few bees in the whole tunnel period from 0 to 10 DAE, counting 4 cramping bees, 13 bees with locomotion problems, and 8 inactive bees. At the monitoring site after the exposure period, there were also few bees that showed unusual behaviour. There were 8 cramping bees, 21 bees with locomotion problems, and 21 inactive bees from 11 to 30 DAE.

Overall, there was no negative impact on behaviour observed in the Oxamyl 10GR treatment groups T1 and T2.

D. BROOD DEVELOPMENT AND COLONY CONDITION

At the first assessment of colony condition before set-up in the tunnel tents (6 DBE), the mean colony sizes were comparable in the four treatment groups. Mean strength of the colonies (number of honey bees according to Liebefeld method) was 8391 honey bees in C, 8563 honey bees in T1, 8344 honey bees in T2, and 8016 honey bees in R.

In the control and the treatment group T2, an increase of the mean colony size was observed from the first (6 DBE) to the second assessment (3 DAE, after installation of the hives in the tunnel tents), whereas the mean number of honey bees per colony was decreasing in the treatment group T1 and the reference item group R. In these treatment groups, there were less brood cells than in the control already at the first assessment, which seems to result in a smaller colony size at the second assessment and probably in the following assessments, too. The mean colony sizes were 9563 honey bees in the control, 6953 honey bees in T1, 9016 honey bees in T2, and 6125 honey bees in R.

At the third assessment on 9 DAE, shortly before the relocation of the colonies to the monitoring site, there were no major developments in the mean colony sizes. There were 9938 honey bees in the control, 7875 honey bees in T1, 9391 honey bees in T2, and 6360 honey bees in R.

After the relocation to the monitoring site, on 14 DAE, the mean colony size strongly increased in all treatment groups. There were 13297 honey bees in the control, 9750 honey bees in T1, 14641 honey bees in T2, and 9360 honey bees in R.

On the fifth assessment on 18 DAE, the mean colony size was 12954 honey bees in the control, 9438 honey bees in T1, 13032 honey bees in T2, and 8063 honey bees in R.

Six days later on 24 DAE, the mean colony sizes were similar in the three treatment groups: there were 13000 honey bees in C, 8735 honey bees in T1, 10563 in T2, and 7047 honey bees in R.

On the last assessment on 30 DAE, the mean colony size was 11985 honey bees in the control, 7656 honey bees in T1, 9532 honey bees in T2, and 5469 honey bees in R.

Overall, there was no negative effect in the Oxamyl 10GR treatment groups T1 and T2 on the size of the colonies (number of honey bees).

Brood of all stages (eggs, larvae, capped brood) was present in all colonies of the treatment groups C and T1 at all assessments during the study except for the replicate Cd, which had no egg cells on the last assessment on 30 DAE. In T2, there was no queen left at the assessment on 14 DAE, and the colony did not manage to install a new queen until the end of the study. This results in various missing brood stages in the replicate T2b from 14 to 30 DAE. The other replicates in the treatment group T2 developed well during this period.

At the first assessment before the installation of the hives in the tunnels (6 DBE), the mean total amount of brood cells (brood of all stages) was similar in the treatment groups C and T2 and a bit lower in T1 and R. There were 20750 brood cells in C, 14650 brood cells in T1, 21850 brood cells in T2, and 11250 brood cells in R.

At the assessments shortly after the introduction of the hives into the tunnels on 3 DAE, no major development occurred in the numbers of brood cells. There were 21250 brood cells in C, 14100 brood cells in T1, 16450 brood cells in T2, and 10700 brood cells in R.

At the third assessment on 9 DAE, there were 18700 brood cells in C, 10900 brood cells in T1, 15400 brood cells in T2, and 7850 brood cells in R. In the reference item treatment group R, Ra and Rd had no larvae cells, whereas Rb had only 200 larvae cells, and Rc had 600 larvae cells on 9 DAE, which is considered to be an effect of the toxic reference item.

On the following assessment on 14 DAE, there were 16350 brood cells in C, 12450 brood cells in T1, 15850 brood cells in T2, and 7150 brood cells in R. In the replicate Rb, there were no egg or larvae cells, whereas in the replicate Rd, no larvae cells could be found.

On the fifth assessment on 18 DAE, there were 17500 brood cells in C, 11200 brood cells in T1, 12450 brood cells in T2, and only 4700 brood cells in R. In the replicates Rc and Rd, no larvae cells were present on this assessment.

On the assessment on 24 DAE, the mean number of brood cells was strongly decreasing in all treatment groups. There were 8200 brood cells in C, 5300 brood cells in T1, 5100 brood cells in T2, and 3250 brood cells in R.

On the last assessment on 30 DAE, the mean number of brood cells stayed at a similar level, counting 8450 brood cells in C, 5200 brood cells in T1, 5700 brood cells in T2, and 4000 brood cells in R. In the replicates Rc and Rd, there were no pupae cells present.

Overall, there does not seem to be a test item effect on honey bee brood development and colony condition in the Oxamyl 10GR treatment groups T1 and T2. There was an effect in the toxic reference item group R, resulting in low numbers of larvae and pupae cells at various assessments.

E. DEVELOPMENT OF THE HONEY BEE BROOD IN INDIVIDUAL CELLS

According to the development time of a worker honey bee from egg to imago (adult bee) that normally averages approximately 21 days, it can be assumed that almost all young bees hatch until the assessment date BFD+21. Therefore, the study covered one complete development cycle of the honey bee brood.

The control colonies showed a successful development with rising brood index values over the entire assessment period. The brood indices on BFD+15 remained on almost the same level as on BFD+11, which is not unusual because a normal developing bee is expected to be in the same stage (pupa) at both assessments. The mean brood index in the control reached a final value of 2.32 and the mean compensation index was 2.89 on BFD+21. The termination rates on BFD+21 were between 29.32 and 72.47 with a mean value of 53.73. This value is very slightly higher than the desired termination rate of ≤50% for the control, and therefore, the validity criteria was not met. However, this value is not statistically different from 50.00 (one sample t-Test, $p \leq 0.05$), and the relatively low standard deviation allows a reasonable comparison of the control to the other treatment groups.

In the test item treatment group T1, the overall development of the brood in the observed cells was similar to the control. The final mean values on BFD + 21 were 2.12 for the brood indices and 2.80 for the compensation indices. The brood index and compensation index in T1 were statistically not significantly different from the control on any assessment after the application (BFD + 6, BFD + 11, BFD + 15, BFD + 21). The termination rate was very slightly higher than in the control but varied among the three replicates: the range was from 24.07 to 92.67 with a mean value of 57.68 on BFD + 21 (not significantly different from the control).

In the test item treatment group T2, the brood index showed a good development in the observed cells except for one replicate (T2c) with a very low brood index. The final brood index is in a range of 0.12 to 4.02 with a mean value of 2.51. The compensation index on BFD + 21 is in a range of 0.12 to 4.20 with a mean value of 2.99. The termination rates are between 19.63 and 97.52 with a mean value of 49.91. There were no statistically significant differences compared to the control.

In the treatment group R, the effect of the reference item was clearly detectable. In three of the four treatment groups, no single observed cell showed a successful development. At the assessment after application (BFD + 6), the mean brood index decreased from 1.00 to 0.47, and the mean compensation index decreased to 0.60. The mean brood index reached a final value of 0.37, and the mean compensation index was 1.06 on BFD + 21. The brood indices were statistically significantly different from the control at all assessments after the application (BFD + 6, BFD11, BFD + 15, BFD + 21, pooled t-Test, $p \leq 0.05$). The compensation indices were statistically significantly different from the control on BFD + 6, BFD + 15, and BFD + 21, pooled t-Test, $p \leq 0.05$). Consequently, very high termination rates between 70.73 and 100.00 (mean: 92.68) were calculated on BFD + 21 in treatment R (significantly different from the control on BFD + 6, BFD + 11, BFD + 15, BFD + 21; one-sided pooled t-test, $p \leq 0.05$).

Overall, there was no negative effect in the Oxamyl 10GR treatment groups T1 and T2 on the development of the marked eggs. There was a clear effect in the toxic reference item group R, resulting in low brood and compensation indices and high termination rates.

Table 95 Brood/ Compensation indices per treatment group

Treatment group/ Replicate	Brood/ Compensation indices at x days after brood area fixing day (BFD0) for marked cells containing eggs at the first assessment					Termination rate
	BFD0[a]	BFD + 22	BFD + 11	BFD + 15	BFD + 21	BFD + 21
Ca	1.00/ 1.00	1.20/ 1.22	1.47/ 1.83	1.47/ 1.96	1.84/ 2.94	63.30
Cb	1.00/ 1.00	1.77/ 1.77	2.02/ 2.05	2.01/ 2.49	2.51/ 3.19	49.81
Cc	1.00/ 1.00	0.93/ 1.03	1.18/ 1.57	1.13/ 1.20	1.38/ 1.55	72.47
Cd	1.00/ 1.00	2.19/ 2.22	2.84/ 2.92	2.83/ 2.95	3.53/ 3.86	29.32
Mean C	**1.00/ 1.00**	**1.52/ 1.56**	**1.88/ 2.09**	**1.86/ 2.15**	**2.32/ 2.89**	**53.73**
STD[b]	0.00/ 0.00	0.57/ 0.54	0.73/ 0.59	0.74/ 0.75	0.93/ 0.97	18.74
T1a	1.00/ 1.00	0.85/ 0.89	0.94/ 0.94	0.93/ 0.99	1.14/ 1.27	77.14
T1b	1.00/ 1.00	2.25/ 2.41	2.74/ 3.29	2.73/ 3.36	3.16/ 4.19	36.82
T1c	1.00/ 1.00	2.64/ 2.70	3.05/ 3.28	3.04/ 3.34	3.80/ 4.27	24.07
T1d	1.00/ 1.00	0.32/ 0.53	0.31/ 1.12	0.29/ 1.30	0.37/ 1.47	92.67
Mean T1	**1.00/ 1.00**	**1.52/ 1.63**	**1.76/ 2.16**	**1.75/ 2.25**	**2.12/ 2.80**	**57.68**
STD	0.00/ 0.00	1.11/ 1.08	1.34/ 1.30	1.35/ 1.28	1.63/ 1.65	32.49
T2a	1.00/ 1.00	2.70/ 2.79	3.33/ 3.53	3.31/ 3.50	4.02/ 4.20	19.63
T2b	1.00/ 1.00	2.60/ 2.60	3.03/ 3.03	3.01/ 3.02	3.70/ 3.75	26.03
T2c	1.00/ 1.00	0.12/ 0.14	0.10/ 0.10	0.10/ 0.10	0.12/ 0.12	97.52
T2d	1.00/ 1.00	1.86/ 2.24	2.07/ 3.20	2.07/ 3.41	2.18/ 3.90	56.47
Mean T2	**1.00/ 1.00**	**1.82/ 1.94**	**2.13/ 2.47**	**2.12/ 2.51**	**2.51/ 2.99**	**49.91**
STD	0.00/ 0.00	1.19/ 1.22	1.46/ 1.59	1.45/ 1.62	1.78/ 1.92	35.58
Ra	1.00/ 1.00	0.32/ 0.75	0.38/ 2.10	0.49/ 1.88	0.00/ 2.05	100.00
Rb	1.00/ 1.00	1.53/ 1.56	1.91/ 1.93	1.17/ 1.17	1.46/ 1.46	70.73
Rc	1.00/ 1.00	0.02/ 0.05	0.00/ 0.00	0.00/ 0.00	0.00/ 0.00	100.00
Rd	1.00/ 1.00	0.00/ 0.03	0.00/ 0.23	0.00/ 0.33	0.00/ 0.74	100.00
Mean R	**1.00/ 1.00**	**0.47[c]/ 0.60[c]**	**0.57[c]/ 1.07**	**0.42[c]/ 0.85[c]**	**0.37[c]/ 1.06[c]**	**92.68[c]**
STD	0.00/ 0.00	0.72/ 0.72	0.91/ 1.10	0.55/ 0.85	0.73/ 0.89	14.64

[a] BFD: Brood area fixing day

[b] STD: Standard deviation

[c] Significantly different from the control (one-sided pooled t-test, $p \leq 0.05$)

F. RESIDUE ANALYSIS

1. Nectar from forager bees (honey stomach content)

Residues of oxamyl in treated nectar specimens from treatment group T1were in the range of 0.070 to 0.082 mg/kg and from treatment group T2 in the range of 0.012 to 0.019 mg/kg. No residues of oxamyl were detected at or above the limit of detection (LOD = 0.0003 mg/kg) in untreated nectar specimens.

Table 96 Residues in nectar from forager bees (honey stomach content)

Eurofins sample code	Treatment	Timing	Residue[a] (mg/kg)
L14-03580-L1-001A//16-NFB-A	Ce[b]	3DAE[c]	n.d.[d]
L14-03580-L1-007A//14-NFB-A	Ce	5DAE	n.d.
L14-03580-L1-002A//24-NFB-A	T1e[e]	3DAE	0.070
L14-03580-L1-008A//22-NFB-A	T1e	5DAE	0.082
L14-03580-L1-003A//20-NFB-A	T2e[e]	3DAE	0.019
L14-03580-L1-009A//18-NFB-A	T2e	5DAE	0.012

[a] LOQ: 0.001 mg/kg
[b] Ce: Control specimens
[c] DAE: Days after exposure
[d] Not detectable (<LOD = 0.0003 mg/kg)
[e] T1/T2: Treated specimens

2. Pollen from forager bees (pollen loads)

Residues of oxamyl in treated pollen specimens from treatment group T1 were in the range of 0.041 to 0.049 mg/kg and from treatment group T2 in the range of 0.009 to 0.011 mg/kg. For the untreated pollen specimens, oxamyl was detected below the LOQ level (<0.001 mg/kg).

Table 97 Residues in pollen from forager bees (pollen loads)

Eurofins sample code	Treatment	Timing	Residue[a] (mg/kg)
L14-03580-L1-001A//15-PFB-A	Ce[b]	3DAE[c]	<LOQ (0.0004)
L14-03580-L1-007A//13-PFB-A	Ce	5DAE	<LOQ (0.0004)
L14-03580-L1-002A//23-PFB-A	T1e[d]	3DAE	0.049
L14-03580-L1-008A//21-PFB-A	T1e	5DAE	0.041
L14-03580-L1-003A//19-PFB-A	T2e[d]	3DAE	0.011
L14-03580-L1-009A//17-PFB-A	T2e	5DAE	0.009

[a] LOQ: 0.001 mg/kg
[b] Ce: Control specimens
[c] DAE: Days after exposure
[d] T1/T2: Treated specimens

3. Flowers

Residues of oxamyl in treated flowers specimen from *Phacelia tanacetifolia* plants from treatment group T1 were in the range of 0.333 mg/kg to 0.495 mg/kg and from treatment group T2 in the range of 0.137 mg/kg to 0.505 mg/kg. No residues of oxamyl were detected at or above the limit of detection (LOD = 0.0003 mg/kg) in untreated flower specimens.

Table 98 Residues in flowers

Eurofins sample code	Treatment	Timing	Residue[a] (mg/kg)
L14-03580-01-004A-A	Ce[b]	3DAE[c]	n.d.[d]
L14-03580-01-010A-A	Ce	5DAE	n.d.
L14-03580-01-005A-A	T1e[e]	3DAE	0.333
L14-03580-01-011A-A	T1e	5DAE	0.495
L14-03580-01-006A-A	T2e[e]	3DAE	0.505
L14-03580-01-012A-A	T2e	5DAE	0.137

[a] LOQ: 0.001 mg/kg
[b] Ce: Control specimens
[c] DAE: Days after exposure
[d] Not detectable (<LOD = 0.0003 mg/kg)
[e] T1/T2: Treated specimens

III. CONCLUSION

It can be concluded that there was no negative effect on honey bees of the 8.625 kg a.s./ha in-furrow or 5.5 kg a.s./ha broadcast applications of Oxamyl 10GR as a granular application during the seeding of *Phacelia tanacetifolia* on mortality, flight intensity, behaviour, colony size, or colony condition. The termination rates, brood indices, and compensation indices of the individually marked cells in the Oxamyl 10GR treatments were on the same level as the control.

In the nectar samples taken from the forager bees, a maximum value of 0.082 mg oxamyl/kg was found in the in-furrow application treatment group T1. A maximum value of 0.049 mg oxamyl/kg could be found in the pollen samples taken from the forager bees in T1, whereas a maximum value of 0.505 mg oxamyl/kg could be found in the flower samples of the broadcast treatment group T2.

(Berg, C., 2015b)

RMS comments and conclusion

The study followed the methodology indicated in OECD 75 (2007) with some recommendations in EFSA (2013). Further methodological details have been added in the summaryby the RMS.

Oxamyl 10GR was applied during the seeding of *Phacelia tanacetifolia* (attractive plant), after 55 days the hives were introduced in the tunnel and the first assessment of mortality, flight intensity and behaviour was done. 3 and 5 days later forager bees and flowers were sampled for residues. The RMS wonders how well this design matches the proposed in-furrow application to potato (at planting) and to tobacco (at tran-planting), when the roots are already developed and ready to absorb the active substance. Also, the time to flowering of Phacelia tanacetifolia should be compare to those of potato and tobacco, to exclude possible difference in degradation of the substance due to different times from application. **The Applicant should address these issues.**

It is noted that the statistical power of the test is not indicated and due to the high variability in the termination rates, brood development and compensation indices among the replicates of each treatment group, the reliability of the biological results of this study is compromised.

CP 10.3.1.5.1 Cage tests*

On the basis of the risk assessment, Oxamyl 10GR will pose a low risk to honey bees (Point B.9.5.1 in this document). No further testing is needed. It can be concluded that Oxamyl 10GR will be safe to honey bees when used according to Good Agricultural Practice.

CP 10.3.1.5.2 Tunnel test to investigate effects of feeding on contaminated honey dew or flowers

On the basis of the risk assessment, Oxamyl 10GR will pose a low risk to honey bees (Point B.9.5.1 in this document). No further testing is needed. It can be concluded that Oxamyl 10GR will be safe to honey bees when used according to Good Agricultural Practice.

B.9.5.1.6 Field tests with honey bees

On the basis of the risk assessment, Oxamyl 10GR will pose a low risk to honey bees (Point B.9.5.1 in this document). No further testing is needed. It can be concluded that Oxamyl 10GR will be safe to honey bees when used according to Good Agricultural Practice.

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 product Oxamyl 10GR rather than the active substance. Laboratory studies were conducted to assess effects on the sensitive indicator species, the Phytoseiid mite, *Typhlodromus pyri*, and the parasitic wasp, *Aphidius rhopalosiphi*. Summaries of these studies are given in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

B.9.5.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

Extended laboratory studies were conducted with *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp. Summaries of these studies are given below.

Poecilus cupreus

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.6.2.2/01

Reference: --	**Report:**	Schmitzer, S. (2000); Oxamyl 10G (10% w/w): An extended laboratory study to evaluate the effects on the ground beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) **DuPont Report No.:** DuPont-3244 **Guidelines:** BBA VI 23-2.1.8 (1991), Heimbach U., DRAFT 1999, ring-test group protocol, Versailles, France, 1999.

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s./kg

Testing Facility: IBACON, Rossdorf, Germany

GLP: Yes.

Materials and methods:

Mortality and food consumption were assessed during a 14-day exposure of adult (4-5 weeks) carabid beetles, *Poecilus cupreus*, to the granules of Oxamyl 10 GR. Oxamyl 10 GR was evenly incorporated into LUFA 2.1 soil, at a rate of 55 kg product/ha. This was equivalent to 38.5 mg Oxamyl 10 GR/kg dry soil (assuming soil

density is 1.43 g/cm3), in a depth of 10 cm or 3.85 mg Oxamyl/kg dry soil. An untreated control and two toxic standard were also tested: a) 1500 mL Afugan EC 30/ha in 400 L water/ha (corresponding to 441 g a.i./ha) was applied to test units containing LUFA 2.1 soil and b) 1000 mL Afugan EC 30/ha in 400 L water/ha (corresponding to 294 g a.i./ha) was applied to test units containing quartz sand. Test units were plastic boxes (18.3x13.6x6cm) filled with 500 g dry soil (1.6 cm depth). To assure adequate substrate for mixing granules, 500 g soil instead of 250 g was used for each test unit. Soil moisture in the Oxamyl 10 GR treatment, Control and Toxic Standard Group with LUFA 2.1 was about 55% of maximum water holding capacity of LUFA 2.1 soil. In the toxic standard with quartz sand substrate, 250 g (dry weight) quartz sand (layer of about 1 cm) was moistened to about 70 % ± 5 % of its maximum water holding capacity.

Five replicates of 6 adult beetles (3 males & 3 females) each were exposed during the study. Punctured deep frozen fly pupae were fed on day0, 1, 2, 4, 7, 10 (1 pupa per viable beetle).

Mortality, abnormal behaviour and food consumption of the beetles were assessed on day 0, 1, 2, 4, 7, 10 and 14. Missing pupae were also denoted as consumed.

Temperature: 20 - 21 °C. Relative Humidity in the Test Units: 71 %. Light: 16 h light: 8 h dark, 1087 - 1398 lux.

Findings:

Mortality and behavioural abnormalities

	Test substance		Control		Toxic standard 294 g Pyrazophos/ha (applied on quartz sand)		Toxic standard 441 g Pyrazophos/ha (applied on Lufa 2.1 soil)	
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	76.7 ± 9.1	0.0 ± 0.0	13.3 ± 13.9
2nd day	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	70.0 ± 7.5	23.3 ± 9.1	20.0 ± 7.5	3.3 ± 7.5
4th day	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	93.3 ± 9.1	0.0 ± 0.0	26.7 ± 9.1	0.0 ± 0.0
7th day	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	93.3 ± 9.1	0.0 ± 0.0	26.7 ± 9.1	0.0 ± 0.0
10th day	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	93.3 ± 9.1	0.0 ± 0.0	26.7 ± 9.1	0.0 ± 0.0
14th day	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	93.3 ± 9.1	0.0 ± 0.0	30.0 ± 7.5	0.0 ± 0.0

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

[b] time period after application

[c] percentage values represent group means ± standard deviation from five replicates
Beh. abn. = Behavioural abnormalities; SD = Standard Deviation

Food consumption

	Test substance		Control		Toxic standard (quartz sand)		Toxic standard (Lufa 2.1 soil)	
Time[a]	Pupae/ beetle #	Consumption[b] %	Pupae/ beetle #	Consumption %	Pupae/ beetle #	Consumption %	Pupae/ beetle #	Consumption %
days 0 - 14	4.1	141.9	2.9	100.0	3.4	117.8	3.0	104.3
days 7 - 14	1.4	164.0	0.8	100.0	1.5	180.0	0.7	87.3

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

Mortality in the control group was 0.0% (Table). Results for the toxic reference substance fell within acceptable ranges, indicating validity of the study. Oxamyl 10 GR applied at 55 kg product/ha resulted in corrected beetle mortality of 0.0%. The mortality results were not statistically significant (Dunnett-Test, multiple comparison, p = 0.05) when compared to the control group. There was no reduction in food consumption (4.1 pupae/beetle for the test group vs. 2.9 pupae/beetle for the control group) as a result of exposure to Oxamyl 10 GR. The food consumption was higher compared to the control group.

Table 99 Effects on mortality and food consumption of the ground beetle, *Poecilus cupreus*, exposed to Oxamyl 10 GR mixed into LUFA 2.1 soil at 3.85 mg Oxamyl/kg dry soil

Test substance	Oxamyl 10 GR
Test organism	*Poecilus cupreus*
Exposure	14d, LUFA 2.1 soil, granule incorporation, 3.85 mg Oxamyl/kg dry soil
Control Mortality Mortality (Abbott's correction) (55 kg Oxamyl 10 GR/ha)	0.0% 0.0%
Reduction in Food Consumption (55 kg Oxamyl 10 GR/ha)	-41.4 %
441 g Afugan/ha in LUFA soil (Toxic Reference Standard No.1)	30% Mortality
294 g Afugan/ha in sand (Toxic Reference Standard No.2)	93.3% Mortality

Conclusion:

The results of this study indicate that no effects of Oxamyl 10G (10% w/w) on the mortality and behaviour of the carabid beetle, *P. cupreus* if mixed in standardized soil at a concentration of 55 Kg Oxamyl 10G/ha.

RMS comments and conclusion

The ground dwelling predatory species (selected to be relevant to the intended uses of preparations) study DuPont 3244, originally submitted under EU Rev8 Point IIA 8.3.2.2 and conducted with test material Oxamyl 10GR, was conducted under guideline BBA VI 23-2.1.8 (1991). The study was evaluated according to Heimbach (2000).Validity criteria are met:

Control Mortality: validity criteria: ≤6.7 %; actual in 0.0 % at day 14.

Toxic Standard Mortality: 65 % ± 35 % in LUFA soil (actual 30 % mortality).

Conclusion – the study is acceptable.

Aleochara bilineata

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.6.2.2/02

Reference: --	**Report:**	Drexler, A. (2000); Oxamyl 10G (10% w/w): An extended laboratory study to evaluate the effects on the staphylinid beetle, *Aleochara bilineata* Gyll **DuPont Report No.:** DuPont-3245, Revision No. 1 **Guidelines:** SETAC-ESCORT (1994); Richtlinie zur Prüfung der Nebenwirkung von Pflanzenschutzmitteln auf Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) (erweiterter Laborversuch). (Moreth L. & Naton E. 1992).

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s./kg

Testing Facility: IBACON, Rossdorf, Germany

GLP: Yes

Materials and methods:

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10G
	Lot/Batch #:	D1410-381
	Purity:	100 g a.s./L
	Description:	Blue granules
	CAS#:	None for the formulation 23135-22-0 for oxamyl active substance
2.	Control:	LUFA 2.1 soil (moistened to 10% (v/v) with deinonised water)
	Test vehicle:	Granules mixed to soil
	Toxic reference:	Afugan 30 EC (pyrazophos a.s.30.6%)
3.	Test organism	
	Species:	*Aleochara bilineata*
	Age at dosing:	1-4 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:	19 to 21°C exposure; 18 to 21°C post exposure
	Photoperiod (exposure):	16 hour photoperiod (780 lux - 1212 lux
	Photoperiod (post exposure)	16 hour photoperiod (231 lux - 1721 lux)

Emergence of the F-1 generation of the staphylinid beetle, *Aleochara bilineata*, and the parasitism success on Delia pupae were evaluated under extended laboratory conditions. Adult beetles (10♂ and 10♀ per test unit, four replicates per treatment) were exposed for 28 days to Oxamyl 10 GR in beakers containing treated natural soil (LUFA 2.1) which had been aged for 28, 14, 7 and 0 days under laboratory conditions. The Oxamyl 10 GR was applied as granules, which were evenly mixed into the soil with a mixer at a rate of 55 kg Oxamyl 10 GR/ha. Taking into consideration the density of LUFA 2.1 soil (1.43 g/cm3) 55 kg Oxamyl 10 GR/ha corresponds to 38.5 mg Oxamyl 10 GR/kg dry soil or 3.85 mg Oxamyl/kg dry soil. The soil was then aged in the laboratory for 28, 14, 7 and 0 days before introduction of the beetles. An untreated control (LUFA 2.1 soil) and toxic standard (3.4 L Afugan EC 30 in 400 L water/ha applied as spray at 4 mg/cm2; 1 kg pyrazophos/ha) were also tested. Once a week ca. 500 Delia antiqua pupae per container were added at day 7, 14 and 21. Soil moisture was 10% (v/v). Mortality and abnormal behaviour of the beetles were assessed on day 1, 3 and 7; the total numbers of emerged beetles from the offered fly pupae were assessed until emerging of the F1-generation had finished.

Findings:

	Emerged Beetles							
	Unit 1 #	Unit 2 #	Unit 3 #	Unit 4 #		total #	mean	SD
Control	961	794	881	943		3579	895	75
Test Substance aged for 28 days	551	934	809	806	n.s.	3100	775	161
Test Substance aged for 14 days	681	614	707	698	*	2700	675	42
Test Substance aged for 7 days	499	615	646	679	*	2439	610	78
Test Substance aged for 0 days	418	510	652	550	*	2130	533	97
Toxic Standard	517	403	286	599	*	1805	451	136

mean/SD = mean number of 4 replicates and Standard Deviation

n.s. = not significant compared to the control; * = significant compared to the control, Dunnett-Test, $\alpha = 0.05$

Results for the toxic reference substance fell within acceptable ranges, indicating validity of the study (Table). Exposure to Oxamyl 10 GR aged for 28, 14, 7, or 0 days in LUFA 2.1 soil caused a 13.4%, 24.6%, 31.8%, or 40.4% reduction of emerging F-1 generation beetles compared to controls. No abnormalities or intoxication symptoms were observed in the adult beetles at any of the Oxamyl 10 GR treatments.

Table 100 Effects on adult beetle mortality and reproduction (parasitism success) of the staphylinid beetle, *Aleochara bilineata*, exposed to Oxamyl 10 GR mixed into LUFA 2.1 soil at 3.85 mg Oxamyl/kg dry soil

Test substance	Oxamyl 10 GR	
Test organism	*Aleochara bilineata*	
Exposure	28d, LUFA 2.1 soil, granule incorporation, 3.85 mg Oxamyl/kg dry soil	
Effects Observed	↓ Reproduction	7 day Mortality
Aged 28 days	13.4%	0%
Aged 14 days	24.6%	0%
Aged 7 days	31.8%	2.5%
Aged 0 days	40.4%	0%
Toxic Standard	49.6%	8.75%

* Equivalent to parasitism success.

Conclusion:

Staphylinid beetles, *A. bilineata*, exposed to freshly treated soil experienced no mortality, but a 40% reduction of reproduction relative to controls. After aging of the test substance of 14 days or less significant reduction of reproduction occurred. There were no significant effects observed in the rove beetle when Oxamyl 10G is applied at 55kg product/ha and aged for 28 days. No effect on adult behaviour was observed.

RMS comments and conclusion

The ground dwelling predatory species (selected to be relevant to the intended uses of preparations) study DuPont 3245, Revision No. 1, originally submitted under EU Rev8 Point IIA 8.3.2.2 and conducted with test material Oxamyl 10GR, was conducted under guideline SETAC-ESCORT (1994).

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 well below the minimum 60% at several days.

Validity criteria:

Reproduction Rate of Control: was ≥45 beetles per female corresponding to 30% parasitism rate (actual 89.5 beetles per female). Fulfilled.

Reduction of Reproduction in the Toxic Standard: was at the limit of the minimum reduction requested of 50% (actual 49.6 %) but this was achieved at 3 x the concentration recommended.

Conclusion: the test is acceptable.

***Pardosa* spp.**

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.6.2.2/03

Reference: --	**Report:**	Bruhnke, C. (2000); Oxamyl 10G: An extended laboratory study to evaluate the effects on the spider *Pardosa* spp. (Araneae, Lycosidae) **DuPont Report No.:** DuPont-4053 **Guidelines:** BBA VI 23-2.1.9 (1994) and Heimbach et al., 2000 draft, "Testing side effects of pesticides on spiders (Pardosa spp.) in the laboratory".

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s./kg

Testing Facility: Dr. U. Noack-Laboratorium for Angewandte Biologie, Sarstedt, Germany

GLP: No

I. MATERIALS AND METHODS

A. MATERIALS

1.	Test material:	Oxamyl 10G
	Lot/Batch #:	D1410-377
	Purity:	100 g a.s./L
	Description:	Blue-green granules
	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:	5 frozen adult *Drosophilia hydrii* per living spider 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)

Materials and methods:

Oxamyl 10 GR was tested on Lycosid "wolf" spiders (*Pardosa* spp.) under extended laboratory conditions. Thirty-four spiders (17 male and 17 female each) were used for each test group, reference group and control, respectively. Standard LUFA 2.1 soil was treated with 3.85 mg Oxamyl/kg dry soil weight. The control was LUFA 2.1 soil treated with demineralised water. The toxic reference group was treated with KARATE (50 g/L Lambda- cyhalothrin) at 60 mL/ha (= 3.0 g a.s./ha) in 400 L water/ha by spraying. The soil was moistened to 55% of its maximal water holding capacity before use.

Oxamyl 10 GR was mixed into the soil as intact granules and the reference substance was sprayed to the test units. The spiders were fed with frozen adult *Drosophila hydii*.

Mortality and behaviour of the spiders were recorded on the application day (day 0) 2 hours after application and thereafter, on test days 1, 2, 3, 4, 7, 10, 14, 17 and 21. Feeding rate was determined on days 1, 2, 3, 4, 8, 11, 15, and 18 (24 hr feeding interval). The effects were compared with corresponding parameters of the control and a toxic reference group.

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).

Findings:

Mortality

Day	Mortality [%]		
	Control	Test Item 38.5 mg/kg	Reference Item
2 h	0.0	0.0	0.0
1	0.0	0.0	70.6
2	0.0	2.9	70.6
3	0.0	2.9	97.1
4	0.0	2.9	100.0
7	0.0	11.8	-
10	0.0	14.7	-
14	0.0	14.7	-
17	0.0	14.7	-
21	0.0	17.6	-

- = all spiders were dead

Feeding rate

Day	Eaten flies / alive spiders and day		
	Control	Test Item 38.5 mg/kg	Reference Item
1	3.2	3.3	0.0
2	2.6	2.1	0.0
3	2.4	2.2	0.0
4	1.6	1.5	-
8	1.7	2.1	-
11	1.9	2.1	-
15	3.0	2.8	-
18	2.1	1.7	-
∑ day 1 - 4	9.8	9.1	0.0
∑ day 7 - 14	3.6	4.2	-
∑ day 15 - 21	5.1	4.5	-
∑ overall	18.5	17.8	0.0
Mean feeding rate [flies per spider and day]	2.3	2.2	0.0
Feeding capacity	-	0.96	0.0
Total number of consumed flies	623	562	0

Mortality percentages in the control, treatment group (3.85 mg Oxamyl/kg dry soil), and toxic standard (KARATE 60 mL/ha) groups were 0.0%, 17.6% and 100%, respectively (Table). The mortality results were statistically significant for both Oxamyl 10 GR and the toxic reference (Fisher Exact Test, $p = 0.05$) when compared to the control group. Mean feeding rate (flies/spiders/day) was 2.3 in the control group, 2.2 in the Oxamyl 10 GR group and 0.0 in the toxic reference group. The feeding rates of the Oxamyl 10 GR treated spiders were not statistically different from the control spiders (t-test, $p > 0.05$).

Table 101 Effects on mortality and food consumption of the wolf spider, *Pardosa spp.*, exposed to Oxamyl 10 GR mixed into LUFA 2.1 soil at 3.85 mg Oxamyl/kg dry soil

Test substance	Oxamyl 10 GR
Test organism	*Pardosa* spp.
Exposure	21d, LUFA 2.1 soil, granule incorporation, 3.85 mg Oxamyl/kg dry soil
Mortality (Abbott's correction)	17.6%
Reduction in Food Consumption	+4.3%
50g/ lambda-cyhalothrin (Toxic Reference Standard)	100% Mortality

Conclusion:

Pardosa spp. exposed to Oxamyl 10 GR granules mixed into LUFA 2.1 soil at a rate of 3.85 mg Oxamyl/kg dry soil experiences statistically significant lethal effects compared to the control, but below the value requiring further testing. Mortality of the spiders was 17.6% (relative to controls) after 21 days when Oxamyl 10 GR was applied at a rate of 3.85 mg Oxamyl/kg dry soil. No statistically significant sublethal effects were recorded. The mean feeding rates of the control and treatment groups were 2.3 and 2.2 (flies/spider/day) respectively.

RMS comments and conclusion

The ground dwelling predatory species (selected to be relevant to the intended uses of preparations) study DuPont 4053, originally submitted under EU Rev8 Point IIA 8.3.2.2 and conducted with test material Oxamyl 10GR, was conducted under guideline BBA VI 23-2.1.9 (1994).

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%).

The LR50/ER50 cannot be calculated.

The test is acceptable.

B.9.5.2.3 Semi-field studies with non-target arthropods

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

B.9.5.2.4 Field studies with non-target arthropods

Oxamyl 10GR demonstrated very low toxicity to non-target to non-target arthropods in Tier II studies. No effects >50% were observed on any of the species indicating that no further studies were warranted.

B.9.5.2.5 Other routes of exposure for non-target arthropods

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

B.9.6 Risk assessment for arthropods

Non-target arthropod risk assessment

Tests conducted to examine the potential effects of Oxamyl 10GR on non-target arthropods are reported in detail in this document and in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU. A summary of the relevant end points is given in Table .

Table 102 Summary of effects of Oxamyl 10GR on non-target arthropods

Species	Test (and test substance and test design)	Measurement endpoint	Endpoint value	Reference
Aphidius rhopalosiphi	Not valid			DuPont-2609[b]
Typhlodromus pyri	Tier 1 laboratory (Oxamyl 10 SL[a], sprayed 2-D exposure)	LR_{50} Effect on reproduction	1.8 g a.s./ha ≥0.8 g a.s./ha Supportive information	DuPont-4037[b]
Poecilus cupreus	Tier 2 extended laboratory (Oxamyl 10GR, 3.85 mg oxamyl/kg dry soil mixed into LUFA 2.1 soil)	14-d corrected mortality Reduction in Feeding rate (relative to controls) LR_{50}/ER_{50} for food consumption (EC_{50})	0% -41.4% >55 kg prod./ha (3.85 mg a.s./kg dws)	DuPont-3244[c]
Aleochara bilineata	Tier 2 extended laboratory (Oxamyl 10GR, 3.85 mg oxamyl/kg dry soi mixed into LUFA 2.1 soil)	7 d mortality: 0 d aged soil 7 d aged soil 14 d aged soil 28 d aged soil Reduction in reproduction: 0 d aged soil 7 d aged soil 14 d aged soil 28 d aged soil LR_{50}/ER_{50} for reproduction (EC_{50})	 0% 2.5% 0% 0% 40.4% 31.8% 24.6% 13.4% >55 kg prod./ha (3.85 mg a.s./kg dws)	DuPont-3245 Revision No. 1[c]
Pardosa spp.	Tier 2 extended laboratory (Oxamyl 10GR, 3.85 mg oxamyl/kg dry soil mixed into LUFA 2.1 soil)	21 d mortality 21 d Reduction in feeding rate LR_{50}/ER_{50} for food consumption (EC_{50})	17% 4.3% >55 kg prod./ha (3.85 mg a.s./kg dws)	DuPont-4053[c]

[a] Oxamyl 10SL was used for testing honeybees and standard sensitive species (*Aphidius* and *Typhlodromus*) in place of Oxamyl 10GR because no standard protocols exist for testing with the granular formulation. These are included here for completeness.

[b] Study is summarised in the Oxamyl dRAR a.s. Vol. 3 B9.

[c] Study summarised in this document

The following equations were used to calculate the HQs:

$$\textbf{In-field HQ} = \frac{\text{Application rate x MAF}}{LR_{50}}$$

$$\textbf{Off-field HQ} = \frac{\text{Application rate x MAF x (drift factor/veg. distr. factor) x correction factor}}{LR_{50}}$$

Where,

- Application rate = maximum proposed single GAP application rate (g/ha)
- MAF = multiple application factor (ratio of soil DT_{50}: spray application interval plus the number of applications)
- LR_{50} (lethal rate causing 50% mortality in g/ha)
- Drift factor = crop-specific and growth-stage specific drift at a specified distance (%)
- Vegetation distribution factor = correction factor used to take into consideration the effect of the field boundary and vegetated filter strip on reducing drift; default value of 10
- Correction factor (uncertainty factor): this factor takes into consideration the uncertainty with the extrapolation from *T. pyri* and *A. rhopalosiphi* to all off-field non-target arthropods; default value = 10

Tier 1 risk assessment

Input parameters for the non-target arthropod worst-case Tier 1 risk assessment, for Oxamyl 10GR use in tobacco, soil treatment, were the following:

- Application rate: 5500 g a.s./ha (equivalent to 55 kg Oxamyl 10GR/ha)
- MAF: 1.0 (default value for 1 application; see ESCORT II Appendix III)
- *Typhlodromus pyri* LR_{50} = 1.8 g a.s./ha (supportive information)
- Drift factor = 1.49% (drift value for granule broadcast application, 1.5 m distance according to EFSA 2004[4]; see the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10GR, DuPont-40953 EU)
- Vegetation distribution factor = 10 (default value)
- Correction factor (uncertainty factor) = 10 (default value)

Although reliable toxicity endpoints are not available for the two standard species *A. rhopalosiphi* and *T. pyri*, the Tier 1 is presented for illustrative purposes based on supportive LR_{50} for *Typhlodromus pyri*.

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

Table 103 Tier 1 summary of non-target arthropod in-field and off-field hazard quotients (HQ) for Oxamyl 10GR use in tobacco at 5500 g a.s./ha

Species	LR_{50} (g a.s./ha)	In-field HQ	Off-field HQ	Trigger
T. pyri	1.8 Supportive information	3056	46	2
A. rhopalosiphi	 Study not accepted			2

The study with *A. rhopalosiphi* is not valid/acceptable. Based on the Tier 1 risk assessment for the sensitive indicator species, *Typhlodromus pyri*, Oxamyl 10GR poses a potential risk to in-field and off-field non-target arthropods (all HQ values >2), if used according to Good Agricultural Practice with application at 55 kg oxamyl 10GR/ha in tobacco. Hence it is concluded unacceptable risk for both the indicator species. A higher tiered assessment and the evaluation of potential effects on additional species is triggered.

Tier 2 risk assessment for non-target arthropods

To address the need for a refined risk assessment for non-target arthropods, the following additional tests were conducted with Oxamyl 10GR:Extended laboratory studies were conducted with *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp., which are relevant to the proposed use pattern of Oxamyl 10GR. In these studies with the soil-dwelling arthropods, Oxamyl 10GR was evenly incorporated into LUFA 2.1 soil at a rate of 55 kg Oxamyl 10GR/ha. This was equivalent to 38.5 mg Oxamyl 10GR/kg dry weight soil based on a soil density of 1.43 g/cm^3 for LUFA 2.1 soil. All soil arthropod species showed acceptable risk by **ER_{50} (EC_{50}) at >55 kg Oxamyl 10GR/ha (38.5 mg Oxamyl 10GR/kg dry weight soil)**. The results of these studies were submitted in the EU Dossier 2001 and included in the EU approval review. The studies have been reviewed by the RMS according to current guidelines and judged acceptable.

In-field

Oxamyl 10GR is a nematicide for use in potatoes and tobacco as a single application in-furrow of 1000 g a.s./ha at planting and 3000 g a.s./ha at planting (BBCH 00), respectively, and in tobacco as evenly incorporated into soil depth of at least 10 cm after broadcast application at a rate of 5500 g a.s./ha at pre-planting (BBCH 00). In-field exposure to foliage-dwelling arthropods was not considered because this group will not be present in the field during the application of the product. According to the proposed use pattern, soil-dwelling arthropods are mainly exposed to Oxamyl 10GR below ground, which is already considered in the exposure regime of the extended laboratory studies with *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp. Predicted environmental concentrations were generated to simulate applications of oxamyl to potatoes or tobacco in the EU. The predicted soil concentrations (PEC_s) of oxamyl were determined based upon the recommendations of the FOCUS group. Details of the methods and assumptions used in the PEC_s calculation are presented in DuPont-40857 EU, summarized in theOxamyl 10GR dRAR Vol 3 B8.dR A summary of the predicted environmental concentrations in soil for oxamyl in comparison with the relevant EC_{50} for non-target arthropod species is provided in Table .

Table 104 Tier 2 in-field risk assessment for non-target arthropods for the use of Oxamyl 10GR in potato and tobacco

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

Note of the RMS: for this use pattern the Applicant used an endpoint of 7.69, stating that it is adjusted to a soil depth of 5 cm. As a consequence, the Applicant concluded an acceptable risk.

Off-field

Off-field exposure might occur through drift of dust particles during application. The amount of dust-drift reaching the off-crop habitat is calculated using dust drift values provided by EFSA (2004)[5], in accordance with PEC_{sw} calculations (see the Oxamyl dRAR Vol 3 B8). For broadcast granular application, a maximum of 1.49% of the application rate was assumed to reach off-crop areas at 1 m from the edge of the crop (worst-case scenario). In-furrow application to potato and tobacco is performed during transplanting and dust development is not expected to occur for this application method as demonstrated by a field study (DuPont–38691 EU, summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 6, DuPont-40933 EU).

The following equation was used to calculate the predicted environmental rate (PER):

Off-field PER = Application rate × MAF × (drift factor/veg. distr. factor) × correction factor

Where,

- Application rate = maximum proposed GAP application rate (g/ha)
- MAF = multiple application factor (ratio of soil DT_{50}: spray application interval plus the number of applications)
- Drift factor = 1.49% (drift value for granule broadcast application, 1.5 m distance according to EFSA 2004[5]; see the Oxamyl dRAR Vol 3 B8)
- Vegetation distribution factor = correction factor used to take into consideration the effect of the field boundary and vegetated filter strip on reducing drift; default value of 10
- Correction factor (uncertainty factor): this factor takes into consideration the uncertainty with the extrapolation from limited number of indicator species to all off-field non-target arthropods; default value = 5

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

Table 105 Tier 2 off-field risk assessment for non-target arthropods for the use of Oxamyl 10GR in potato and tobacco

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

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

Conclusion:

Considering a risk assessment using tier 2 extended laboratory data of *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp., Oxamyl 10GR poses no unacceptable risk to non-target arthropods.

RMS comments and conclusion

Reliable toxicity endpoints are not available for the two standard species *A. rhopalosiphi* and *T. pyri*, hence a unacceptable risk is assumed. The extended laboratory studies conducted with the soil-dwelling arthropods *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa spp*., have been reviewed by the RMS according to current guidelines and judged acceptable. These studies have been considered adequate to refine the in-field risk assessment of non-target arthropods, taking into account that in-field exposure to foliage-dwelling arthropods is considered unlikely during the application of the product.

A Tier 2, the in-field risk assessment to soil-dwelling arthropods for use on potato at 1 x 1000 g a.s./ha (in-furrow) and on tobacco at 1 x 5500 g a.s./ha (broadcast) is acceptable. For use in Tobacco in furrow at 1 x 3000 g a.s./ha (Table 104), the Applicant used a toxicity endpoint of 7.69 mg a.s./kg soil instad of 3.85 mg a.s./kg soil, stating that it is adjusted to a soil depth of 5 cm. As a consequence, the Applicant concluded an acceptable risk. The RMS cannot understand the rationale behind this adjustment and has used the EC50 = 3.85 (mg a.s./kg soil), concluding that unacceptable risk in-field for this use pattern cannot be excluded. Anyhow, consideration should be given to the fact that ER_{50} (EC_{50}) is actually a "higher than" value (>3.85 mg a.s./kg) and it is very closed to the PEC (4.0 mg a.s./kg). In addition, the RMS acknowledges that, based on the DTsoil of 5.3 days, a population recovery may be expected by recolonization within one year.

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

The off-field higher tier risk assessment the soil dwelling arthropods is acceptable. **The risk to foliage dwelling organisms present off-field remains to be addressed.**

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

B.9.7.1 Earthworms

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.8.1/01

Reference: --	**Report:**	Luhrs, U. (2000); Oxamyl 10G (10% w/w): Acute toxicity to the earthworm, *Eisenia fetida* (Savigny) in artificial soil **DuPont Report No.:** DuPont-3850 **Guidelines:** OECD 207 (1984), ISO 11268-1 (1993)

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s/kg

Materials and methods:

Test facility: IBACON GmbH (Rossdorf, Germany). The acute toxicity of Oxamyl 10 GR to earthworms, *Eisenia fetida* (Savigny), was estimated in a 14-day soil exposure laboratory study. Adults of approximately 4-5 months, with clitellum, and body weight of 300-600 mg were used. Acclimatisation was 1 day, in artificial soil, under test conditions Four replicates of ten clitellated adult earthworms each were exposed to a nominal concentration of 62.5 mg, 125 mg, 250 mg, 500 mg, and 1000 mg of Oxamyl 10 GR/kg dry artificial soil(OECD soil). Granules were pulverised and introduced to the soil in a sand mixture. The soil was well ventilated and moistened to ca. 40 – 60% of the water capacity with deionised water. The water content was 27.2% - 28.7% corresponding to 50.5% - 53.3% of the water holding capacity (on a dry soil weight basis) at the study start and from 28.1% to 28.8% (corresponding to 52.2% to 53.5% of the water holding capacity) at the end of the study. The control was replicated four times, with ten earthworms in each replicate. Test units were filled with 500 g dw artificial soil (635 g wet weight). At start the watercontent was 56.0% to 57.4% of the total water holding capacity. Soil water was kept within 10% of the initial soil water content.The pH at start was 5.7 to 5.8 and at the end of test was 5.7. Temperature was in the range 19- 20 °C. Light Regime was 16 hours light, 8 hours dark (400 - 800 lux). Earthworms were assessed for mortality and behavioural effects after 7 and 14 days of exposure and earthworm body weights were assessed at day 0 and day 14.

The toxic standard, 2-chloracetamide, is tested once a year. The 14-day LC50 of the most recent test was 17.8 mg 2-chloracetamide/kg dry soil, indicating validity of the study.

Mortality and body weight changes of the worms were tested for normality and homogeneity of variance using Kolmogoroff-Smirnov-Test and Cochran-Test. Because data of mortality did not fulfil the criterion of homogeneity, Student-t-Test for non homogeneous variances (pairwise comparison, onesided) = 0.05, was used. Because data of body weight changes were normally distributed and homogeneous, Dunnett-Test (multiple comparison, one-sided) = 0.05, was used. The software to perform the statistical analysis was SYSSTAT 9 and EASY ASSAY, Multiple Testing, © SPiRiT, Version 4.0.

Findings:

Cumulative mortality, mean body weight, and average weight change values are provided in Table 106. No significant sublethal behavioural effects were observed.

Table 106 Summary of mortality and body weight changes in earthworms exposed to Oxamyl 10 GR for 14 days following application to soil

Concentration mg/kg	Cumulative Mortality (%)		Mean body weight/earthworm (mg)		Average weight change
	Day 0	Day 14	Day 0	Day 14	%
0 (water control)	0	0	384.8	378.9	-1.6
62.5	0	0	384.8	320.7	-16.7[b]
125	0	0	386.1	314.0	-18.6[b]
250	0	0	375.0	289.5	-22.8[b]
500	1	2.5	384.9	263.5	-31.7[b]
1000	10	25.0[a]	411.8	273.8	-33.4[b]

[a] significant at $p<0.05$ (Student-t test)
[b] significant at $p<0.05$ (Dunnett test)

Conclusion:

The acute earthworm LC50 of Oxamyl 10 GR could not be determined because mortality at the highest dose tested was <50%. Therefore, the LC50 is >1000 mg Oxamyl 10 GR/kg soil (equivalent to >100mg a.i./kg soil).

RMS comments and conclusion

The RMS added additional information and made some corrections to the study summary..

The earthworms study DuPont-3850, originally submitted under EU Rev8 Point IIA 10.6.1.1 and conducted with test material Oxamyl 10GR, was conducted under guidelines OECD 207 (1984) and ISO 11268-1 (1993). A review of this study indicates that it fully meets the current guideline OECD 207 (1984).

The study is valid and relied upon.

B.9.7.1.1 Earthworms - sub-lethal effects

Chronic earthworm studies were conducted with Oxamyl 10GR and oxamyl metabolites. The summary of the study with the representative formulation is reported hereunder. Summaries of these studies with metabolites are included in dRAR Vol. 3 a.s. B9.

Reference: --	**Report:**	Luhrs, U. (2001); Oxamyl 10G (10% w/w): Effects on reproduction and growth of the earthworm, *Eisenia fetida*, (Savigny 1826), in artificial soil **DuPont Report No.:** DuPont-4296 **Guidelines:** ISO 11268-2, 1998 and BBA VI 2-2 (1994)

1. Test material: Oxamyl 10GR
   Lot/Batch #: D1410-377
   Purity: 100 g a.s./kg

Materials and methods:

Test facility: IBACON GmbH (Rossdorf, Germany). The sublethal toxicity of Oxamyl 10 GR to earthworms, *Eisenia fetida* Savigny, was estimated in a 56-day soil exposure laboratory study based on ISO 11268, Part 2 (1998), and BBA VI 2-2 (1994). Acclimatization of earthworms was for 4 days, in artificial soil, under test environmental conditions. 8 to 9 months (but all within 4 weeks of the same age), with well-developed clitellum. Four replicates of ten clitellated adult earthworms each were exposed to the nominal concentrations of 4.0, 8.0, 16.0, 32.0 and 64.0 mg Oxamyl 10 GR/kg dry artificial soil (OECD soil), to a water treated control and to the toxic standard, Derosal SC 360 g/L, at 2.18 mg Carbendazim/kg. Test units were filled with 500 g dw artificial soil (635 g wet weight). At start the watercontent was 56.0% to 57.4% of the total water holding capacity. Soil water was kept within 10% of the initial soil water content.The pH at start was 5.7 to 5.9 and at the end of test was 5.8 to 6.0. Temperature was in the range 18- 21 °C. Light Regime was 16 hours light, 8 hours dark. One day after application of IN-A2213, 5 g/container of finely ground and moistened cattle manure was scattered uniformly on the soil surface. Food was added the same way each week for the first four weeks of the experiment, when the food of the previous week was almost completely consumed. If the food was not quite fully consumed, the added amount of food was adjusted to account for visually estimated consumption. After removing the adult worms on day 28, the food was mixed into the substrate.Adult earthworms were sorted from

soil and assessed for mortality, weight loss, and sublethal effects after 28 days. Soil was replaced in the test container and juveniles were allowed to grow for another 28 days, at which time they were removed from the soil and counted and sublethal effects were assessed. The amount of food added per test container was recorded throughout the experiment.

Mortality data were analysed for significance by using Fisher-exact-test (two-sided, = 0.05). 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; = 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), = 0.05.The software to perform the statistical analysis was SYSSTAT 9 and EASY ASSAY, Multiple Testing, © SPiRiT, Version 4.0.

Findings:

The results of this study did not reveal any acute toxic effects of Oxamyl 10G (10% w/w) to *Eisenia fetida*. No mortality was observed in any of the groups treated with Oxamyl 10G. The bodyweights of the worms increased in all treatment groups as well as the control group indicating the validity of the test. Cumulative mortality and weight loss of adults at 28 days, earthworm reproduction, and feeding activity are reported below (Table 107) for each treatment. No significant sublethal behavioural effects were observed up to concentrations of 64.0 mg Oxamyl 10 GR/kg in this study.

The reproduction rates were not significantly different compared to the control (Dunnett-test; P=0.05). In the toxic standard treatment (2.18 mg Carbendazim/kg), reproduction was lowered by 92.9% and the body weight increase was not significantly lower ompared to the control..

The amount of food added over the entire experimental time was 21.3 ±0.5 g/container in the control and 20.0 to 22.0 g/container in the groups treated with Oxamyl 10G. The results indicate that the food consumption of those earthworms exposed to different rates of the test item was comparable to the control whereas as food consumption of the earthworms exposed to the toxic standard item appeared to be reduced. It can be concluded that exposure of earthworms to Oxamyl 10G in the concentrations from 4.0 mg/kg to 64.0 mg/kg dry artificial soil does not lead to a considerable reduction of food consumption.

Table 107 Effects of Oxamyl 10 GR on earthworm mortality, body weight and reproduction

Endpoint	Control	4.0 mg/kg	8.0 mg/kg	16.0 mg/kg	32.0 mg/kg	64.0 mg/kg	Toxic Standard 2.18 mg Carbendazim/kg
Mortality [%]	0	0	0	0	0	0	2.5%
Body Weight Change [%]	+22.1	+25.9	+24.4	+27.7	+18.2	+30.5	+9.3
Reproduction Number of juveniles	210	235	237	240	241	244	15
Amount of food added [g]	21.3	22.0	22.0	22.0	20.0	20.0	17

Conclusion:

Mortality, growth, reproduction and food consumption of the earthworms exposed to Oxamyl 10G were not affected. The NOEC of Oxamyl 10 GR for sublethal effects on the earthworm *Eisenia fetida* was ≥64.0 mg/kg dry soil (equivalent to 6.4 mg a.s./ka dry soil).

RMS comments and conclusion

The RMS added several additional information to the study summary.

The earthworm – sub-lethal effects study DuPont-4296, originally submitted under EU Rev8 Point IIA 8.4.2 and conducted with test material Oxamyl 10GR, 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 test is valid: the mean control mortality was 0%, there were more than 30 juveniles per control unit after the 8 week testing period (was 210), the coefficient of variance for the mean number of juveniles in the untreated control did not exceed 30% (was 7.9%).

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

Conclusion. The study is acceptable. 56d NOEC of Oxamyl 10 GR ≥64.0 mg/kg dry soil (equivalent to 6.4 mg a.s./ka dry soil).

B.9.7.1.2 Earthworms - field tests

The earthworm TER_{lt} values for oxamyl applied as 1 × 5500 g a.s./h on tobacco was much below the relevant Regulation (EC) 546/2011 trigger value of 5. Therefore, field-testing using the formulated product was performed.

Study submitted at the EU level as an addendum to the EU Dossier in 2003 for Annex I inclusion and included in the first EU approval review.

B.9.8.1.2/01

Reference: --	**Report**	Luhrs, U. (2004); Oxamyl 10GR: field study to evaluate the effects on earthworms **DuPont Report No.:** DuPont-9157 **Guidelines:** BBA VI, 2-3 (1994), ISO 11268-3 (1999)

Deviations: The following deviations occurred during the study period:

- Efficacy of extraction method was <60% at the second sampling (50.9%) - due to the dry weather at this sampling point, the soil conditions were not ideal for the method and 60% efficacy could not be reached by adapting the method. This is deemed not to have an impact on the study as efficacies in all groups of <60% occurred and at this sampling point, all treatments could be compared to one another.
- The applied rate in Plot 1 of the test item differed more than 10% from the target rate (i.e. +21.8%) – the reason was that the soils surface in the test field was rougher than the surface on which the validation of the granule applicator was performed causing a higher output of granules. This is deemed not to have had an impact on the study results as Plot 1 did not show extreme abundance or biomass values after the application. In addition the mean application rate over all 6 plots was 5.5%, which is within the acceptable range.

GLP: yes (certified laboratory)

Test substance: Oxamyl (DPX-D1410) 10GR. Purity: 9.94% w/w oxamyl. Batch No. DPX-D1410-443. CAS No. 23135-22-0.

Materials & Methods:

The study of a blocked design with three treatment groups and six replicates/treatment group was conducted in a 4600m^2 field in Darmstadt-Dieburg, Germany in order to determine the effect of oxamyl on earthworm populations. The test site was arable land and 3 weeks prior to the application of the test substance, the remaining plants of the previous crop, mustard were mulched. Eight days after the application of the test substance, potatoes (Variety Agria) were planted. The field was divided into 18 experimental plots; 6 plots per treatment group and 2.5m distance between the plots and approximately 8m distance to the fields next to the test site. The plots were 10m x10.5m (105m^2).

The test substance was distributed on the soil surface using a granule applicator and was immediately incorporated into the soil to a depth of 10cm using a cultivator. The toxic standard, Derosal SC360 was applied the same day at a rate of 4kg carbendazim/ha using a movable plot sprayer for field applications. The control plot was untreated. Soil cultivation following application was performed in all treatment groups.

During the experimental period from April 2003 to April 2004, four earthworm sampling events were undertaken using the electrical octet method in combination with hand sorting. Earthworms were collected and stored in moistened separate plastic ice-boxes. Within two days of collection, species of earthworms collected were identified and adults and sub adults of each species were weighed using the glass-tube method. Juvenile earthworms were identified to species level where possible, but were at least divided into tanylobous and epilobous species and were weighed in groups for each sample.

Endpoints determined were total earthworm abundance, total biomass, abundance of juveniles and abundance of the two dominant species, *Lubricus terrestris* and *Aporrectodea caliginosa*. On the day of application, (*ca.* 6 hours after application) and one day after application (*ca.* 22 hours after application) the soil surface was visually inspected for earthworms.

Findings:

Environmental Conditions:

The environmental conditions during the study period are fully detailed in the study report. Overall, the field trial was conducted in an arable field typical of those used for commercial potato growing. The weather during the study period was not atypical, although precipitation was slightly lower and air temperature was slightly higher during the summer than the long-term average from the closest German weather station (23km from the test site). In general there is no reason to assume that the results obtained during this study were attributable to an atypical situation (environment, agricultural practices etc..).

Sublethal Effects:

Following a surface check (*ca.* 6 hours post application), one earthworm was observed on the soil surface of one of the replicates of the control plot. No additional earthworms were observed over the duration of the study in any of the other treatment plots on any of the sampling dates. Based on the above, it can be stated that there were no behavioural effects of Oxamyl 10GR on earthworm populations in this study.

Total Earthworm Abundance:

The mean total earthworm density ranged between 94.0 and 102.3 earthworms/m^2 in the different treatment plots at the first assessment before the application. The following Table indicates the total earthworm abundance during the experimental period.

Table : Total earthworm abundance

Treatment Plots	B.10 Sampling Date											
	April 23rd & 24th, 2003			June 4th & 5th, 2003			October 22nd & 23rd, 2003			April 20th & 21st, 2004		
	Ind./m²	%		Ind./m²	%		Ind./m²	%		Ind./m²	%	
	Pre-evaluation			4 weeks Post Application			6 months Post Application			12 months Post Application		
Control	95.3	100.	-	38.3	100.0	-	110.5	100.0	*	88.8	100.0	-
Oxamyl 10GR	102.3	0	n.s.	25.0	65.2	n.s.	66.8	60.5	*	90.5	101.9	n.s.
Toxic Standard	94.0	107. 3 95.6	n.s.	12.2	31.7	n.s.	68.5	62.0	*	74.7	84.1	n.s

n.s. not significant; * statistically significantly different (Student t-test $\alpha<0.05$)

One month after application the mean earthworm abundance was 38.3 earthworms/m^2 in the control which was deemed to be a result of soil cultivation. The total earthworm abundance in the Oxamyl 10GR treatment plot was reduced to 65.2% (25 ind/m^2) of the untreated control one month after application but was not statistically significantly different from the control (Student t-test, $\alpha > 0.05$) and decreased to 60.5% (66.8 ind./m^2) of the control one month after application (statistically significantly reduced compared to the control, Student t-test, $\alpha<0.05$). After one year of exposure, the total earthworm abundance in the Oxamyl 10GR treatment plot was the same level as that of the control group (101.9% of the control) which was not statistically significantly different compared to the control (Student t-test, $\alpha > 0.05$). This indicates that the effects due to Oxamyl 10GR on earthworm abundance were only short-term and that the earthworm population treated with Oxamyl 10GR completely recovered to the same level as the control within one year after application. Four weeks post-application, earthworm abundance within plots treated with the toxic standard were 31.7% of the control plot abundance thus fulfilling the guideline recommendations as there was a reduction in abundance of between 40 – 80%.
The earthworms collected in the control plots over the experimental period are considered to represent the natural development of the earthworm population in this study site. Earthworm abundance usually decreases in the summer due to a reduction in the moisture content of the soil and abundance then increases steadily until the spring. The total number of earthworms observed at the third sampling date is therefore considered to be slightly higher than usual. However, no reasoned statement was provided by the study report author regarding this observation.

Earthworm Biomass:
The earthworm biomass development in the control group followed a similar pattern to the earthworm abundance values. In the control, the biomass decreased from 31.6 g/m^2 in April 2003 to 14.6 g/m^2 in June 2003 and then increased to 26.8 g/m^2 the following autumn. On the final sampling date, the biomass in the control was 27.0 g/m^2. The following Table details the earthworm biomass in all groups in comparison to the control group.

Table: Total earthworm biomass

Treatment Plots	B.11 Sampling Date											
	April 23rd & 24th, 2003			June 4th & 5th, 2003			October 22nd & 23rd, 2003			April 20th & 21st, 2004		
	G/m²	%		g/m²	%		g/m²	%		g/m²	%	
	Pre-evaluation			4 weeks Post Application			6 months Post Application			12 months Post Application		
Control	31.7	100.	-	14.6	100.0	-	26.8	100.0	-	27.0	100.0	-
Oxamyl 10GR	34.9	0	n.s.	14.0	95.7	n.s.	17.0	63.3	*	33.2	123.0	n.s.

Toxic Standard	30.9	110.1 97.4	n.s.	7.5	51.1	n.s.	19.9	74.3	n.s.	28.1	104.0	n.s

Mean value of 6 plots, calculated on the exact raw data
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$
* significantly different compared to the control, Student-t-test, $\alpha = 0.05$

At the final sampling date, the total earthworm biomass in the Oxamyl 10GR treated plots was 33.2 g/m^2 (equivalent to 123% of the control biomass), which was not statistically significantly different compared to the control (Student t-test, $\alpha > 0.05$), thus indicating no treatment related long-term effect on total earthworm biomass in plots treated with Oxamyl 10GR at 55 kg Oxamyl 10GR/ha (GAP).

Earthworm Species Composition and Abundance:

The earthworms collected during the study belonged to seven epilobous and three tanylobous species. The two most abundant species of earthworm collected from the test site were *Lumbricus terrestris* and *Aporrectodea caliginosa*. At the first sampling, the majority of tanylobous juvenile earthworms were individuals of the species *L. terrestris*. However, these juveniles were not determined. On the 2nd sampling date, 4 weeks after application, determination of tanylobous juvenile earthworms was undertaken (with the exception of 13 samples) and all were determined to be juveniles of *L. terrestris*. Therefore, all tanylobous juveniles of the 1st sampling and the 13 mentioned samples were considered to be juveniles of the species *L. terrestris*.

Generally earthworm species composition varies depending on the soil parameters of each site. However, *A. calliginosa* is described as an abundant species of aranble land and *L. terrestris* appears in higher densities when disturbance of arable soil is reduced (e.g. by ploughless ciltivation) which was the case in the test site used in this study. Therefore, the dominance of these two species can be viewed as typical and representative for European arable fields.

The mean density of *L. terrestris* ranged between 11.5 and 23.2 earthworms/m^2 in the control plots during the study (see Table B.9.6.8-3 below). At the second sampling, the numbers of both dominant earthworm species in the Oxamyl 10GR treated group were slightly but not statistically significantly reduced compared to the control (Student t-test, $\alpha > 0.05$). Abundance of *L. terrestris* was slightly lower than in the control at the third sampling and slightly highest at the fourth sampling but at both sampling dates not statistically different compared to the control (Student t-test, $\alpha > 0.05$).

Table: Abundance of *L. terrestris*

Treatment Plots	**B.12 Sampling Date**											
	April 23rd & 24th, 2003			**June 4th & 5th, 2003**			**October 22nd & 23rd, 2003**			**April 20th & 21st, 2004**		
	Ind./m^2 b	**% a**		**Ind./m^2 b**	**% a**		**Ind./m^2 b**	**% a**		**Ind./m^2 b**	**% a**	
	Pre-evaluation			4 weeks Post Application			6 months Post Application			12 months Post Application		
Control	23.2	52.1	-	11.8	72.4	-	11.5	26.5	-	15.8	48.0	-
Oxamyl 10GR	20.0		n.s.	9.2	73.3	n.s.	8.2	30.2	*	19.7	39.3	n.s.
Toxic Standard	28.5	44.9 59.6	n.s.	4.7	80.0	n.s.	8.2	24.5	n.s.	10.7	26.4	n.s

Mean value of 6 plots, calculated on the exact raw data
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$
* significantly different compared to the control, Student-t-test, $\alpha = 0.05$
% of determined worms (including determined juveniles of *L. terrestris*)

estimated number of species assuming all tanylobous juveniles were *L. terrestris*.

A. caliginosa density was only slightly reduced in the Oxamyl 10GR treated plots when compared to the control at the second sampling (Student t-test, $\alpha > 0.05$) and significantly reduced compared to the control at the third sampling (Student t-test, $\alpha < 0.05$) (see Table B.9.6.8-4, below). However, this reduction was deemed to be only a short-term effect since after one year exposure to Oxamyl 10GR the abundance of this species was even higher that in the control and not statistically significant (Student t-test, $\alpha > 0.05$).

Table: Abundance of *A. caliginosa*

Treatment Plots	B.13 Sampling Date											
	April 23rd & 24th, 2003			June 4th & 5th, 2003			October 22nd & 23rd, 2003			April 20th & 21st, 2004		
	Ind./ m²	% [1]		Ind./ m²	% [1]		Ind./ m²	% [1]		Ind./ m²	% [1]	
	Pre-evaluation			4 weeks Post Application			6 months Post Application			12 months Post Application		
Control	17.3	39.0	-	3.3	20.4	-	27.5	63.5	-	14.3	43.4	-
Oxamyl 10GR	2038	46.8	n.s.	2.3	18.7	n.s.	16.7	61.7	*	25.7	51.3	n.s.
Toxic Standard	15.8	33.1	n.s.	2.2	37.1	n.s.	22.7	68.0	n.s.	24.7	61.2	n.s

Mean value of 6 plots, calculated on the exact raw data
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$
* significantly different compared to the control, Student-t-test, $\alpha = 0.05$
1 % of determined worms (including determined juveniles of *L. terrestris*)

Juvenile Earthworms:

The mean number of juvenile earthworms ranged between 74.0 and 77.5 juvenile earthworms/m² in the different treatments at the pre-evaluation stage of the study (see Table B.9.6.8-5 below). In the Oxamyl 10GR treated plots, juvenile numbers were significantly reduced 4 weeks and 6 months post application (Student t-test, $\alpha < 0.05$). One year after application, the comparable numbers of juvenile earthworms were found in the control and Oxamyl 10GR treated plots with 70.8 and 59.0 juvenile earthworms/m², respectively (Student t-test, $\alpha > 0.05$). In plots treated with the toxic standard, the number of juvenile earthworms remained statistically significantly reduced compared to the control plots (Student t-test, $\alpha < 0.05$) one year after treatment.

Table: Abundance of juvenile earthworms

Treatment Plots	B.14 Sampling Date											
	April 23rd & 24th, 2003			June 4th & 5th, 2003			October 22nd & 23rd, 2003			April 20th & 21st, 2004		
	Ind./m²	%		Ind./m²	%		Ind./m²	%		Ind./m²	%	
	Pre-evaluation			4 weeks Post Application			6 months Post Application			12 months Post Application		
Control	74.0	77.6	-	33.2	86.5	-	78.5	71.0	-	70.8	79.7	-
Oxamyl 10GR	77.5	75.7	n.s.	20.3	81.3	*	48.0	71.8	*	59.0	65.2	n.s.
Toxic Standard	74.3	79.1	n.s.	9.0	74.0	*	43.2	63.0	*	44.2	59.2	*

Mean value of 4 plots, calculated on the exact raw data
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$
* significantly different compared to the control, Student-t-test, $\alpha = 0.05$

Conclusion:

In this study, Oxamyl 10GR, applied at a rate of 55 kg Oxamyl 10GR/ha, caused slight but statistically significant effects on the total abundance and biomass of a natural earthworm population, within the first 6 months post application of the test substance (Student t-test, $\alpha < 0.05$). However, one year after application of the test substance, the abundance and biomass of the earthworm population in the Oxamyl 10GR treated plots had recovered to levels above that observed in the control plots (Abundance: 101.9% of control; biomass: 123.0% of control). No behavioural effects of the test substance were observed in the treated plots when compared to the control plots.
The abundance of *A. caliginosa* was slightly, but statistically significantly reduced (Student t-test, $\alpha < 0.05$) when compared to the control plots 6 months after exposure but displayed no statistically significant effect one year after exposure (Student t-test, $\alpha > 0.05$). The abundance of *L. terrestris* was not significantly different compared to the control throughout the experimental period (Student t –test, $\alpha > 0.05$).
The abundance of juvenile earthworms was slightly, but statistically significantly reduced up to the third sampling date 6 months after treatment (Student t-test, $\alpha > 0.05$), but showed no statistically significant effect after 1 year of exposure (Student t-test, $\alpha > 0.05$).
Following initial transient effects over the first 6 months of the study, earthworm populations recovered within the latter 6 months of the study period. Therefore, it can be concluded that Oxamyl 10GR at an application rate of 55kg Oxamyl 10GR/ha (5.5 kg a.i./ha) does not cause long-term effects to natural earthworm populations in the field in typical German field conditions.

RMS comments and conclusion

The earthworm - field studies study DuPont-9157 was originally submitted as Post Annex I Inclusion confirmatory data and was included in the Oxamyl Volume 3 Addendum to Annex B (Ecotoxicology) to the Draft Report and Proposed Decision prepared by the RMS IE (May 2010). The study report and the study summary were not submitted for the present renewal process. The RMS retrieved the summary reported above from the cited Addendum.

The study was conducted with test material Oxamyl 10GR, according to guidelines BBA VI, 2-3 (1994), and ISO 11268-3 (1999). The RMS is aware that the ISO guideline has been recently revised (2014).

Conclusion: Due to the non-availability of the study, the RMS could not evaluate its reliability/acceptability.

Study submitted in the EU Dossier in 2008 and included in the first EU approval review.

B.9.8.1.2/02

Reference: --	**Report**	Luhrs, U. (2007a); Oxamyl 10GR: Field study to evaluate the effects on earthworms in The Netherlands **DuPont Report No.:** DuPont-14075 **Guidelines:** BBA VI, 2-3 (1994), ISO 11268-3 (1999)

Deviations: The following study plan deviations were reported:

- Test item granules were incorporated into the soil to a depth of 8cm instead of 10cm due to hardness of the soil (working depth of harrow was limited to 8 cm). Although this meant that the test

item was distributed in a smaller soil volume, this was deemed not to have had an impact on the study results because it is assumed the active ingredient moved into the lower soil layers following subsequent irrigation.

- The sampling size was reduced to 0.125 m^2 rather than 0.25 m^2 (which was intended for the electrical extraction method – but due to soil conditions at the first sampling, the extraction method had to be adapted to hand sorting, for which a sampling size of 0.125 m^2 is sufficient). This was deemed not to have had an impact on the study results.

- When applying the toxic standard - due to the plot size of 9 m x 12 m (instead of 10 m x 10 m), the plot application system had to be modified to a spraying width of 2 m with 4 nozzles (instead of 2.5 m width with 5 nozzles), to be of a compatible width. This was deemed not to have had an impact on the study results as the toxic standard was applied at the intended rate.

GLP: yes (certified laboratory)
Testing facility: IBACON, Rossdorf, Germany
Test substance: Oxamyl (DPX-D1410) 10GR.; Purity: 9.5% w/w oxamyl; Batch No. DPX-D1410-460; Blue/green solid.

Materials & Methods:
The effects of Oxamyl 10GR on earthworms in the field were estimated in a field study conducted in Houwerzijl in the northern Netherlands (18 May 2004 – 13 May 2005). The test site was arable land (field size *ca.* 3800 m² subdivided in 24 experimental plots; soil type: light to mid-clayey loam (according to DIN)) which had been used as grassland for at least 50 years. The field had received 50 tons/ha liquid cattle manure yearly for the previous three years and 800 kg KAS/ha (calcium, ammonium, nitrate, 27% N) and 19 days prior to the start of the study (first sampling), the grass was killed using 5 L/ha Touchdown (a.i. glyphosate trimesium) + 2 L/ha Vegoil (cabbage seed oil). During the study period, management of the field was conducted according to agricultural practice. During the experimental time no fertilization was performed. Additional plant protection product treatment required by Dutch authorities against phythophthora disease, were as follows: 0.44 L/ha Shirlan (a.i. fluazinam) + 0.167 L/ha Karate (a.i. lambda-cyhalothrin) applied on 7, 14, 21, 28 July and 4, 17 and 25 August 2004.
Potatoes (variety "Agria") were planted under typical field conditions the day after the test substance application (26 May 2004), and the dams were later ridged. The potatoes were not harvested in autumn 2004.
The experiment was performed with six replicates and 4 treatments (untreated control, Oxamyl 10GR applied at 40 and 55 kg/ha (equivalent to 4.0 and 5.5 kg oxamyl/ha), and toxic standard); the size of each plot was 9 × 12 m (108 m²), with at least 1.5 m distance between the plots. The test item, Oxamyl 10GR, was distributed on the soil surface using a granule applicator and was incorporated into the top soil layer of about 8 cm using a rotary harrow immediately after application on 25 May 2004. The toxic standard, Brabant Carbendazim Flowable (500 g/L), was applied the same day at a rate of 4 kg carbendazim/ha using a movable plot sprayer for field applications, the control was left untreated. Soil cultivation (with a rotary harrow) after application was performed in all treatment groups. All plots were irrigated 2 and 3 days after application (27 and 28 May 2004) with a total of *ca*. 22 mm water.
The soil surface was visually checked for earthworms 1, 2 and 3 days after application to check for sub-lethal effects.

Over the experimental period from May 2004 to May 2005 four earthworm samplings (before application and cultivation, 1 month after application, 5 months after application and 1 year after application), and were performed using hand sorting.
Living earthworms were collected and stored separately in cool, moistened plastic ice-boxes. Within three days, adult and subadult earthworms were weighed using the glass-tube method for living earthworms and the species was identified. Juvenile earthworms were identified to species if possible, but were at least separated into tanylobous and epilobous species and were weighed in groups for each sample.
Endpoints measured were total earthworm abundance, total biomass, abundance of juveniles and abundance of the three dominant species *Aporrectodea caliginosa, Lumbricus rubellus,* and *Allolobophora chlorotica* (and *Lumbricus terrestris*).

Findings:
All validity criteria of the study were met

Environmental Conditions:
The weather conditions were warm and dry at the start of the experiment but the conditions during the study period were not considered to be atypical (see Table B.9.6.8-6 below). In general there was no reason to assume that the results obtained during this study were attributable to an atypical situation (environment, agricultural practices etc.). Relative humidity on the day of application ranged from 55 – 77%, wind velocity ranged from 1.8 – 5.8 m/s. The soil pH before the start of the study was reported to be 6.6 (n = 3).

Table: Environmental conditions

Sampling date	**Details (and date)**	**Air temperature range (°C)**	**Soil temperature range (°C)***	**Water content of soil (%)**	**Soil PH (n = 8)**
1st sampling date (18th & 19th May 2004)	First earthworm collection (pre-evaluation)	16.3 – 21.0	14.1 – 15.3	19.3 – 26.8	5.6
Date of application (25th May, 2004)	Application of test substance	11.8 – 14.2	13.1 – 14.2	nr	nr
2nd sampling date (28th & 29th June, 2004)	2nd earthworm collection (4 weeks after application)	17.0 – 20.3	15.3 – 17.7	16.1 – 27.7	6.3
3rd sampling date (18th & 19th Oct., 2004)	3rd earthworm collection (5 months after application)	6.4 – 14.1	8.4 – 10.7	23.2 – 37.1	5.9
4th sampling date (9th & 10th May, 2005)	4th earthworm collection (12 months after application)	8.3 – 11.7	10.1 – 11.0	31.4 – 41.9	6.1

* measured in a depth of c.a. 15 cm; nr = not reported

nr = not recorded

Sublethal Effects:

The soil surface checks at 1, 2 and 3 days after application found no earthworms in any treatment group at any date, suggesting that Oxamyl 10GR had no behavioural effects on earthworm populations within 3 days after application.

Total Earthworm Abundance:

The mean earthworm density ranged between 311.3 and 325.3 earthworms/m² in the different treatments at the first assessment before the application (see Table B.9.6.8-7 below). One month after application the mean earthworm abundance ranged at the same level in all treatment groups. Five months after the application the total abundance in the Oxamyl 10GR treated groups was slightly reduced compared to the control, but not statistically significant (81.3 and 75.3% of the control, Student-t test, $\alpha > 0.05$). After one year of exposure the total earthworm abundance in the Oxamyl 10GR groups had the same level as in the control (92.0 and 83.8% of the control) and was not statistically significantly different compared to the control (Student-t test, $\alpha > 0.05$). By the third and fourth sampling date, earthworm abundance following exposure to the toxic standard were significantly reduced by > 40%, relative to controls, thus fulfilling the validation criteria (40 – 80% reduction in abundance recommended).

Therefore, it can be concluded that Oxamyl 10GR at a rates of 40 and 55 kg product per ha has no long-term effect on the total earthworm abundance under field conditions.

In general earthworm densities were considered unusually high in all test plots on the third and fourth sampling dates, in particular on the fourth sampling date, as usually a decrease in earthworm abundance is observed between autumn and spring. However, the prevailing conditions (in terms of temperature, soil moisture and supply of food as rotting potatoes) were very favourable for earthworms in Spring 2005, and many hatching juveniles and cocoons were found in the soil then, which may explain the unusual findings.

Table: Total earthworm abundance

Treatment Plots	1st Sampling date Pre-evaluation			2nd sampling date 4 weeks post application			3rd sampling date 5 months post application			4th sampling date 12 months post application		
	Ind./m²	%		Ind./m²	%		Ind./m²	%		Ind./m²	%	
Control	314.7	100	-	337.3	100	-	702.4	100	-	813.0	100	-
Oxamyl 10GR 40 kg/ha	325.0	103.3	n.s.	372.0	110.3	n.s.	570.8	81.3	n.s.	747.7	92	n.s.
Oxamyl 10GR 55 kg/ha	325.3	103.4	n.s.	330.0	97.8	n.s.	529.0	75.3	n.s.	681.7	83.8	n.s.
Toxic Standard	311.3	98.9	n.s.	269.3	79.8	n.s.	390.3	55.6	*	485.3	59.7	*

Mean value of 6 plots, calculated on the exact raw data
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$
* significantly different compared to the control, Student-t-test, $\alpha = 0.05$

Earthworm Biomass:

The mean earthworm biomass ranged between 83.6 and 87.4 g/m² in the different treatments at the first assessment before the application (see Table B.9.6.8-8 below). At the second sampling (one month after treatment) an increase of the earthworm biomass was observed in the control and in both Oxamyl 10GR treated groups. The biomass in the 40 kg Oxamyl 10GR/ha group represented 97.5% of the control, in the 55 kg Oxamyl 10GR/ha group 87.0% of the control was found (not significant, Student-t test, $\alpha > 0.05$). At the third sampling 5 months after application the earthworm biomass

increased in all treatment groups. However, the increase in the oxamyl-treated groups was lower than in the control, representing 77.4% of the control in the 40 kg Oxamyl 10GR/ha group (not statistically significant compared to the control, Student-t test, α >0.05) and 68.9% of the control in the 55 kg Oxamyl 10GR/ha group (statistically significant compared to the control, Student-t test, α <0.05).
At the fourth sampling date (12 months after application) the total earthworm biomass in the Oxamyl 10GR treated groups reached 95.4 % of the control in the 40 kg Oxamyl 10GR/ha group and 85.5% of the control in the 40 kg Oxamyl 10GR/ha group. Both values were not statistically significantly different compared to the control (Student-t test, α >0.05), thus indicating no Oxamyl 10G treatment related long-term effect on total earthworm biomass.
The earthworm biomass in toxic standard treatment was statistically significantly reduced (to maximally 58.0% of the control) at the second, third and fourth sampling.

Table: Total earthworm biomass (fresh weight)

Treatment Plots	1st Sampling date Pre-evaluation			2nd sampling date 4 weeks post application			3rd sampling date 5 months post application			4th sampling date 12 months post application		
	Ind./m²	%		Ind./m²	%		Ind./m²	%		Ind./m²	%	
Control	83.8	100	-	120.4	100	-	176.4	100	-	188.3	100	-
Oxamyl 10GR 40 kg/ha	86.2	102.8	n.s.	117.4	97.5	n.s.	136.5	77.4	n.s.	179.6	95.4	n.s.
Oxamyl 10GR 55 kg/ha	83.6	99.7	n.s.	104.8	87	n.s.	121.6	68.9	*	161.6	85.5	n.s.
Toxic Standard	87.4	104.3	n.s.	69.9	58	*	117.0	66.3	*	138.2	73.4	*

Mean value of 6 plots, calculated on the exact raw data
- not applicable
n.s. not significantly different compared to the control, Student t-test, α = 0.05
* significantly different compared to the control, Student-t-test, α = 0.05

Earthworm Species Composition & Abundance:
The three most abundant species were *Aporrectodea caliginosa, Allolobophora chlorotica,* and *Lumbricus rubellus*. *Lumbricus terrestris* was found in higher densities at the 4th sampling and was also evaluated for this sampling.

Aporrectodea caliginosa:
The most abundant species, *Aporrectodea caliginosa,* was found at the same abundance level as in the control at the 2nd sampling in the 40 kg Oxamyl 10GR/ha group and at a slightly lower abundance in the 55 kg Oxamyl 10GR/ha group (see Table B.9.6.8-9 below). In October 2004, the numbers of *A. caliginosa* decreased in all treatment groups. The abundance of *A. caliginosa* was slightly reduced in the 40 kg Oxamyl 10GR/ha group and reduced in the 55 kg Oxamyl 10GR/ha group but without statistical significance (Student-t test, α >0.05). At the fourth sampling date the abundance of *A. caliginosa* reached the level of the control in the 40 kg Oxamyl 10GR/ha group and a slightly lower value than the control in the 55 kg Oxamyl 10GR/ha group. Since there were no statistically significant differences compared to the control (Welch-t test, α >0.05) and the proportion of *A. caliginosa* in the population at each sampling date was also comparable the control Oxamyl 10GR is not considered to cause an effect on *A. caliginosa*.
The abundance of *Aporrectodea caliginosa* in the toxic standard treatment was statistically significantly reduced at the second and third sampling (Student-t test, α <0.05).

Table : Abundance of *Aporrectodea caliginosa*

Treatment Plots	1st Sampling date Pre-evaluation			2nd sampling date 4 weeks post application			3rd sampling date 5 months post application			4th sampling date 12 months post application		
	Ind./m²	%[1]		Ind./m²	%[1]		Ind./m²	%[1]		Ind./m²	%[1]	
Control	152.3	82.6	-	202.0	79.0	-	197.8	69.3	-	187.7	64.9	-
Oxamyl 10GR 40 kg/ha	148.3	77.7	n.s.	199.3	80.3	n.s.	144.7	68.5	n.s.	163.7	62.6	n.s.
Oxamyl 10GR 55 kg/ha	148.0	76.3	n.s.	169.7	77.7	n.s.	123.0	67.7	n.s.	153.0	63.6	n.s.
Toxic Standard	152.7	75.7	n.s.	122.0	81.3	*	112.7	63.8	*	141.7	66.3	n.s.

Mean value of 6 plots, calculated on the exact raw data
[1]% ratio of determinable earthworms
- not applicable
n.s. not significantly different compared to the control, Student t-test or Welch-t-test, $\alpha = 0.05$
* significantly different compared to the control, Student-t-test or Welch-t-test, $\alpha = 0.05$

Allolobophora chlorotica:

In the control the density of *Allolobophora chlorotica* ranged between 9 and 29 worms/m² within the test period (see Table B.9.6.8-10 below). In both Oxamyl 10GR treatments the density of *A. chlorotica* was at the same or a slightly higher level than the control at the 3rd and 4th collection date except at for the 55 kg Oxamyl 10GR/ha group which was slightly lower in October 2004. These values are regarded as a naturally occurring variation. The lack of a statistical significant difference between control and both test item groups at all sampling dates (Student-t test, $\alpha > 0.05$) indicates no long-term effect of Oxamyl 10GR on *Allolobophora chlorotica.*

In comparison the density of *A. chlorotica* in toxic standard treatment was significantly reduced at the second sampling (Student-t test, $\alpha < 0.05$).

Table: Abundance of *Allolobophora chlorotica*

Treatment Plots	1st Sampling date Pre-evaluation			2nd sampling date 4 weeks post application			3rd sampling date 5 months post application			4th sampling date 12 months post application		
	Ind./m²	%[1]		Ind./m²	%[1]		Ind./m²	%[1]		Ind./m²	%[1]	
Control	8.7	4.7	-	17.7	6.9	-	29.6	10.4	-	22.7	7.8	-
Oxamyl 10GR 40 kg/ha	15.0	7.9	n.s.	9.7	3.9	n.s.	31.3	14.8	n.s.	30.0	11.5	n.s.
Oxamyl 10GR 55 kg/ha	17.3	8.9	n.s.	15.7	7.2	n.s.	21.3	11.7	n.s.	30.0	12.5	n.s.
Toxic Standard	18.7	9.3	*	4.3	2.9	*	13.7	7.7	n.s.	18.3	8.6	n.s.

Mean value of 6 plots, calculated on the exact raw data
[1]% ratio of determinable earthworms
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$
* significantly different compared to the control, Student-t-test, $\alpha = 0.05$

Lumbricus rubellus:
The abundance of *Lumbricus rubellus* was at the same level as in the control at the 2nd sampling and showed slightly reduced values at the 3rd sampling for both test item rates (see Table B.9.6.8-11 below). At the 4th sampling the abundance of *L. rubellus* was comparable to the control in the 40 and 55 kg Oxamyl 10GR group. Since there were no statistically significant differences compared to the control (Welch-t test at the 1s to 3rd sampling and Student-t test at the 4th sampling, $\alpha > 0.05$) it is concluded that the treatment with Oxamyl 10GR up to a rate of 55 kg/ha has no adverse long-term effect on the species of *Lumbricus rubellus.*
In contrast the density of *L. rubellus* in toxic standard treatment was clearly reduced at the second sampling one month after treatment relative to the control.

Table: Abundance of *Lumbricus rubellus*

Treatment Plots	1st Sampling date Pre-evaluation			2nd sampling date 4 weeks post application			3rd sampling date 5 months post application			4th sampling date 12 months post application		
	Ind./m²	%[1]		Ind./m²	%[1]		Ind./m²	%[1]		Ind./m²	%[1]	
Control	13.7	7.4	-	15.3	6.0	-	28.3	9.9	-	19.3	6.7	-
Oxamyl 10GR 40 kg/ha	11.3	5.9	n.s.	19.3	7.8	n.s.	15.1	7.2	n.s.	18.3	7.0	n.s.
Oxamyl 10GR 55 kg/ha	13.7	7.0	n.s.	13.7	6.3	n.s.	13.7	7.5	n.s.	14.3	6.0	n.s.
Toxic Standard	18.7	9.3	n.s.	6.3	4.2	n.s.	21.7	12.3	n.s.	16.0	7.5	n.s.

Mean value of 6 plots, calculated on the exact raw data
[1]% ratio of determinable earthworms
- not applicable
n.s. not significantly different compared to the control, Student t-test or Welch-t-test, $\alpha = 0.05$

Lumbricus terrestris:
Lumbricus terrestris was found in low densities at the 1st to 3rd sampling (see Table B.9.6.8-12 below). Since juveniles were included in the species determination of the 4th sampling it was shown, that *L. terrestris* was also abundant in the test site. The effects of the test item on this species can only be assessed after 1 year of exposure. The results show, that the abundances of *L. terrestris* in the Oxamyl 10GR group were at a comparable level as in the control indicating no long-term effect on this species. The density of *L. terrestris* in the toxic standard treatment was statistically significant reduced at fourth sampling one year after treatment relative to the control (Welch-t test, $\alpha < 0.05$).

Table: Abundance of *Lumbricus terrestris*

Treatment Plots	1st Sampling date Pre-evaluation			2nd sampling date 4 weeks post application			3rd sampling date 5 months post application			4th sampling date 12 months post application		
	Ind./m²	%[1]		Ind./m²	%[1]		Ind./m²	%[1]		Ind./m²	%[1]	

Control	0.3	0.2	-	0.3	0.1	-	1.0	0.4	-	48.7	14.4	-
Oxamyl 10GR 40 kg/ha	0	0	n.e.	0	0	n.e.	0.8	0.4	n.e.	38.7	12.9	n.s.
Oxamyl 10GR 55 kg/ha	0	0	n.e.	0.7	0.3	n.e.	1.0	0.6	n.e.	39.0	14.0	n.s.
Toxic Standard	0	0	n.e.	0.7	0.4	n.e.	1.0	0.6	n.e.	18.7	8.0	*

Mean value of 6 plots, calculated on the exact raw data
[1]% ratio of determinable earthworms
- not applicable
n.e. not evaluated
n.s. not significantly different compared to the control, Welch-t-test, $\alpha = 0.05$
* significantly different compared to the control, Welch-t-test, $\alpha = 0.05$

Juvenile Earthworms:
The mean number of juvenile earthworms in the Oxamyl 10GR treated groups was slightly higher than in the control at the 2nd sampling date (not statistically significant, Welch-t test, $\alpha > 0.05$) (see Table B.9.6.8-13 below). The abundance values found after 5 months and 1 year after application were slightly lower than in the control but without statistical significance (Student-t test, $\alpha > 0.05$) indicating no long-term effect of Oxamyl 10GR to juvenile earthworms. The mean number of juvenile earthworms in toxic standard treatment was statistically significant reduced to about 50% of the control at the third and fourth sampling (Welch-t test, $\alpha < 0.05$).

Table: Abundance of juvenile earthworms

Treatment Plots	**1st Sampling date Pre-evaluation**				**2nd sampling date 4 weeks post application**				**3rd sampling date 5 months post application**				**4th sampling date 12 months post application**			
	Ind./ m²	**% T[1]**	**% C[2]**		**Ind./ m²**	**% T[1]**	**% C[2]**		**Ind./ m²**	**% T[1]**	**% C[2]**		**Ind./ m²**	**% T[1]**	**% C[2]**	
Control	130.3	41.4	-	-	81.7	24.2	-	-	416.9	59.3	-	-	523.7	64.4	-	-
Oxamyl 10GR 40 kg/ha	134.0	41.2	102.8	n.s.	123.7	33.2	151.4	n.s.	359.6	63.0	86.2	n.s.	486.3	65.0	92.9	n.s.
Oxamyl 10GR 55 kg/ha	131.3	40.4	100.8	n.s.	111.7	33.8	136.7	n.s.	347.3	65.7	83.3	n.s.	441.0	64.7	84.2	n.s.
Toxic Standard	109.7	35.2	84.1	n.s.	119.3	44.3	146.1	n.s.	213.7	54.7	51.3	*	271.7	56.0	51.9	*

Mean value of 6 plots, calculated on the exact raw data
[1]% ratio of the total population
[2]% of control
- not applicable
n.s. not significantly different compared to the control, Student t-test or Welch-t-test, $\alpha = 0.05$
* significantly different compared to the control, Student t-test or Welch-t-test, $\alpha = 0.05$

Conclusions:
There were no indications that Oxamyl 10GR had any behavioral effects on earthworm populations.

A soil application of 40 kg Oxamyl 10GR/ha (4.0 kg active substance oxamyl/ha) did not cause statistically significant effects on the abundance and biomass of a natural earthworm population over the whole study period of one year of exposure.
A soil application of 55 kg Oxamyl 10GR/ha (5.5 kg active substance oxamyl./ha) resulted in a slight, statistically significant effect on the total biomass five months after application (31% reduction in total biomass relative to control), but the population appeared to recover after one year (the reductions compared to the control were minimal (14%) and were not statistically significantly different at 12 months). There was also a slight reduction in total earthworm abundance at this higher dose level (24% relative to control), but the reduction was not considered statistically significant and had improved to 16% reduction (relative to controls) by the end of the 1-year study period.
The three most abundant species of earthworms present in the test plots were *Aporrectodea caliginosa, Allolobophora chlorotica,* and *Lumbricus rubellus*, none of which appeared to be affected (in terms of abundance, relative to controls) by exposure to 40 or 55 kg/ha of test substance. The effect of Oxamyl 10GR on the abundance of *Lumbricus terrestris* could only be assessed at the 4th sampling date, one year after the application and also did not indicate any long-term adverse effects at either dose rate.
The abundance of juvenile earthworms in both Oxamyl 10GR treatments was slightly reduced at the 3rd and 4th sampling, compared to the control, but the values were not statistically significant.
Therefore it can be concluded that Oxamyl 10GR, applied at rates of 40 and 55 kg Oxamyl 10GR/ha (equivalent to 4.0 and 5.5 kg oxamyl/ha), does not cause long-term toxic effects to natural earthworm populations in the field under typical conditions in the Netherlands. Although some slight short-term effects on earthworm populations (biomass only) were observed during the first 6 months of the study, populations treated were able to recover completely to levels comparable to the control, within one year after treatment.

RMS comments and conclusion

The earthworm - field studies study DuPont-9157 was originally submitted as Post Annex I Inclusion confirmatory data and was included in the Oxamyl Volume 3 Addendum to Annex B (Ecotoxicology) to the Draft Report and Proposed Decision prepared by the RMS IE (May 2010). The study report and the study summary were not submitted for the present renewal process. The RMS retrieved the summary reported above from the cited Addendum.

The study was conducted with test material Oxamyl 10GR, according to guidelines BBA VI, 2-3 (1994), and ISO 11268-3 (1999). The RMS is aware that the ISO guideline has been recently revised (2014).

Conclusion: Due to the non-availability of the study, the RMS could not evaluate its reliability/acceptability.

Study submitted in the EU Dossier in 2008 and included in the first EU approval review.

B.9.8.1.2/03

Reference: --	**Report:**	Luhrs, U. (2007b); Oxamyl 10GR: Field study to evaluate the effects on earthworms in The UK **DuPont Report No.:** DuPont-14076

		Guidelines: BBA VI, 2-3 (1994), ISO 11268-3 (1999)

Deviations: The following study plan deviations of relevance were reported:

- The reduction in earthworm abundance in the toxic reference (38.8%) was less than the recommended level of 40%. However, the test was still deemed to be valid as the deviation was very slight – it is likely that the cultivation of the field, following test substance application caused a reduction in worm abundance. The toxic reference did have a strong, statistically significant effect on the most abundant worm species and on juvenile earthworms, confirming the sensitivity of the test system.
- Verification of test item application rate was performed for the whole treatment group rather than for each plot as this for practical reasons (due to the size of the tanks used for application). The applied amount was calculated as mean quantity per plot by measuring the amount of product remaining in the applicator. Verification of the reference item was calculated from nozzle output and time spent in each plot. This was considered acceptable.
- Surface searches for earthworms were not conducted at the 3rd and 4th sampling period due to extensive weed cover. This was deemed not to have had an impact on the study results.
- Hand digging (rather than a combination of formalin extraction and hand-digging) was performed as sampling method for the 1st and 2nd sampling date as the formalin method alone was not efficient enough). Also, the concentration of formalin was increased from 0.2 – to 0.5% for the 3rd and 4th sampling to increase extraction efficiency. These changes were deemed not to have had an impact on the study results.

GLP: yes (certified laboratory)
Testing facility: IBACON, Rossdorf, Germany
Test substance: Oxamyl (DPX-D1410) 10GR.; Purity: 9.5% w/w oxamyl; Batch No. DPX-D1410-460; blue/green solid.

Materials & Methods:

The effects of Oxamyl 10GR on earthworms in the field were estimated in a field study conducted in South-West England (Cornwall) (14-June-2004 to 10-June-2005). The test site was arable land (field size *ca.* 7107 m² subdivided in 24 experimental plots; soil type: clay loam (according to USDA classification)), which had been planted with maize in 2002 and 2003.

The field had received the following treatments in the preceding years: March 2002: Touchdown 3 L/ha (a.i. glyphosate); May 2002: Atrazina 3 L/ha (a.i. atrazine) and Atlas Steward 2 L/ha (a.i. gamma-hexachlorocyclohexane); February 2003: Touchdown 3 L/ha (a.i. glyphosate); June 2003: Atrazina 3 L/ha (a.i. atrazine) and Bromotril 0.75 L/ha (a.i. bromoxynil); July 2003: Bromotril 0.75 L/ha (a.i. bromoxynil).

During the study period, management of the field was conducted according to agricultural practice. During the experimental time no field cultivation, fertilising or pesticide treatment was performed. Potatoes (variety "Pentland Dell") were planted on 25th June, 2004 using a Kverneland UN 3000 planter. The potatoes were not harvested in autumn 2004.

The experiment was performed with six replicates and 4 treatments (untreated control, Oxamyl 10GR applied at 40 and 55 kg/ha (equivalent to 4.0 and 5.5 kg oxamyl/ha), and toxic

standard); the size of each plot was 12 × 12 m (144 m²), with at least 5 m distance between the plots. The test item, Oxamyl 10GR, was distributed on the soil surface using a tractor drawn seed drill Väderstad Rapid A 400S and was incorporated into a soil depth of 10 cm using a Rabe power harrow and crumbler roller immediately after application on June 21, 2004. The toxic standard, Delsene 50 FLO (500 g/L), was applied the same day at a rate of 4 kg carbendazim/ha using a self-propelled boom and nozzle Bateman RB15 sprayer. The control was left untreated. Soil cultivation (with a power harrow and crumbler) after application was performed in all treatment groups. Irrigation of the site was not necessary because there was 52.6 mm rainfall during the three days following application.
The soil surface was visually checked for earthworms 1, 2, 3 and 36 days after application to check for sub-lethal effects.
Over the experimental period from June 2004 to June 2005 four earthworm samplings were performed On the 1st (June 14 + 15, 2004) and 2nd (July 27 + 28, 2004) sampling dates, the worms were extracted using hand digging. On the 3rd (October 20 + 21, 2004) and 4th (June 08, 2005) sampling dates, the worms were extracted using the formalin method.
Living earthworms were collected and stored separately in cool, moistened plastic ice-boxes. Within three days, adult and subadult earthworms were weighed using the glass-tube method for living earthworms and the species was identified. Juvenile earthworms were identified to species if possible, but were at least separated into tanylobous and epilobous species and were weighed in groups for each sample.
Endpoints measured were total earthworm abundance, total biomass, abundance of juveniles and abundance of the three dominant species *Aporrectodea caliginosa*, *Lumbricus rubellus,* and *Allolobophora chlorotica* (and *Lumbricus terrestris*).

Findings:

Environmental Conditions:

The weather conditions were summarised as generally wet and mild – typical of the area in South West England. There was no reason to assume that the results obtained during this study were attributable to an atypical situation (environment, agricultural practices etc.). The soil pH ranged from 5.8 – 6.4; maximum water holding capacity ranged from 35.7% – 37.1%; total organic carbon content ranged from 7.2 – 8.1% and cation exchange capacity ranged from 8.3 – 9.6.

Sublethal Effects:

No earthworms were observed on the soil surface in any of the test plots on day 1 or day 3 after application. The soil surface check on day 2 found 4 worms on the soil surface in the control group; 10 in the 40 kg/ha Oxamyl group; 9 in the 55 kg/ha Oxamyl group and 2 in the toxic control group. However, these findings were not considered to indicate significant behavioural changes in the test substance groups - the numbers were within the normal range. On the 2nd sampling date (36 days post application), observed worm numbers on soil surface were comparable in all treatment and control groups (ranging in number from 1 to 3).

Total Earthworm Abundance:

The earthworms collected in the control plot within the experimental time were considered to represent the natural development of the earthworm worm population at this test site during the experimental period.
The reduction in mean abundance of earthworms in the control plot on the second sampling date (July 2004) compared to the start of the experiment in June 2004 (69.9% of the start value), was attributed to the cultivation of the soil which took place after test substance application (Table B.9.6.8-14). The reduction at the end of the experiment (June 2005) compared to the start of the experiment in June 2004 (61.1% of the start value), was attributed to the change in the sampling method from hand sorting to formalin extraction.

The earthworm abundance in the toxic standard treatment was statistically significantly reduced to 38.8% of the control at the third sampling (Student-t test, α <0.05). The value was slightly lower than the required validity criterion (at least 40%) but is still considered to indicate sufficient sensitivity of the test system because of the statistical significance and because the reduction was only slightly lower.
There were no significant differences in total earthworm density between the two Oxamyl 10GR treated groups and the untreated controls, on any of the post-treatment sampling dates, ndicating that Oxamyl 10GR at rates of 40 and 55 kg product per ha has no long-term effect on the total earthworm abundance under field conditions.

Table: Total earthworm abundance

Treatment Plots	1st Sampling date Pre-evaluation			2nd sampling date 5 weeks post application			3rd sampling date 4 months post application			4th sampling date 12 months post application		
	Ind./m²	%		Ind./m²	%		Ind./m²	%		Ind./m²	%	
Control	106.3	100	-	74.0	100	-	112.5	100	-	65.0	100	-
Oxamyl 10GR 40 kg/ha	102.3	96.2	n.s.	80.3	108.6	n.s.	106.5	94.7	n.s.	60.7	93.3	n.s.
Oxamyl 10GR 55 kg/ha	108.8	102.4	n.s.	86.2	116.4	n.s.	111.0	98.7	n.s.	67.0	103.1	n.s.
Toxic Standard	108.7	102.2	n.s.	60.0	81.1	n.s.	68.8	61.2	*	57.7	88.7	n.s.

Mean value of 6 plots, calculated on the exact raw data
- not applicable
n.s. not significantly different compared to the control, Student t-test, α = 0.05
* significantly different compared to the control, Student-t-test, α = 0.05

Earthworm Biomass:
There were no significant differences in total earthworm biomass between the two Oxamyl 10GR treated groups and the untreated controls, on any of the post-treatment sampling dates, indicating that Oxamyl 10GR at rates of 40 and 55 kg product per ha has no long-term effect on the total earthworm biomass under field conditions. The slight reduction of 21.5% for the biomass of the 40 kg Oxamyl 10GR/ha group after one year of exposure was not considered to be treatment related since no effect was observed at the higher rate.
The earthworm biomass in toxic standard treatment was reduced to maximally 82.6% of the control at the third sampling.

Table: Total earthworm biomass (fresh weight)

Treatment Plots	1st Sampling date Pre-evaluation			2nd sampling date 5 weeks post application			3rd sampling date 4 months post application			4th sampling date 12 months post application		
	Ind./m²	%		Ind./m²	%		Ind./m²	%		Ind./m²	%	
Control	34.0	100	-	27.9	100	-	36.8	100	-	15.6	100	-
Oxamyl 10GR 40 kg/ha	31.0	91.1	n.s.	28.8	103.3	n.s.	36.1	98.2	n.s.	12.3	78.5	n.s.
Oxamyl 10GR	33.6	98.8	n.s.	30.1	107.9	n.s.	37.3	101.6	n.s.	18.3	117.4	n.s.

55 kg/ha												
Toxic Standard	34.3	100.9	n.s.	23.2	83.2	n.s.	30.3	82.6	n.s.	14.3	91.5	n.s.

Mean value of 6 plots, calculated on the exact raw data
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$, Welch-t test at 3rd sampling

Earthworm Species Composition & Abundance:
The collected earthworms belonged to four epilobbous and three tanylobous species. The two most abundant species were *Allolobophora chlorotica* and *Aporrectodea caliginosa*..

Allolobophora chlorotica:
In the control, the density of *Allolobophora chlorotica* ranged between 10.2 and 16.3 worms/m² over the test period (see Table B.9.6.8-16 below). At the fourth sampling date the abundance of *A. chlorotica* was significantly reduced in the 40 kg/ha group, relative to controls. However, this reduction was not considered to be treatment related because at the higher rate no statistically significant effect was observed. Therefore, Oxamyl 10GR is not considered to cause significant long-term effects on *A. chlorotica* abundance in the field.
The density of *A. chlorotica* in the toxic standard treatment was significantly reduced (by >75% of control levels) on all three sampling dates post application (2nd, 3rd and 4th sampling dates).

Table: Abundance of *Allolobophora chlorotica*

Treatment Plots	**1st Sampling date Pre-evaluation**				**2nd sampling date 5 weeks post application**				**3rd sampling date 4 months post application**				**4th sampling date 12 months post application**			
	Ind./ m²	**% S[1]**	**% C[2]**		**Ind./ m²**	**% T[1]**	**% C[2]**		**Ind./ m²**	**% T[1]**	**% C[2]**		**Ind./ m²**	**% T[1]**	**% C[2]**	
Control	14.8	46.1	100	-	11.0	42.9	100	-	16.3	27.7	100	-	10.2	44.9	100	-
Oxamyl 10GR 40 kg/ha	13.5	47.6	91	n.s.	10.5	42.3	95.5	n.s.	16.3	27.8	100	n.s.	4.2	25.5	41	*
Oxamyl 10GR 55 kg/ha	16.2	49.5	109	n.s.	11.5	43.7	104.5	n.s.	12.5	19.9	76.5	n.s.	7.2	31.6	70.5	n.s.
Toxic Standard	17.7	55.5	119.1	n.s.	2.2	14.4	19.7	*	2.8	7.1	17.3	*	2.5	17.2	24.6	*

Mean value of 6 plots, calculated on the exact raw data
[1]% of determined species
[2]% of control
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$; Welch-t-test at 4th sampling
* significantly different compared to the control, Student t-test, $\alpha = 0.05$; Welch-t-test at 4th sampling

Aporrectodea caliginosa:
Aporrectodea caliginosa was the second most abundant species at the test start but numbers decreased to a very low level in all test plots by the 4th sampling date (Table B.9.6.8-17) – in fact, absolute abundance values were too low to assess potential test item or toxic control effects on this sampling date. On both of the other sampling dates post application, there were no significant differences in abundance of *A. caliginosa* between the two Oxamyl 10GR

treated groups and the untreated controls, suggesting that Oxamyl 10GR does not cause long-term effects on *Aporrectodea caliginosa* at rates of 40 kg Oxamyl 10GR/ha and 55 kg Oxamyl 10GR/ha in the field. However, no significant differences in abundance of *A. caliginosa* between the toxic standard treated groups and the untreated controls were observed either.

Table: Abundance of *Allolobophora caliginosa*

Treatment Plots	1st Sampling date Pre-evaluation				2nd sampling date 5 weeks post application				3rd sampling date 4 months post application				4th sampling date 12 months post application			
	Ind./ m^2	% S^1	% C^2		Ind./ m^2	% T^1	% C^2		Ind./ m^2	% T^1	% C^2		Ind./ m^2	% T^1	% C^2	
Control	12.7	39.4	100	-	11.0	42.9	100	-	31.2	52.8	100	-	1.8	8.1	100	-
Oxamyl 10GR 40 kg/ha	9.8	34.7	77.6	n.s.	8.7	34.9	78.8	n.s.	30.2	51.3	96.8	n.s.	2.3	14.3	127.3	n.s.
Oxamyl 10GR 55 kg/ha	10.3	31.6	81.6	n.s.	10.8	41.1	98.5	n.s.	36.5	58.1	117.1	n.s.	3.2	14.0	172.7	n.s.
Toxic Standard	8.2	25.7	64.5	n.s.	8.2	54.4	74.2	n.s.	29.2	72.9	93.6	*	3.5	24.1	190.9	n.s.

Mean value of 6 plots, calculated on the exact raw data
[1]% of determined species
[2]% of control
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$; Welch-t-test at 1st sampling
* significantly different compared to the control, Student t-test, $\alpha = 0.05$; Welch-t-test at 1st sampling

Juvenile Earthworms:

The mean number of juvenile earthworms in the toxic standard treatment was reduced to 53.9% of the control at the third sampling (Table B.9.6.8-18).

There were no significant differences in the mean number of juvenile earthworms between the two Oxamyl 10GR treated groups and the untreated controls, on any of the post-treatment sampling dates, indicating that Oxamyl 10GR at rates of 40 and 55 kg product per ha has no long-term effect on juvenile earthworms under field conditions.

Table: Abundance of juvenile earthworms

Treatment Plots	1st Sampling date Pre-evaluation				2nd sampling date 5 weeks post application				3rd sampling date 4 months post application				4th sampling date 12 months post application			
	Ind./ m^2	% T^1	% C^2		Ind./ m^2	% T^1	% C^2		Ind./ m^2	% T^1	% C^2		Ind./ m^2	% T^1	% C^2	
Control	72.3	68.0	100	-	48.0	64.9	100	-	53.5	47.6	100	-	24.3	65.1	100	-
Oxamyl 10GR 40 kg/ha	72.3	70.7	100	n.s.	54.7	68.0	113.9	n.s.	47.7	44.8	89.1	n.s.	43.8	72.3	103.5	n.s.

Oxamyl 10GR 55 kg/ha	75.7	69.5	104.6	n.s.	59.5	69.1	124.0	n.s.	48.0	43.2	89.7	n.s.	44.3	66.2	104.7	n.s.
Toxic Standard	76.3	70.2	105.5	n.s.	43.8	73.1	91.3	n.s.	28.8	41.9	53.9	n.s.	43.2	74.9	102.0	n.s.

Mean value of 6 plots, calculated on the exact raw data
[1]% ratio of the total population
[2]% of control
- not applicable
n.s. not significantly different compared to the control, Student t-test, $\alpha = 0.05$
* significantly different compared to the control, Student t-test, $\alpha = 0.05$;

Conclusions:

There were no indications that Oxamyl 10GR had any behavioural effects on earthworm populations.

The only noteworthy finding in the Oxamyl 10GR-treated plots was a statistically significant decrease in the density of the most abundant species *Allolobophora chlorotica* after 1 year of exposure to 40 kg Oxamyl 10GR/ha (59% reduction in abundance, relative to controls). However, at the higher treatment rate (55 kg Oxamyl 10GR/ha) the reduction was only slight and not statistically significant, thus the effect in the 40 kg Oxamyl 10GR/ha group was not considered to be treatment related.

Therefore it can be concluded that Oxamyl 10GR, applied at rates of 40 and 55 kg Oxamyl 10GR/ha (equivalent to 4.0 and 5.5 kg oxamyl/ha), does not cause long-term toxic effects to natural earthworm populations in the field in typical UK conditions.

RMS comments and conclusion

The earthworm - field studies study DuPont-9157 was originally submitted as Post Annex I Inclusion confirmatory data and was included in the Oxamyl Volume 3 Addendum to Annex B (Ecotoxicology) to the Draft Report and Proposed Decision prepared by the RMS IE (May 2010). The study report and the study summary were not submitted for the present renewal process. The RMS retrieved the summary reported above from the cited Addendum.

The study was conducted with test material Oxamyl 10GR, according to guidelines BBA VI, 2-3 (1994), and ISO 11268-3 (1999). The RMS is aware that the ISO guideline has been recently revised (2014).

Conclusion: Due to the non-availability of the study, the RMS could not evaluate its reliability/acceptability.

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

Species level testing

Reproduction studies were conducted to evaluate the effect of oxamyl and its metabolites IN-A2213, IN-D2708, and IN-N0079 on *Collembola* and *Hypoaspis* following exposure to soil treated with oxamyl and its metabolites IN-A2213, IN-D2708, and IN-N0079 (see the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU).

Higher tier testing

Other non-target soil macro-organisms are not expected to be at risk from exposure to oxamyl and its major metabolites *via* soil. Evidence from earthworm, ground-dwelling non-target arthropod, Collembola, and predatory mite studies and risk assessments show acceptable risk of toxicity in non-target invertebrate fauna following exposure to oxamyl and its soil metabolites. Therefore, no additional testing in soil macro-organisms other than earthworms was conducted. Oxamyl 10GR, when applied according to its proposed use, is expected to pose negligible risk to other soil non-target macro-organisms.

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

Application conditions, exposure scenario, and risk assessment assumptions

The risk assessment for soil organisms will consider the following exposure scenarios for Oxamyl 10GR: in-furrow application to potatoes at 1 × 1000 g a.s./ha and to tobacco at 1 × 3000 g a.s./ha, and broadcast application followed by soil incorporation to tobacco at 1 × 5500 g a.s./ha. Details of the predicted environmental concentrations for oxamyl in soil are provided in dRAR VOL 3 a.s. B8 and in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10GR, DuPont-40953 EU. Good Agricultural Practices are summarised in the Oxamyl EU Renewal Dossier, Document D, Part 1, DuPont-40925 EU.

Toxicity endpoints

Summaries of the acute and chronic toxicity endpoints of the active substance oxamyl, its metabolites and Oxamyl 10GR are provided in Table 108 to Table 110 110.

Table 108 Oxamyl toxicity endpoint values for soil organisms

Species	Test/duration	Measurement endpoint	Endpoint value (mg a.s./kg soil)	Reference[a]
Eisenia fetida	14 d	LC_{50}	112	AMR 3068
Folsomia candida	28 d	NOEC EC_{10}	0.25 0.435	DuPont-39676
Hypoaspis aculeifer	14 d	NOEC	16	DuPont-39677

[a] Reports are reviewed and summarised in the dRAR Vol. 3 a.s. B9..

Table 109 Toxicity of Oxamyl 10GR to soil organisms

Species	Test/duration	Measurement endpoint	Endpoint value (mg a.s./kg soil)	Reference
Eisenia fetida	14 d	LC_{50}	>100	DuPont-3850[a]
Eisenia fetida	56 d	NOEC	6.4	DuPont-4296[b]

[a] Study summarised in this document

[b] Report is reviewed and summarised in dRAR Vol. 3 a.s. B9..

Table 110 Toxicity of the metabolites of oxamyl to soil organisms

Test substance	Species	Test/duration	Measurement endpoint	Endpoint value (mg/kg soil)	Reference[a]
IN-A2213	*Eisenia fetida*	14 d	LC_{50}	>1000	DuPont-4130
	Eisenia fetida	56 d	NOEC EC_{10}	25 26.6	DuPont-39672
	Folsomia candida	28 d	NOEC	100	DuPont-39673
	Hypoaspis aculeifer	14 d	NOEC	100	DuPont-39674
IN-D2708	*Eisenia fetida*	14 d	LC_{50}	>1000	DuPont-4132
	Eisenia fetida	56 d	NOEC	100	DuPont-41042
	Folsomia candida	28 d	NOEC	100	DuPont-41043
	Hypoaspis aculeifer	14 d	NOEC	100	DuPont-41044
IN-N0079	*Eisenia fetida*	14 d	LC_{50}	640	DuPont-4134
	Eisenia fetida	56 d	NOEC	50	DuPont-41045
	Folsomia candida	28 d	NOEC	12.5	DuPont-41046
	Hypoaspis aculeifer	14 d	NOEC EC_{10}	25 38.71	DuPont-41047

[a] Reports are reviewed and summarised in dRAR Vol. 3 a.s. B9.

Exposure assessment (predicted environmental concentrations [PEC])

Predicted environmental concentrations were generated to simulate applications of oxamyl to potatoes or tobacco in the EU. The predicted soil concentrations (PEC_s) of oxamyl and relevant soil metabolites IN-A2213, IN-D2708, and IN-N0079 were determined based upon the recommendations of the FOCUS group.

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

A soil bulk density of 1.5 g/cm^3 and a soil depth of 5 cm (in-furrow application to tobacco at 1 × 3000 g a.s./ha) or 10 cm (in-furrow application to potatoes at 1 × 1000 g a.s./ha and a broadcast application to tobacco at 1 × 5500 g a.s./ha) were assumed.

Details of the methods and assumptions used in the PEC_s calculation are presented in DuPont-40857 EU, summarized in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10GR, DuPont-40953 EU.

A summary of the predicted environmental concentrations in soil for oxamyl and its metabolites for the purposes of calculating toxicity exposure ratios for soil organisms is provided in Table 111.

Table 111 Maximum predicted concentrations of oxamyl and its metabolites IN-A2213, IN-D2708, and IN-N0079 in soil for the use of Oxamyl 10GR in potato and tobacco

Test substance component	Soil depth (cm)	Maximum PEC_s (mg a.s./kg soil)
Potato at 1 × 1000 g a.s./ha		
Oxamyl	10	0.667
IN-A2213	10	0.256
IN-D2708	10	0.280
IN-N0079	10	0.030
Tobacco at 1 × 3000 g a.s./ha		
Oxamyl	5	4.000
IN-A2213	5	1.538
IN-D2708	5	1.681
IN-N0079	5	0.183
Tobacco at 1 × 5500 g a.s./ha		
Oxamyl	10	3.667
IN-A2213	10	1.410
IN-D2708	10	1.541
IN-N0079	10	0.167

Furthermore, refined PEC_s calculations were conducted for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios (EFSA, 2012a[6], 2012b[7]).

Details of the methods and assumptions used in the PEC_s calculation are presented in DuPont-40857 EU, summarized in the Oxamyl EU Dossier, Document M-CP, Section 9 for Oxamyl 10GR, DuPont-40953 EU.

Maximum refined PEC_s values for oxamyl are summarized in Table 112.

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

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

Table 112 Maximum predicted concentrations of oxamyl in soil for the use of Oxamyl 10GR in potato and tobacco using EFSA scenarios

Test substance component	Soil depth (cm)	Maximum PEC_s (mg a.s./kg soil)
Potato at 1 × 1000 g a.s./ha(EFSA CTC Scenario)		
Oxamyl	20	0.469
Tobacco at 1 × 3000 g a.s./ha (EFSA CTS Scenario)		
Oxamyl	20	1.199
Tobacco at 1 × 5500 g a.s./ha		
Oxamyl	20	2.202

Toxicity exposure ratios for earthworms TER_a and TER_{lt}

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

Active substance

Acute toxicity: Exposure

According to the commission Regulation (EU) No 283/2013, a study on sub-lethal effects on earthworms should be required when the active substance can contaminate soil and the acute risk assessment of earthworms is no longer a requirement. Nevertheless, since the acute toxicity data are available for oxamyl and its metabolites, the RMS has included the relative studies with their summaries in the present document, and an acute risk assessment has also been presented here.

The calculated PEC_S and TER_a values for oxamyl, oxamyl as contained in Oxamyl 10GR following use in potato and tobacco are shown in Table 113.

Table 113 Acute TERs for earthworms exposed to maximum potential predicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in potato and tobacco

Test substance component	Duration of test (days)	LC_{50} (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_a
Potato at 1 × 1000 g a.s./ha				
Oxamyl	14	112	0.667	168
Oxamyl 10GR	14	>100	0.667	>150
Tobacco at 1 × 3000 g a.s./ha				
Oxamyl	14	112	4.000	28
Oxamyl 10GR	14	>100	4.000	>25
Tobacco at 1 × 5500 g a.s./ha				
Oxamyl	14	112	3.667	31
Oxamyl 10GR	14	>100	3.667	>27

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

Chronic toxicity: Exposure

The calculated PEC_s and TER_{lt} values for Oxamyl 10GR use in potato and tobacco are shown in Table 114.

Table 114 Chronic TERs for earthworms exposed to maximum potential predicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in soil in potato and tobacco

Test substance component	Duration of test (days)	NOEC (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_{lt}
Potato at 1 × 1000 g a.s./ha				
Oxamyl 10GR	56	6.4	0.667	9.6
Tobacco at 1 × 3000 g a.s./ha				
Oxamyl 10GR	56	6.4	4.000	**1.6**
Tobacco at 1 × 5500 g a.s./ha				
Oxamyl 10GR	56	6.4	3.667	**1.7**

Values in bold are below the relevant trigger of 5

The TER_{lt} values exceed the relevant Regulation (EC) 546/2011 trigger value of 5 for earthworms for the proposed use in potato. For the proposed uses in tobacco, the TER_{lt} values are below the trigger value, indicating a potential chronic risk to earthworm. Therefore, refined PEC_s calculations were conducted for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios.

Refined TER calculations are presented in Table 115.

Table 115 Refined chronic TERs for earthworms exposed to maximum potential predicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in soil in potato and tobacco using EFSA scenarios

Test substance component	Duration of test (days)	NOEC (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_{lt}
Potato at 1 × 1000 g a.s./ha (EFSA CTS Scenario)				
Oxamyl 10GR	56	6.4	0.469	14
Tobacco at 1 × 3000 g a.s./ha (EFSA CTS Scenario)				
Oxamyl 10GR	56	6.4	1.199	5.3
Tobacco at 1 × 5500 g a.s./ha (EFSA CTS Scenario)				
Oxamyl 10GR	56	6.4	2.202	**2.9**

Values in bold are below the relevant trigger of 5

Based on refined PEC_s values chronic TERs are above the trigger of Regulation (EC) 546/2011 trigger value of 5 for earthworms for the proposed in-furrow use in potatoes and tobacco. However, for broadcast application to tobacco at 1 x 5500 g a.s./ha, the TER is below the trigger, indicating a potential chronic risk to earthworms.

To further address the chronic risk to earthworms and evaluate the potential long-term effect of oxamyl, three earthworm field studies in Germany (DuPont-9157), United Kingdom (DuPont-14076), and The Netherlands (DuPont-14075) were performed. **The RMS highlights that the reports of the field studies could not be found among the submitted documentation. (please refer to Point B.9.7.1.2 in this document). The Applicant is requested to submit the study reports and to address the possible deviations of the studies from the current version of the ISO 11268-3 (2014) guideline.**

At present, in absence of the field studies, the broadcast application to tobacco at 1 x 5500 g a.s./ha,is concluded to be at risk. Metabolites

Acute toxicity: Exposure

The calculated PEC_{soil} and TER_a values for IN-A2213, IN-D2708, and IN-N0079 for the use of Oxamyl 10GR in potato and tobacco are shown in Table 116.

Table 116 Acute TERs for earthworms exposed to maximum potential predicted environmental concentration of IN-A2213, IN-D2708, and IN-N0079 in soil for the use of Oxamyl 10GR in potato and tobacco

Test substance	Duration of test (days)	LC_{50} (mg/kg soil)	Maximum PEC_{soil} (mg/kg soil)	TER_a
Potato at 1 × 1000 g a.s./ha				
IN-A2213	14	>1000	0.256	>3906
IN-D2708	14	>1000	0.280	>3571
IN-N0079	14	640	0.030	21333
Tobacco at 1 × 3000 g a.s./ha				
IN-A2213	14	>1000	1.538	650
IN-D2708	14	>1000	1.681	595
IN-N0079	14	640	0.183	3497
Tobacco at 1 × 5500 g a.s./ha				
IN-A2213	14	>1000	1.410	709
IN-D2708	14	>1000	1.541	649
IN-N0079	14	640	0.167	3832

The TER_a value for the oxamyl metabolites IN-A2213, IN-D2708, and IN-N0079 exceed the relevant Regulation (EC) 546/2011 trigger value of 10 for earthworms. Therefore, it can be concluded that acute risk to earthworms from the metabolites IN-A2213, IN-D2708, and IN-N0079 following the use of Oxamyl 10GR in potato and tobacco will be low.

Chronic toxicity: Exposure

The calculated PEC_{soil} and TER_{lt} values for IN-A2213, IN-D2708, and IN-N0079 for the use of Oxamyl 10GR in potato and tobacco are shown in Table 117.

Table 117 Chronic TERs for earthworms exposed to maximum potential predicted environmental concentration of IN-A2213, IN-D2708, and IN-N0079 in soil for the use of Oxamyl 10GR in potato and tobacco

Test substance	Duration of test (days)	NOEC/EC10 (mg/kg soil)	Maximum PEC_{soil} (mg/kg soil)	TER_{lt}
Potato at 1 × 1000 g a.s./ha				
IN-A2213	56	26.6	0.256	104
IN-D2708	56	100	0.280	357
IN-N0079	56	50	0.030	1667
Tobacco at 1 × 3000 g a.s./ha				
IN-A2213	56	26.6	1.538	17
IN-D2708	56	100	1.681	59
IN-N0079	56	50	0.183	273
Tobacco at 1 × 5500 g a.s./ha				
IN-A2213	56	26.6	3.667	7
IN-D2708	56	100	1.541	65
IN-N0079	56	50	0.167	299

The TER_{lt} values for the oxamyl metabolites IN-A2213, IN-D2708, and IN-N0079 exceed the relevant Regulation (EC) 546/2011 trigger value of 5 for earthworms. Therefore, it can be concluded that chronic risk to

earthworms from the metabolites IN-A2213, IN-D2708, and IN-N0079 following the use of Oxamyl 10GR in potato and tobacco will be low.

Overall, it can be concluded that risk to earthworms from the use of Oxamyl 10GR at the recommended GAP rates will be low.

Toxicity exposure ratios for Collembola and soil mites TER_{lt}

The TER_{lt} values were determined for oxamyl and its metabolites based on the ratio of the respective NOEC values to the maximum initial PEC_s.

Active substance

Chronic toxicity: Exposure

The calculated PEC_s and TER_{lt} values for oxamyl for Oxamyl 10GR use in potato and tobacco are shown in Table 118.

Table 118 Chronic TERs for non-target soil meso- and macrofauna exposed to maximum potential predicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in soil in potato and tobacco

Test substance component	Species	Duration of test (days)	NOEC (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_{lt}
Potato at 1 × 1000 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	0.667	**0.37**
Oxamyl	*Hypoaspis aculeifer*	14	16	0.667	24
Tobacco at 1 × 3000 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	4.000	**0.06**
Oxamyl	*Hypoaspis aculeifer*	14	16	4.000	**4.0**
Tobacco at 1 × 5500 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	3.667	**0.07**
Oxamyl	*Hypoaspis aculeifer*	14	16	3.667	**4.4**

Values in bold are below the relevant trigger of 5.

TER_{lt} values are below the relevant Regulation (EC) 546/2011 trigger value of 5 for soil meso- and macro-organisms, indicating a potential risk to soil meso- and macrofauna. Therefore, refined PEC_s calculations were conducted for oxamyl using the FOCUS model PEARL 4.4.4 and the EFSA Tier 2A soil scenarios.

Refined TER calculations are presented in Table 119.

Table 119 Refined chronic TERs for non-target soil meso- and macrofauna exposed to maximum potential redicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in soil in potato and tobacco using EFSA scenarios

Test substance component	Species	Duration of test (days)	NOEC (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_{lt}
Potato at 1 × 1000 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	0.469	**0.53**
Oxamyl	*Hypoaspis aculeifer*	14	16	0.469	34
Tobacco at 1 × 3000 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	1.199	**0.21**
Oxamyl	*Hypoaspis aculeifer*	14	16	1.199	13
Tobacco at 1 × 5500 g a.s./ha					
Oxamyl	*Folsomia candida*	28	0.25	2.202	**0.11**
Oxamyl	*Hypoaspis aculeifer*	14	16	2.202	7.3

Values in bold are below the relevant trigger of 5.

Based on refined PEC_s values, chronic TERs are above the trigger of Regulation (EC) 546/2011 trigger value of 5 for *Hypoaspis aculeifer* for all proposed uses, indicating acceptable risk to soil mites following application of Oxamyl 10GR according to the proposed use pattern. However, for *Collembola*, TER values are below the relevant trigger, indicating a potential risk. The RMS notes that even if the EC10 = 0.435 mg a.s./kg soil would be used instead of the NOEC=0.25 mg a.s./kg soil, the conclusion of risk would not change.

Therefore, a higher tier assessment based on *Collembola* population modelling was performed.

Higher tier assessment for Collembola

A population modelling study was performed to evaluate potential effects of oxamyl on *Collembola* following applications to potato and tobacco (see dRAR Vol 3 a.s. B9.).

For this purpose, the SpringSim (SPRINGtails SIMulation) 2.1 model has been used to simulate population dynamics of *Folsomia candida* over the course of 15 years. The population development was monitored during model runs, and to determine possible effects of the test item, comparisons between the abundance of *F. candida* before and during treatments, and during and after treatments were calculated. Simulations were conducted using PEC_s values calculated from field applications according to the GAP for uses on potato and tobacco using first order degradation kinetics with the geomean soil DT50 of 5.3 days.

The population modelling study concludes that "*It appears that in-furrow applications of oxamyl, both on potatoes and tobacco, have a moderate effect on populations of F. candida, which does not impair the capacity for recovering. Broadcast applications on tobacco cause a higher impact on populations living inside the field, as unlike the case of in-furrow applications, in this case 100% of the landscape is treated, and there are no "sources" to help the population to grow.*

Population-level effects of oxamyl appear to be stronger for broadcast applications on tobacco. When the model landscape is located entirely within a treated field, the population is not able to recover completely for at least 3 years. However, when recolonization from outside the field is taken into account, population density inside the field recovers more quickly, and in simulation year 16 (3 years after the last of 10 years annual applications) is almost entirely within the confidence limits of control year. Even in this scenario, the untreated area in the simulated landscape is only 18% of the total surface. It is thus likely that in a more realistic scenario, in which the contribution of the off-fields areas as source habitats is more considerable, the population inside the field would recover more quickly.

Therefore, while applications of oxamyl cause effects on collembolan populations living within treated fields, according to the modelling results shown in the present study, these effects appear to be transient and do not pose a long-term risk for populations of F. candida."

RMS: Since the correctness of toxicity input data into the model have been questioned by the RMS, the reliability of the results is doubtful. In addition some elements of uncertainty have been identified (see Vol 3 a.s. B9).

Metabolites

Chronic toxicity: Exposure

The calculated PEC_s and TER_{lt} values for IN-A2213, IN-D2708, and IN-N0079 for Oxamyl 10GR use in potato and tobacco are shown in Table 120.

Table 120 Refined chronic TERs for non-target soil meso- and macrofauna exposed to maximum potential predicted environmental concentration of oxamyl in soil for the use of Oxamyl 10GR in soil in potato and tobacco

Test substance component	Species	Duration of test (days)	NOEC (mg a.s./kg soil)	Maximum PEC_s (mg a.s./kg soil)	TER_{lt}
Potato at 1 × 1000 g a.s./ha					
IN-A2213	*Folsomia candida*	28	100	0.256	391
	Hypoaspis aculeifer	14	100	0.256	391
IN-D2708	*Folsomia candida*	28	100	0.280	357
	Hypoaspis aculeifer	14	100	0.280	357
IN-N0079	*Folsomia candida*	28	12.5	0.030	417
	Hypoaspis aculeifer	14	25	0.030	833
Tobacco at 1 × 3000 g a.s./ha					
IN-A2213	*Folsomia candida*	28	100	1.538	65
	Hypoaspis aculeifer	14	100	1.538	65
IN-D2708	*Folsomia candida*	28	100	1.681	59
	Hypoaspis aculeifer	14	100	1.681	59
IN-N0079	*Folsomia candida*	28	12.5	0.183	68
	Hypoaspis aculeifer	14	25	0.183	137
Tobacco at 1 × 5500 g a.s./ha					
IN-A2213	*Folsomia candida*	28	100	1.410	71
	Hypoaspis aculeifer	14	100	1.410	71
IN-D2708	*Folsomia candida*	28	100	1.541	65
	Hypoaspis aculeifer	14	100	1.541	65
IN-N0079	*Folsomia candida*	28	12.5	0.167	75
	Hypoaspis aculeifer	14	25	0.167	150

The TER_{lt} values for the oxamyl metabolites IN-A2213, IN-D2708, and IN-N0079 exceed the relevant Regulation (EC) 546/2011 trigger value of 5. Therefore, it can be concluded that chronic risk to soil meso- and macrofauna from the metabolite IN-A2213, IN-D2708, and IN-N0079 following the use of Oxamyl 10GR in potato and tobacco will be low.

RMS conclusion

The chronic risk to collembolan from the active substance remains to be addressed.

The risk to soil meso- and macrofauna is acceptable for the oxamyl metabolites.

B.9.9 Effects on soil nitrogen transformation

B.14.7.1 B9.9.1 Laboratory test to investigate impact on soil microbial activity

Study submitted in the EU Dossier in 2001 and included in the first EU approval review.

B.9.10.1/01

Reference: --	**Report**	Wachter, S. (2000); Oxamyl 10G: Assessment of the effects on soil microflora **DuPont Report No.:** DuPont-3793 **Guidelines:** BBA VI 1-1 (1990)

Materials:

MATERIALS

1.	Test material:	Oxamyl 10GR	
	Lot/Batch#:	D1410-394	
	Purity:	100 g a.s/kg	
	Description:	Solid / blue-green	
	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 20 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:	6.9	6.5
	% Total organic carbon:	1.06	2.78
	CEC (meg/100 g):	9.5	24.7
	Water holding capacity (%):	40.8	48.2
	Microbial biomass (% of total soil organic carbon):	8.4	62.4
	Clay (%) < 2 µm	8.5	9.6
	Silt (%) 63 µm to ≥ 2 µm	27.8	82.4
	Sand (%) ≥ 63 - 2000 µm	63.7	8.0
	NO_3^--N (mg/100 gdw)	1.76	5.20
4.	Environmental conditions		
	Temperature:	18 to 22°C	
	Photoperiod:	Continuous dark	

Materials and methods:

The effects of Oxamyl 10 GR formulated product on soil nitrogen transformation (ammonification and nitrification) and microbial respiration (carbon mineralisation) were examined for 28 days in a loamy silt soil and in a loamy sand soil (effects on nitrogen transformation were examined for 56 days) in laboratory studies. The test on nitrogen turnover contained 3 replicates of each treatment group: soil amended with Lucerne meal treated with water, soil amended with Lucerne meal treated with Oxamyl 10 GR at a rate equivalent to 5.5 and 27.5 kg as/ha (1 time and 5 times the maximum field application rate), equivalent to 7.33 and 36.67 mg a.s/kg soil dry weight, and soil amended with Lucerne meal treated with the reference product Herbogile liquide (dinoterb formulation) at a rate equivalent to 20 L/ha (5-times the field application rate). 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 test on short term respiration contained 3 replicates of each treatment group: untreated soil (control), soil treated with Oxamyl 10 GR at a rate equivalent to 5.5 and 27.5 kg as/ha (1x and 5x the field application rate) and soil treated with the reference product Herbogile liquide (dinoterb formulation) at a rate equivalent to 20 L/ha (5-times the 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.

Observations

Samples were collected for determination of nitrogen transformation at 3h, and at days 14, 28, and 56 (only loamy sand soil) following application of the test item.

Short-term respiration was measured in soil samples taken 3 hours, 14 days and 28 days after applying test material. The rate of oxygen uptake was measured for up to 24 hours following the addition of glucose.

Statistics

Statistical calculations were done by the Easy Assay computer program (Ratte, 1995). The assay of data included the NOEC and LOEC by a multiple t-test procedure according to Dunnett (Ratte, 1995).

Findings:

Summary of $N0_3^-$-N, ~+ -N, NO_2^-—*N* and N_{min} (sum of $N0_3^-$-N, NH/ -N, NO_2^--*N)* content of soil (mg/ 100 g dry weight) and the deviation from the control for the loamy sand soil for the assessments on day 1 (3 h), day 14, day 28 and day 56.

Time	+ 3 h	+ 14 d	+ 28 d	+ 56 d
Control				
NH_4^+-N	0.12	0.20	0.20	0.22
NO_3^--N	1.76	1.88	3.39	4.99
NO_2^--N	b.q.	b.q.	b.q.	0.06
$N_{min.}$	1.88	2.08	3.59	5.27
Oxamyl 10G 1X field rate				
NH_4^+-N	0.12	0.21	0.20	0.14
NO_3^--N	1.73	2.30	4.11	5.67
NO_2^--N	b.q.	b.q.	b.q.	b.q.
$N_{min.}$	1.85	2.51	4.31	5.81
Deviation from the control (%)				
NH_4^+-N	0.00	5.00	0.00	-36.36
NO_3^--N	-1.70	22.34	21.24	13.63
NO_2^--N	-	-	-	-
$N_{min.}$	-1.60	20.67	20.06	10.25
Oxamyl 10G 5 X field rate				
NH_4^+-N	0.19	0.19	0.20	0.17
NO_3^--N	1.91	2.81	5.13	6.23
NO_2^--N	b.q.	b.q.	b.q.	0.06
$N_{min.}$	2.10	3.00	5.33	6.46
Deviation from the control (%)				
NH_4^+-N	58.33	-5.00	0.00	-22.73
NO_3^--N	8.52	49.47	51.33	24.85
NO_2^--N	-	-.	-	-
$N_{min.}$	11.70	44.23	48.47	22.58
Reference substance				
NH_4^+-N	0.24	0.18	0.23	0.11
NO_3^--N	1.92	3.13	5.49	7.92
NO_2^--N	b.q.	0.65	b.q.	0.12
$N_{min.}$	2.16	3.96	5.72	8.15
Deviation from the control (%)				
NH_4^+-N	100.00	-10.00	15.00	-50.00
NO_3^--N	9.09	66.49	61.95	58.72
NO_2^--N	-	-	-	100.00
$N_{min.}$	14.89	57.77	59.33	54.65

b.q. = below the limit of quantitation ,
- no deviation from the control was calculated because the measured values were below the limit of quantitation

Nitrate-N/100 g dry weight, loamy sand soil (56d)

mg Nitrate-N/100 g dry weight (56 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	9,62	0,868	5,01	4,99	-
	8,01	0,869	4,17		
	11,10	0,867	5,79		
Oxamyl 10G 1x the field application rate	12,30	0,875	6,35	5,67	13,63
	10,50	0,857	5,54		
	9,83	0,866	5,13		
Oxamyl 10G 5x the field application rate	12,50	0,879	6,43	6,23	24,85
	12,00	0,872	6,22		
	11,50	0,862	6,03		
Reference substance	14,70	0,868	7,65	7,92	58,72
	14,90	0,869	7,75		
	15,90	0,859	8,37		

Results ofthe short-term respiration test

Short term respiration test, % deviation from control

% Deviation from control			
Loamy sand soil			
Time	**Oxamyl 10G, 1-times field application rate**	**Oxamyl 10G, 5-times field application rate**	**Reference substance**
3 h	-1.89	-5.66	3.77
14 d	0.00	-11.63	-30.23
28 d	-6.82	-9.09	-25.00
Loamy silt soil			
3 h	-8.50	-18.00	-11.00
14 d	3.43	2.58	0.43
28 d	3.80	11.96	-16.30

A summary of the findings is presented in Table and

Nominal oxamyl concentration	Mean NO3--N Levels (Day 56)		Mean Formation rate NO3--N (Day 56)	
	mg/100g dry soil	% Deviation from controla	mg /kg/d	% Deviation from control
Control (0.0)	4.99	--	0.58	--
5.5 kg a.s./ha (7.33 mg a.s/kg dw)	5.67	13.63	0.70	21
27.5 kg a.s./ha (36.67 mg a.s/kg dw)	6.23	24.85	0.80	33

Negative value = % inhibition, positive value = % stimulation

Table 122
. Levels of mineralised nitrogen in the loamy silt soil and the loamy sand soil treated with Oxamyl 10 GR at the 1 time and 5 times the field application rate differed < 25% from the corresponding untreated control soil at the end of the studies. Oxamyl 10 GR at concentrations of 1 time and 5 times the field application rate resulted in deviations < 25% from the controls on short-term respiration after 28 days in both soil types.

Table 121 Summary of effects (%)[a] of Oxamyl 10 GR on mineralised nitrogen level (N_{min}) in loamy silt soil and in loamy sand soil amended with Lucerne meal

Day	Treatment Group	
	Oxamyl 10 GR 5.5 kg as/ha (1X field rate)	Oxamyl 10 GR 27.5 kg as/ha (5X field rate)
Loamy Silt Soil		
0	-1.24	1.77
14	5.27	10.41
28	3.91	16.92
Loamy Sand Soil		
0	-1.60	11.70
14	20.67	44.23
28	20.06	48.47
56	10.25	22.58

[a] % Effect: [(measured parameter in treated soil / measured parameter in control soil)-1] x100

Effects on nitrate formation concentration and nitrate formation rate at the end of the study (56d).

Nominal oxamyl concentration	Mean NO_3^--N Levels (Day 56)		Mean Formation rate NO_3^--N (Day 56)	
	mg/100g dry soil	% Deviation from control[a]	mg /kg/d	% Deviation from control
Control (0.0)	4.99	--	0.58	--
5.5 kg a.s./ha (7.33 mg a.s/kg dw)	5.67	13.63	0.70	21
27.5 kg a.s./ha (36.67 mg a.s/kg dw)	6.23	24.85	0.80	33

Negative value = % inhibition, positive value = % stimulation

Table 122 Summary of effects (%)[a] of Oxamyl 10 GR on respiration in loamy silt soil and in loamy sand soil

Day	Treatment Group	
	Oxamyl 10 GR 5.5 kg as/ha (1X field rate)	Oxamyl 10 GR 27.5 kg as/ha (5X field rate)
Loamy Silt Soil		
0	-8.50	-18.00
14	3.43	2.58
28	3.80	11.96
Loamy Sand Soil		
0	-1.89	-5.66
14	0.00	-11.63
28	-6.82	-9.09
56	-1.89	-5.66

[a] % Effect: [(measured parameter in treated soil / measured parameter in control soil)-1] x100

Conclusion:

Oxamyl 10 GR, applied at 1x and 5x the field application rate had no significant effect on soil nitrogen transformation (16.92% in loamy silt soil and 22.58% in loamy sand soil) or carbon mineralisation (11.96% in loamy silt soil and –5.66% in loamy sand soil). Under anticipated conditions of field use Oxamyl 10 GR is categorised as having low risk to soil microflora.

RMS comments and conclusion

The effects on soil nitrogen transformation study DuPont-3793, originally submitted under EU Rev8 Point IIA 10.7.1. and conducted with test material Oxamyl 10GR, was conducted under guideline BBA VI 1-1 (1990). A review of this study according the current guideline (OECD 216, 2000) was conducted.

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 (not at 7d).The RMS revised the summary by including tables and several additional information in the text. As requested in the OECD 216, the nitrate formation rate was also calculated and used to express the results (see table above). The nitrate formation rate in the 5.5 kg a.s./ha treatment, in the relevant sandy loam soil, was <25% diffent from control (actual 21%), while in the 27.5 kg a.s./ha treatment it was >25% diffent from control (actual 33%).

Validity criterion:

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 56d was 21%.

Conclusion: the study is not valid.

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

No additional testing is required since it can be predicted that Oxamyl 10GR will have no significant effect on soil microflora.

B.9.10 Risk assessment for soil nitrogen transformation

Application conditions, exposure scenario, and risk assessment assumptions

The risk assessment for soil microflora will consider the following exposure scenarios for Oxamyl 10GR: in-furrow application to potatoes at 1 × 1000 g a.s./ha, in-furrow application to tobacco at 1 × 3000 g a.s./ha, and broadcast application followed by soil incorporation to tobacco at 1 × 5500 g a.s./ha. Details of the predicted environmental concentrations for oxamyl in soil are provided in the Oxamyl 10GR dRAR Vol 3 B8 . Good Agricultural Practices are summarised in the Oxamyl EU Renewal Dossier, Document D, Part 1, DuPont-40925 EU.

Toxicity endpoints

Summaries of the nitrogen transformation studies Oxamyl 10GR and oxamyl metabolites are provided in Table 123.

Table 123 Effects of Oxamyl 10GR and metabolites on soil nitrogen transformation

Test item	Test	Test concentration (mg/kg soil d.w.)	Corresponding application rates relative to parent compound oxamyl	Parameter	% effect[a]	Reference
Oxamyl 10GR	Not valid					DuPont-3793[b]
IN-A2213	56-day laboratory	4.9 49	3× 32×	Nitrate formation	<25% (+9.7) >25% (+35%)	DuPont-4131[c]
IN-D2708	Not valid					DuPont-4133[c]
IN-N0079	56-day laboratory	3.0, 15 30	16×, 82×, 163×	Nitrate formation	<25% (+6, +15) >25% (+28)	DuPont-4135[c]
IN-T2921	28-day laboratory Contraddictory data Not reliable	3.53, 17.65 35.3	no PEC	Nitrate formation	>25% (+27, +27) <25% (0%)	DuPont-4736[c]

[a] % deviation from the control.

[b] Study summarised in this document.

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

Exposure assessment (predicted environmental concentrations [PEC])

Predicted environmental concentrations were generated to simulate applications of oxamyl to potatoes or tobacco in the EU. The predicted soil concentrations (PEC_s) of oxamyl and relevant soil metabolites IN-A2213, IN-D2708, and IN-N0079 were determined based upon the recommendations of the FOCUS group.

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

A soil bulk density of 1.5 g/cm^3 and a soil depth of 5 cm (in-furrow application to tobacco at 1 × 3000 g a.s./ha) or 10 cm (in-furrow application to potatoes at 1 × 1000 g a.s./ha and a broadcast application to tobacco at 1 × 5500 g a.s./ha) were assumed.

Details of the methods and assumptions used in the PEC_s calculation are presented in DuPont-40857 EU, summarized in the Oxamyl EU Renewal Dossier, Document M-CP, Section 9 for Oxamyl 10GR, DuPont-40953 EU.

A summary of the predicted environmental concentrations in soil for oxamyl and its metabolites for the purposes of calculating toxicity exposure ratios for soil micro-organisms is provided in Table 124.

Table 124 Maximum predicted concentrations of oxamyl and its metabolites IN-A2213, IN-D2708, and IN-N0079 in soil for the use of Oxamyl 10GR in potato and tobacco

Test substance component	Soil depth (cm)	Maximum PEC_s (mg a.s./kg soil)
Potato at 1 × 1000 g a.s./ha		
Oxamyl	10	0.667
IN-A2213	10	0.256
IN-D2708	10	0.280
IN-N0079	10	0.030
Tobacco at 1 × 3000 g a.s./ha		
Oxamyl	5	4.000
IN-A2213	5	1.538
IN-D2708	5	1.681
IN-N0079	5	0.183
Tobacco at 1 × 5500 g a.s./ha		
Oxamyl	10	3.667
IN-A2213	10	1.410
IN-D2708	10	1.541
IN-N0079	10	0.167

Risk assessment for soil micro-organisms

Oxamyl 10GR

Laboratory testing was conducted to evaluate the effects of Oxamyl 10GR on non-target soil micro-organisms. Information on this test is found under Point B.14.7.1 of this document. Soil was treated with one (5.5 kg oxamyl/ha) and five times (27.5 kg oxamyl/ha) the maximum single application use rate of Oxamyl 10GR, and effects on nitrogen transformation and carbon mineralisation were evaluated. The nitrate formation rate in the 5.5 kg a.s./ha treatment, in the relevant sandy loam soil, was <25% diffent from control (actual 21%), while in the 27.5 kg a.s./ha treatment it was >25% diffent from control (actual 33%). Since the study was judged not valid, the results are not reliable. No conclusion can be drawn about the risk of Oxamyl 10GR risk to soil microflora function.

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

Laboratory testing was conducted to evaluate the effects of oxamyl metabolites, IN-A2213, IN-D2708, and IN-N0079 on non-target soil micro-organisms. Detailed information on the tests conducted with the metabolites is found in the Oxamyl dRAR a.s. Vol 3 B9..

Soil was treated with 49 mg IN-A2213/kg soil (which is 32-times the maximum PEC_S), and to 15 mg IN-N0079/kg soil (which is 82-times the maximum PEC_s), respectively, and effects on nitrogen transformation and carbon mineralisation were evaluated. The results of the two studies on IN-A2213, and IN-N0079 demonstrated that nitrate formation rate and carbon mineralisation in treated soil were comparable to those obtained in control soils; the deviations in measured activity at the end of the study period (28 days) being less than 25% for all parameters examined. It may be concluded that oxamyl metabolites IN-A2213, and IN-N0079 at rates ≥32-times the maximum PEC_s would be expected to pose low risk to soil microflora function.

The risk of IN-D2708 cannot be assessed because the study with this metabolite was judged not valid.

RMS conclusion

The study with Oxamyl 10GR is not valid, hence no conclusion can be drawn about the risk of Oxamyl 10GR risk to soil microflora function (see this document).

The risk of metabolites IN-A2213 and IN-N0079 is acceptable, but no conclusion can be drawn for IN-D2708 because the test is not valid (see dRAR a.s. Vol. 3B9).

Conclusion: data gap for effect to micro-organisms function for Oxamyl 10GR and IN-D2708.

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. However, seedling emergence and vegetative vigour studies were performed.

B.9.11.2 Testing on non-target plants

The effects of oxamyl on the germination, seedling emergence, vegetative vigour, and phytotoxicity of a range of terrestrial non-target plants were assessed in laboratory studies. Summaries of these studies are given in the Oxamyl dRAR Vol 3 .

B.9.11.3 Extended laboratory studies on non-target plants

The risk assessment to non-target terrestrial plants demonstrated a low risk following application of Oxamyl 10GR according to the proposed use pattern, therefore, further extended laboratory studies were not considered necessary.

B.9.11.4 Semi-field and field tests on non-target plants

This is not an EC data requirement.

B.9.11.5 Summary of screening data

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

Application conditions

For field application, Oxamyl 10GR is labelled for single uses on potatoes at-planting at a maximum of 1.0 kg oxamyl/ha in-furrow, at-planting or on tobacco at a maximum of 5.5 kg oxamyl/ha broadcast pre-planting. Good Agricultural Practices are summarised in Table 3.

Toxicity to non-target terrestrial plants

Results of the seedling emergence and vegetative vigour studies performed with the spray formulation Oxamyl 24L, are summarised in Table 125 and Table 126, respectively. The seedling emergence test is not fully valid and the results can be used as additional information. The full validity of the vegetative vigour study could not established, hence the results are to be considered as supportive information.

Table 125 Effects of Oxamyl 24L on seedling emergence of ten non target-terrestrial plants (soil application)

Species	Genus/species	Oxamyl 24SL ER_{50} (kg a.s./ha)[a]	Reference[b]
Corn	*Zea mays*	>2.24	DuPont-5817 Additional information
Oat	*Avena sativa*	>2.24	
Onion	*Allium cepa*	>2.24	
Sorghum	*Sorghum bicolor*	>2.24	
Cucumber	*Cucumis sativus*	>2.24	
Oilseed rape	*Brassica napus*	>2.24	
Pea	*Pisum sativum*	>2.24	
Soybean	*Glycine max*	>2.24	
Sugar beet	*Beta vulgaris*	>2.24	
Tomato	*Lycopersicon esculentum*	>2.24	

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

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

Table 126 Effects of Oxamyl 24SL on vegetative vigour of ten non target-terrestrial plants (foliar application)

Species	Genus/species	Oxamyl 24SL ER_{50} (kg a.s./ha)[a]	Reference[b]
Corn	*Zea mays*	>2.24	DuPont-34275 Supportive data
Oat	*Avena sativa*	>2.24	
Onion	*Allium cepa*	>2.24	
Perennial ryegrass	*Lolium perenne*	>2.24	
Cucumber	*Cucumis sativus*	>2.24	
Pea	*Pisum sativum*	>2.24	
Oilseed rape	*Brassica napus*	>2.24	
Soybean	*Glycine max*	>2.24	
Sugar beet	*Beta vulgaris*	>2.24	
Tomato	*Lycopersicon esculentum*	>2.24	

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

[b] Report is reviewed and summarised in the Oxamyl dRAR a.s Vol 3 B9..

Exposure assessment

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

In-furrow application to potato and tobacco is performed during transplanting, and dust development is not expected to occur for this application method. This was demonstrated by a field study (DuPont–38691 EU, summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 6, DuPont-40933 EU); based on the off-field measurements, dust drift during an in-furrow application on potatoes was zero. Consequently, non-target plants in the off-field will not be exposed to dust drift, and therefore, the risk to non-target terrestrial plants can be considered as low.

For broadcast application to tobacco, dust-drift may occur during application. The amount of dust-drift reaching the off-crop habitat is calculated using dust drift values provided by the EFSA (2004)[8], in accordance with PEC_{sw} calculations (see the Oxamyl 10GR dRAR Vol 3 B8). For broadcast granular application, a maximum of 1.49% of the application rate was assumed to reach off-crop areas at 1 m from the edge of the crop (worst-case scenario). The application rate of Oxamyl 10GR is 5.5 kg product/ha, equivalent to 5500 g a.s./ha, giving a maximum off-field predicted environmental rate of 81.95 g a.s./ha.

Assessment of risk to non-target terrestrial plants

Oxamyl 10GR is used as a nematicide applied as a granular application. Therefore toxicity to plants and the risk of exposure can be considered as low. However, to prove low toxicity of oxamyl to non-target terrestrial plants, data from seedling emergence vegetative vigour studies for the Oxamyl 24L spray formulation were presented above as supporting information. For completeness sake, a risk assessment is performed for Oxamyl 10GR based on worst-case assumptions for broadcast application.

Non-target plant testing conducted with the oxamyl spray formulation Oxamyl 24L to evaluate potential effects of oxamyl following pre-emergent (soil) and post-emergent (foliar) exposure resulted for all tested species with an EC_{50} >2240 g a.s/ha (supportive information).

The resulting TER values are given in Table 127127.

Table 127Oxamyl 10GR: TERs for terrestrial non-target plants based on broadcast application of 5500 g a.s./ha to tobacco

Buffer distance (meters)	Application rate (g a.s./ha)	Dust drift value[a] (%)	PEC_{drift} (g a.s./ha)	EC_{50} (g a.s./ha)	TER
1	5500	1.49	81.95	>2240	>27

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

Based on worst-case dust drift value, the TER value exceed the relevant Regulation (EC) 546/2011 trigger value of 5 for non-target terrestrial plants, indicating an acceptable risk to non-target terrestrial plants following broadcast application to tobacco.

RMS comments and conclusion

The seedling emergence test is not fully valid and the results can be used as additional information. The full validity of the vegetative vigour study could not established, hence the results are to be considered as supportive information. Both studies show effects much lower that 50% at 2240 g a.s./ha (the maximum concentration tested). The conservative assumptions in the risk assessment, and the TER (>27) exceedance of the trigger 5 can represent weight of evidence of a likely low risk to plants growing adjacent to the application site.

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

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

B.9.13.1 Summary of available data from preliminary tests used to assess biological activity and dose range finding, which may provide information on other non-target species (flora and fauna)

Data from 9icide screening studies with oxamyl and metabolites of oxamyl are summarised in the Oxamyl EU Renewal Dossier, Document M-CA, Section 8, DuPont-40935 EU.

B.9.13.2 A critical assessment as to the relevance of the preliminary test data to potential impact on non-target species

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 10GR will pose low risk to non-target organisms when used according to Good Agricultural Practices.

B.9.13.3 Monitoring data

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

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

No risk assessments for other terrestrial organisms are required.

B.9.15 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

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company Report No GLP or GEP status (where relevant) Published or not	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner
B.9.1.1.2/01	[redacted]	1999	Oxamyl 10G: An acute oral toxicity study with the northern bobwhite. [redacted] DuPont-2955 GLP: Yes Published: No		N		DuPont
B.9.1.1.2/02	Thompson, H.M.		DuPont-15823				
B.9.1.1.2/03	Thompson, H.M.		DuPont-15827, Revision No. 1				
B.9.3.1/01	[redacted]	2000a	Oxamyl 10G: Static, acute, 96-hour, (LC_{50}) test to rainbow trout, *Oncorhynchus mykiss.* [redacted] DuPont-2912 GLP: Yes Published: No		N		DuPont

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B.9.3.1/02	[redacted]	2000b	Oxamyl 10G: Static-renewal, acute, 96-hour, (LC_{50}) test to bluegill sunfish, *Lepomis macrochirus.* [redacted] DuPont-2913 GLP: Yes Published: No		N		DuPont
B.9.3.1/03	Ward, T.J.	2000	Oxamyl 10G: Acute, 48-hour EC_{50} to *Daphnia magna.* T.R. Wilbury Laboratories, Inc. DuPont-2555 GLP: Yes Published: No		N		DuPont
B.9.3.1/04	Boeri, R.L., Ward, T.J.	2000	Oxamyl 10G: Influence on growth and growth rate of the alga, *Selenastrum capricornutum.* T.R. Wilbury Laboratories, Inc. DuPont-3914 GLP: Yes Published: No		N		DuPont
B.9.6.1.1.1/01	Shur, A.	1999	Acute oral and contact toxicity to the honey bee, *Apis mellifera* L. GAB Biotechnologie, GmbH DuPont-2718 GLP: Yes Published: No		N		DuPont
B.9.6.1.5/01	Berg, C.	2015a	Oxamyl 10GR Tunnel Studies - Effects on bumble bees and brood -potatoes Eurofins Agroscience Services EcoChem GmbH DuPont-39666 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to	DuPont

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B.9.6.1.5/02	Berg, C.	2015b	Oxamyl (DPX-D1410) 10GR [100 g/kg]: A semi-field study to evaluate effects on the brood of honey bees (Apis mellifera; Hymenoptera, Apidae) in Phacelia tanacetifolia in Germany 2014 Eurofins Agroscience Services EcoChem GmbH DuPont-39667 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has	DuPont
B.9.6.2.2/01	Schmitzer, S.	2000	Oxamyl 10G (10% w/w): An extended laboratory study to evaluate the effects on the ground beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae). IBACON DuPont-3244 GLP: Yes Published: No		Y		DuPont
B.9.6.2.2/02	Drexler, A.	2000	Oxamyl 10G (10% w/w): An extended laboratory study to evaluate the effects on the staphylinid beetle, *Aleochara bilineata* Gyll. IBACON DuPont-3245 RV1 GLP: Yes Published: No		Y		DuPont
B.9.6.2.2/03	Bruhnke, C.	2000	Oxamyl 10G: An extended laboratory study to evaluate the effects on the spider *Pardosa* spp. (Araneae, Lycosidae). Dr. U. Noack-Laboratorium for Angewandte Biologie DuPont-4053 GLP: None Published: No		Y		DuPont

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B.9.8.1/01	Luhrs, U.	2000	Oxamyl 10G (10% w/w): Acute toxicity to the earthworm, *Eisenia fetida* (Savigny) in artificial soil. IBACON DuPont-3850 GLP: Yes Published: No		N		DuPont
B.9.8.1.2/01	Luhrs, U. (2004)		DuPont-9157				
B.9.8.1.2/02	Luhrs, U. (2007a)		DuPont-14075				
B.9.8.1.2/03	Luhrs, U. (2007b)		DuPont-14076				
B.9.10.1/01	Wachter, S.	2000	Oxamyl 10G: Assessment of the effects on soil microflora. GAB Biotechnologie, GmbH DuPont-3793 GLP: Yes Published: No		N		DuPont

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B.9.6.1.5/01	Berg, C.	2015a	Oxamyl 10GR Tunnel Studies - Effects on bumble bees and brood -potatoes Eurofins Agroscience Services EcoChem GmbH DuPont-39666 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to	DuPont
B.9.6.1.5/02	Berg, C.	2015b	Oxamyl (DPX-D1410) 10GR [100 g/kg]: A semi-field study to evaluate effects on the brood of honey bees (Apis mellifera; Hymenoptera, Apidae) in Phacelia tanacetifolia in Germany 2014 Eurofins Agroscience Services EcoChem GmbH DuPont-39667 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has	DuPont
B.9.4.1/04	Boeri, R.L., Ward, T.J.	2000	Oxamyl 10G: Influence on growth and growth rate of the alga, *Selenastrum capricornutum.* T.R. Wilbury Laboratories, Inc. DuPont-3914 GLP: Yes Published: No		N		DuPont
B.9.6.2.2/03	Bruhnke, C.	2000	Oxamyl 10G: An extended laboratory study to evaluate the effects on the spider *Pardosa* spp. (Araneae, Lycosidae). Dr. U. Noack-Laboratorium for Angewandte Biologie DuPont-4053 GLP: None Published: No		Y		DuPont

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B.9.6.2.2/02	Drexler, A.	2000	Oxamyl 10G (10% w/w): An extended laboratory study to evaluate the effects on the staphylinid beetle, *Aleochara bilineata* Gyll. IBACON DuPont-3245 RV1 GLP: Yes Published: No		Y		DuPont
B.9.1.1.2/01	[redacted]	1999	Oxamyl 10G: An acute oral toxicity study with the northern bobwhite. [redacted] DuPont-2955 GLP: Yes Published: No		N		DuPont
B.9.8.1/01	Luhrs, U.	2000	Oxamyl 10G (10% w/w): Acute toxicity to the earthworm, *Eisenia fetida* (Savigny) in artificial soil. IBACON DuPont-3850 GLP: Yes Published: No		N		DuPont
B.9.8.1.2/01	Luhrs, U. (2004)		DuPont-9157				

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B.9.8.1.2/03	Luhrs, U. (2007b)		DuPont-14076				
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B.9.6.1.1.1/01	Shur, A.	1999	Acute oral and contact toxicity to the honey bee, *Apis mellifera* L. GAB Biotechnologie, GmbH DuPont-2718 GLP: Yes Published: No		N		DuPont

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B.9.1.1.2/02	Thompson, H.M.		DuPont-15823				
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B.9.10.1/01	Wachter, S.	2000	Oxamyl 10G: Assessment of the effects on soil microflora. GAB Biotechnologie, GmbH DuPont-3793 GLP: Yes Published: No		N		DuPont
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B.9.4.1/01	[redacted]	2000a	Oxamyl 10G: Static, acute, 96-hour, (LC_{50}) test to rainbow trout, *Oncorhynchus mykiss.* [redacted] DuPont-2912 GLP: Yes Published: No		N		DuPont

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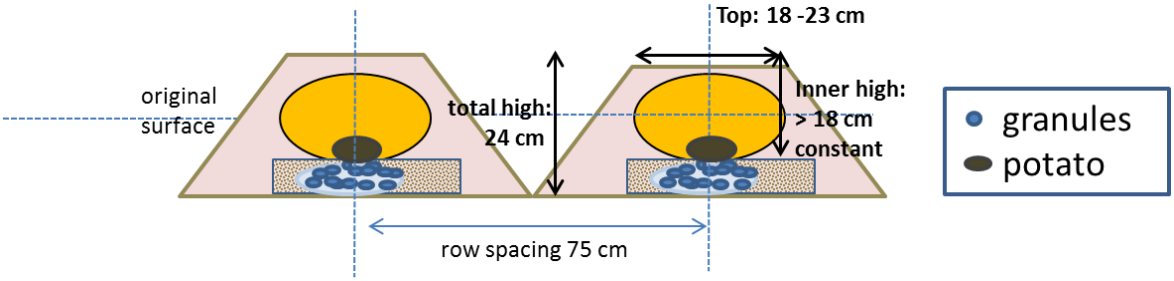
B.9.4.1/02	[redacted]	2000b	Oxamyl 10G: Static-renewal, acute, 96-hour, (LC_{50}) test to bluegill sunfish, *Lepomis macrochirus.* [redacted]. DuPont-2913 GLP: Yes Published: No		N		DuPont

APPENDIX 1

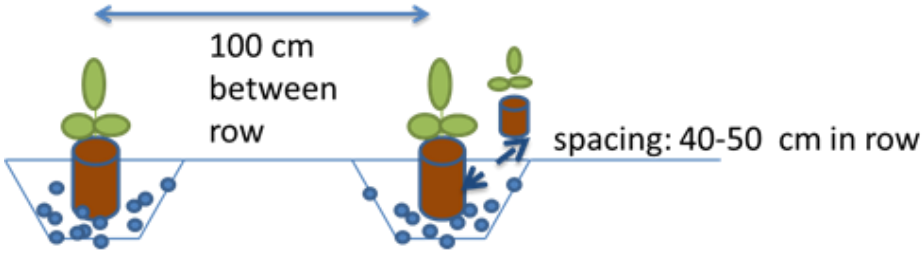
REPRESENTATIVE APPLICATION REGIME

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



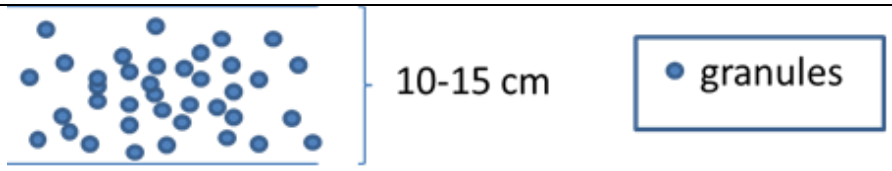
Typical application depth for this use is >9 cm relative to the original soil surface and >18 cm relative to the ridge surface. This application regime results in essentially no granules on the soil surface.

In-furrow application to tobacco at 1 × 3000 g a.s./ha



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

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



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