

European Commission

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



Oxamyl 10SL

**Volume 3 (CP)
ANNEX B.3
Data on application and efficacy**

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

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VERSION HISTORY

Date	Data points containing amendments or additions	Document identifier or version number
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January 2018	Revised RAR after comment CoRMS (France)	

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B.3 DATA ON APPLICATION AND EFFICACY

For efficacy-related elements, only limited information is provided to address the requirements of Article 4(3) of Regulation (EC) No 1107/2009. Detailed consideration of efficacy will occur in the subsequent product authorisation process when a full biological assessment dossier will be submitted. Therefore, only limited efficacy information is provided under the appropriate headings in line with the relevant guidance for renewals - Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 Appendix II (SANCO/2012/11251).

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

B.3.0/1

<p>Reference</p> <p>CP 3.0/01</p>	<p>Report:</p>	<p>Flier, W. (2015); Summary of efficacy data of the plant protection products: Oxamyl 10GR (100 g/kg), granular formulation, Oxamyl 10SL (100 g/L), soluble liquid formulation, Active substance: Oxamyl, efficacy information, supplemental submission in support of renewal</p> <p>DuPont Report No.: DuPont-42980 EU</p> <p>Guidelines: Not applicable Deviations: Not applicable</p> <p>Testing Facility: E. I. DuPont de Nemours and Company, Dordrecht, The Netherlands</p> <p>Testing Facility Report No.: DuPont-42980 EU</p> <p>GLP: No</p> <p>Certifying Authority: Not applicable</p> <p>Information pertinent to Points CP 3.1 through CP 3.6 are summarised in this report.</p>
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B.3.1 Field of use envisaged

Oxamyl 10SL is to be used in agricultural situations and under protected conditions (greenhouse) only.

B.3.2 Effects on harmful organisms

Oxamyl 10SL contains oxamyl, a non-fumigant nematicide used for the control of a range of plant parasitic nematodes.

Oxamyl is systemic in plants. Uptake by plants also occurs when the substance (product) is applied to the soil system. In this case, oxamyl is absorbed by root of plants and translocated to leaves. Direct activity on nematode control occurs in this case as well as control of pests on above-ground plant material.

B.3.3 Details of intended use

Oxamyl is used to control a wide range of important plant parasitic nematodes in a range of crops. Nematode pests that are controlled include *Meloidogyne* sp. (rootknot nematodes), *Globodera* and *Heterodera* sp. (cyst nematodes), *Trichodorus* and *Paratrichodorus* sp. (stubby root nematodes), *Radopholus similis* (burrowing nematode), *Belonolaimus longicaudatus* (sting nematode), *Hoplolaimus galeatus* (lance nematode), *Ditylenchus* sp. (stem and bulb nematodes), and *Pratylenchus penetrans* (root lesion nematode).

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

Considering the solarisation¹ use, Oxamyl 10SL is applied *via* drip irrigation with transparent plastic foil covering soil and before transplant on bare soil (approximately between June and September) at a maximum application rate of 5.5 kg a.s./ha. The recommended Plant Back Interval is 30 days, with the application to bare soil covered with plastic foil to control soil nematodes before transplant.

“Start the irrigation by applying water and nutrients only when the soil or substrate has reached adequate soil moisture add oxamyl 10SL to the irrigation system”
Soil is brought to field capacity (~50000L/ha). Oxamyl is applied at approximately 50% of the irrigation cycle. No further irrigation is typically needed.

¹ Soil bed preparation in greenhouses designated for the growing of tomato, cucurbits (edible and inedible peel), pepper, aubergine, and plants nurseries of the above mentioned crops

Table 1

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

PPP (product name/code)	Oxamyl 10SL (Vydate® 10L)	Formulation type:	SL
active substance 1	Oxamyl (DPX-D1410)	Conc. of as 1:	100 g/L
active substance 2		Conc. of as 2:	
safener	none	Conc. of safener:	n.a.
synergist	none	Conc. of synergist:	n.a.
Applicant:	E. I. DuPont de Nemours and Company	professional use	<input checked="" type="checkbox"/>
Zone(s):	Interzonal	non professional use	<input type="checkbox"/>
Verified by MS:	n		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use No.	Member state(s)	Crop and/or situation (crop destination/purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method/ Kind	Application		Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
						Timing/ Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/season	L product/ ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	Interzonal	Tomato	G	Nematodes	Drip irrigation	a.1) Immediately after transplant a.2) Starting with BBCH 11 (10-14 days after transplant application). Up to 42 days after transplant.	a.1) 1 a.2) 1-3 b) 4	a.1) 10-20 a.2) 10 b) 40-50	a.1) 1- 2 a.2) 1 b) 4-5	n.a.	a.1) n.a. a.2) 28	Apply up to 2 kg as/ha immediately after transplant. Followed by up to 3 appl. of 1 kg as/ha each starting with BBCH 11 (10-14 days after transplant application), up to 42 days after transplanting
2	Interzonal	Solarization: Soil bed preparation in greenhouses designated for the growing of: Tomato, Cucurbits (edible and inedible peel), Pepper, Aubergine, and plants nurseries of the above mentioned crops	G	Nematodes	Drip irrigation with transparent plastic foil covering soil	Before transplant on bare soil (June-September)	a) 1 b) 1	a) 55 b) 55	a) 5.5 b) 5.5	-	n.a.	Plant Back Interval (PBI) = 30days Application to bare soil covered with plastic foil to control soil nematodes before transplant

B.3.4 Application rate and concentration of the active substance

Application rate

The maximum recommended dose rate is shown in Table 2.

Table 2 Maximum recommended dose rates of Oxamyl 10SL—Representative uses

Crop	Application			Application rate		
	Method/ kind	Timing/ growth stage of crop and season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product/ ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Remarks
Tomato	Drip irrigation	a.1) Immediately after transplant a.2) Starting with BBCH 11 (10 to 14 days after transplant application). Up to 42 days after transplant.	a.1) 1 a.2) 1-3 b) 4	a.1) 10–20 a.2) 10 b) 40–50	a.1) 1–2 a.2) 1 b) 4–5	Apply up to 2 kg a.s./ha immediately after transplant. Followed by up to three appl. of 1 kg a.s./ha each starting with BBCH 11 (10 to 14 days after transplant application), up to 42 days after transplanting
Solarization ^a	Drip irrigation ^b	Before transplant on bare soil (June– September)	a) 1 b) 1	a) 55 b) 55	a) 5.5 b) 5.5	Plant Back Interval (PBI) = 30 days Application to bare soil covered with plastic foil to control soil nematodes before transplant

^a Soil bed preparation in greenhouses designated for the growing of: tomato, cucurbits (edible and inedible peel), pepper, aubergine, and plants nurseries of the above mentioned crops

^b With transparent plastic foil covering soil

“Start the irrigation by applying water and nutrients only when the soil or substrate has reached adequate soil moisture add oxamyl 10SL to the irrigation system”
Soil is brought to field capacity (~50000L/ha). Oxamyl is applied at approximately 50% of the irrigation cycle. No further irrigation is typically needed.

B.3.5 Method of application

Oxamyl 10SL is applied to the soil *via* drip irrigation (see details above in Table 2), before transplant (solarisation use); or in the case of tomato, immediately after transplant, or starting with BBCH 11 (10–14 days after transplant application).

B.3.6 Number and timing of applications and duration of protection

Maximum number of applications and their timing

On tomato, Oxamyl 10SL is intended to be applied once immediately after transplant; followed by up to three applications each starting with BBCH 11 (10–14 days after transplant application), up to 42 days after transplanting.

For the solarisation use, Oxamyl 10SL is applied once before transplant on bare soil (approximately between June and September).

For each application, development stage of the harmful organisms concerned

After application of Oxamyl 10SL, the enzyme inhibition results in paralysis of the nematode (nematostatic activity) when applied at the recommended dose rate for the crop, preventing feeding, and disrupting the nematode life cycle. Oxamyl also inhibits egg or cyst hatch in many nematode species.

Duration of protection afforded by the maximum number of applications

A single or split application is recommended (see Table 2).

B.3.7 Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

30 days following protected crops. (as illustrated in Oxamyl RAR vol 3. (AS) B7).

Limitations on choice of succeeding crops

There are no limitations on the crops that can be grown following a crop treated with Oxamyl 10SL.

Description of damage to rotational crops

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

B.3.8 Proposed instructions for use

A European label proposal is included in the Oxamyl EU Renewal Dossier, Document C, DuPont-40925 EU.

B.3.9 Effectiveness

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

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

The active substance oxamyl was introduced by E. I. DuPont de Nemours and Company as a broad-spectrum insecticide and nematocide in 1974.

Oxamyl contained in Oxamyl 10GR was first authorized in Europe (Belgium) in 1975 on cucumber, tomato, and potato. Oxamyl has subsequently been developed for use in a wide range of field and greenhouse grown crops and is currently registered in a large number of European countries including: BE, BG, CY, CZ, ES, F, GR, HR, IE, IT, MT, NL, PL, PT, RO, SL, and UK. The liquid formulation Oxamyl 10SL was first registered in Portugal and Romania in 1975. Current Oxamyl 10SL product registrations are mainly in greenhouse grown fruiting vegetable crops. Oxamyl 10SL registrations exist in BG, CY, ES, GR, HR, IT, MT, PT and RO. DuPont is currently the unique owner of Oxamyl.

Current in FR a product based on 100g/kg is registered at maximum dose rate of 20 kg/ha on potato (twice the present claimed dose rate) and at maximum dose rate of 15 kg/ha on tobacco (half the present claimed dose rate).

Current EU oxamyl containing product registrations are based on three formulations:

- 50 g/kg dry granule (GR);
- 100 g/kg dry granule (GR); and
- 100 g/L soluble concentrate (SL)

Considering that the substance is approved and authorizations of plant protection products containing the substance have already been evaluated according to the uniform Principles (regulation (EC) No 546/2011), no other efficacy documentation is deemed to be necessary at this stage. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

B.3.10 Information on the development of resistance

Oxamyl is classified as an IRAC Group 1A Nematicide and Insecticide (acetylcholine esterase inhibitor). For more information please visit the Insecticide Resistance Action Committee (IRAC) on the web at <http://www.irac-online.org>. Based on historical use data, it is expected that the risk of development of resistance in plant parasitic nematodes is low.

B.3.11 Adverse effects on treated crops

In line with SANCO 10387/2010/rev8 of October 28 2010, for substances already evaluated according to the Uniform Principles of Annex VI of Directive 91/414/EEC, no other efficacy documentation beyond the one provided is deemed to be necessary at this stage.

B.3.12 Observations on other undesirable or unintended side-effects

In line with SANCO 10387/2010/rev8 of October 28 2010, for substances already evaluated according to the Uniform Principles of Annex VI of Directive 91/414/EEC, no other efficacy documentation beyond the one provided is deemed to be necessary at this stage.

B.3.13 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.

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Owner
B.3/01	Flier, W.	2015	Summary of efficacy data of the plant protection products: Oxamyl 10GR (100 g/kg), granular formulation, Oxamyl 10SL (100 g/L), soluble liquid formulation, Active substance: Oxamyl, efficacy information, supplemental submission in support of renewal E. I. DuPont de Nemours and Company DuPont-42980 EU GLP: No Published: No	N	N	DuPont