

*European Commission*

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



**Oxamyl 10GR**

**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

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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.3/01**

<b>Reference:</b> <b>CP 3.0/01</b>	<b>Report</b>	<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><b>DuPont Report No.:</b> DuPont-42980 EU</p> <p><b>Guidelines:</b> Not applicable <b>Deviations:</b> Not applicable</p> <p><b>Testing Facility:</b> E. I. DuPont de Nemours and Company, Dordrecht, The Netherlands</p> <p><b>Testing Facility Report No.:</b> DuPont-42980 EU</p> <p><b>GLP:</b> No</p> <p><b>Certifying Authority:</b> Not applicable</p>
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**Information pertinent to Points CP 3.1 through CP 3.6 are summarised in this report.**

#### **B.3.1 Field of use envisaged**

Oxamyl 10GR is to be used in agricultural situations and under field conditions only.

#### **B.3.2 Effects on harmful organisms**

Oxamyl 10GR 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 potato, Oxamyl 10GR is intended to be applied once at planting (BBCH 00). The maximum intended application rate is 1 kg a.s./ha.

On tobacco, Oxamyl 10GR is intended to be applied once at transplanting (BBCH 00) with a maximum application rate of 3 kg a.s./ha. Also, on tobacco, one application at pre-planting stage (BBCH 00) of the product evenly soil incorporated to a depth of 5–10 cm at a maximum application rate of 5.5 kg a.s./ha.

Soil is brought to field capacity (~50000L/ha). Oxamyl is applied at approximately 50% of the irrigation cycle. No further irrigation is typically needed.

The GAP table of the representative uses is presented in Table 1.

**Table 1 Representative Good Agricultural Practice (GAP) for Oxamyl 10GR—Representative uses**

PPP (product name/code)	Oxamyl 10GR (Vydate® 10G)	Formulation type:	GR
active substance 1	Oxamyl (DPX-D1410)	Conc. of as 1:	100 g/kg
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):	Southern and Central Zones	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)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method/ Kind	Timing/ Growth stage of crop & 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	Water L/ha min/max		
1	Central Zone	Potato	F	Nematodes	In-furrow application/ Application to be made only with tractor mounted equipment	At planting (BBCH 00)	a) 1 b) 1	a) 10 b) 10	a) 1 b) 1	n.a.	90 days	
2	South Zone	Tobacco	F	Nematodes	In-furrow application/ Application to be made only with tractor mounted equipment	At trans-planting (BBCH 00)	a) 1 b) 1	a) 30 b) 30	a) 3 b) 3	n.a.	n.a.	
3	South Zone	Tobacco	F	Nematodes	Evenly soil incorporated to a depth of 10cm/  Application to be made only with tractor mounted equipment	Pre-planting (BBCH 00)	a) 1 b) 1	a) 42.5 - 55 b) 42.5 - 55	a) 4.25 - 5.5 b) 4.25 - 5.5	n.a.	n.a.	

### 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 10GR—Representative uses**

op	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	kg 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	Water L/ha min/max
Potato	In-furrow application/ Application to be made only with tractor mounted equipment	At planting  (BBCH 00)	a) 1  b) 1	a) 10  b) 10	a) 1  b) 1	n.a.
Tobacco	In-furrow application/ Application to be made only with tractor mounted equipment	At trans- planting  (BBCH 00)	a) 1  b) 1	a) 30  b) 30	a) 3  b) 3	n.a.
Tobacco	Evenly soil incorporated to a depth of 5–10 cm/ Application to be made only with tractor mounted equipment	Pre-planting  (BBCH 00)	a) 1  b) 1	a) 42.5–55  b) 42.5–55	a) 4.25–5.5  b) 4.25–5.5	n.a.

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 10GR is applied to the soil with tractor-mounted equipment in a broadcast or in-furrow pattern, followed by soil incorporation when crops are planted or transplanted.

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

#### **Maximum number of applications and their timing**

On potato, Oxamyl 10GR is intended to be applied once in-furrow at planting stage (BBCH 00).

On tobacco, Oxamyl 10GR is intended to be applied once *via* in-furrow application at transplanting stage (BBCH 00). Also, on tobacco, at pre-planting stage (BBCH 00), one application of the product evenly soil incorporated to a depth of 5–10 cm is recommended.

#### **For each application, development stage of the harmful organisms concerned**

After application of Oxamyl 10GR, 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 application is recommended in all crops (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**

All rotational crops may be planted 120 days after last application on potato and tobacco.

#### **Limitations on choice of succeeding crops**

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

#### **Description of damage to rotational crops**

No crop damage due to the use of Oxamyl 10GR 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 10GR is applied to the soil in a broadcast or in-furrow pattern, followed by soil incorporation when crops are planted or transplanted. Oxamyl 10SL is applied *via* drip irrigation in fruiting vegetables. Both products contain 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.

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).



Oxamyl 10GR is applied to the soil with tractor-mounted equipment in a broadcast or in-furrow pattern, followed by soil incorporation when crops are planted or transplanted.

Oxamyl 10GR is intended to be applied once at planting (BBCH 00) on potato. The maximum intended application rate is 1 kg a.s./ha for in furrow application. On tobacco, Oxamyl 10GR is intended to be applied once at transplanting (BBCH 00) with a maximum application rate of 3 kg a.s./ha as in furrow application. Also, on tobacco, one application at pre-planting stage (BBCH 00) of the product evenly soil incorporated to a depth of 5–10 cm at a maximum application rate of 5.5 kg a.s./ha.

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.

No evidence of resistance to the studied nematodes is pointed out on the web site <http://www.pesticideresistance.org>

#### **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.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Owner</b>
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