European Commission

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

ZOXAMIDE

Volume 3 – B.3 (PPP) – ZOXIUM 240 SC

Rapporter Member State: Latvia
Co-Rapporter Member State: France

Version History

When	What
July 2016	Initial RAR

Table of contents

B.3. DATA ON APPLICATION AND EFFICACY

B.3.1. FIELD OF USE ENVISAGED

Agriculture and viniculture.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

ZOXIUM 240 SC is a fungicide belonging to the chemical family of benzamides. It is a non-systemic active ingredient, acting by inhibition of cell division, used to control Oomycete fungi infecting potatoes, table grapes and wine grapes. Zoxamide inhibits germ tube development and mycelium growth by inhibiting cell division. Germ tube elongation and mycelium growth is arrested concomitant with the first cycle of nuclear division, preventing fungal penetration of the host plant.

B.3.3. DETAILS OF INTENDED USE

Historic of use of zoxamide in PPP

Zoxamide is currently registered in different products, used mainly on potatoes, tomatoes and grapes. Overview of current registrations (with Electis, Unicat Pro, etc) is reported in table 3.3.1.

Table 3.3.1. Registered uses of zoxamide.

Country	**Since**	**Reg. No.**	**Product**	**Crop(s)**	**Maximum individual dose** g/ a.s./ha	**Maximum number of treatments**
Austria	28/11/2006	2882	Electis	Potatoes Vines	150 240	3 4
Belgium	16/05/2001	9258P/B	Unikat Pro	Vines, Potatoes, Tabac, Ornamentals	83 150 166 15 g/L	2 10 3 1
Bulgaria	4/02/2009	583	Electis 75WG	Vines.	150	Not available
Croatia						
Cyprus	25/05/2009	2457	Electis 75WG	Vines, Potatoes	150	Not Available
Czech Republic	21/09/2011	4470-9	Unikat Pro	Potato Grape,	150	3 3
Denmark	28/01/2011	572-2	Electis	Potato	150	10
Estonia	24/11/2010	249	Electis	Potato	150	8
Finland	18/02/2003	1,964	Electis	Potato	150	
France	--/--/2002	2020110	Electis Pro	Grape	123	3
France	12/06/2002	2000294	Roxam Combi	Grape	123	3
France	--/--/2002	2020110	Unikat	Grape	123	3
France	11/08/2002	2000338	Aderio	Potato	150	4
France	04/04/2003	2030147	Ozys,	Potato	150	4
France	11/08/2002	2000338	Gavel	Potato	150	4
Germany	16/04/2004	4957	Electis	Potatoes Vines	150 239	3 4

Country	**Since**	**Reg. No.**	**Product**	**Crop(s)**	**Maximum individual dose** g/ a.s./ha	**Maximum number of treatments**
Greece	29/07/2010	60284	Electis 750WG	Vines. Potatoes. Tomatoes	150	4 3 3
Hungary	2/05/2010	04.2/2924-2/2012 NÉBIH	Roxam 75 WG	Grape Potato Tomato	150 150 124	4 8 2
Hungary	15/11/2001	04.2/2771-1/2012 NÉBIH	Electis 75 WG	Grape Potato Tomato	150 150 124	4 8 2
Ireland	21/03/2003	PCS 01821	Electis 75WG	Potato (seed) Potato (ware)	180	10
Italy	18/10/2007	12827	Electis R	Grapes	150	5
Italy	30/04/2009	14546	Premier R	Grapes Tomatoes	150	5
Italy	27/08/2009	14348	Agron	Grapes Tomatoes	150	5
Italy	18/10/2007	12202	Zemix R	Grapes Tomatoes	150	5
Italy	15/10/2009	14803	Electis ZR	Grapes Tomatoes	150	5
Italy	28/01/2014	15744	Reboot	Tomato, Eggplant Potato Grape (table and wine)	150	3
Italy	25/02/2011	14510	Electis Trio	Grapes	180	5
Italy	22/03/2005	12564	Electis MZ	Grapes Potatoes Tomatoes	166 166 166	5
Italy	22/03/2005	14545	Premier MZ	Grapes Potatoes Tomatoes	166 166 166	5
Italy	14/06/2012	14419	Zoram	Grapes	85	3
Italy	10/05/2012	14062	Zoxium	Grapes Tomatoes Potatoes	180	5
Italy	14/06/2012	15188	Astro	Grapes Tomatoes Potatoes	180	5
Italy	08/10/2012	15572	Zominex	Grapes Tomatoes Potatoes	180	5
Latvia	04/05/2001	0179	Elektis 75 dg.	Potato	150	8
Lithuania	11/12/2001	0206/09	Electis 75 WG	Potato	150	8
Luxemb-urg	02/04/2004	1607-117	Electis Pro	Grape Potato Tabac	166 150 166	3
Malta						
Nether-lands	27/01/2006	12783	Uniakat Pro	Potato	150	-
Poland						

Country	**Since**	**Reg. No.**	**Product**	**Crop(s)**	**Maximum individual dose** g/ a.s./ha	**Maximum number of treatments**
Portugal	05/03/2004 (by Dow); 04/06/2009 (by Gowan)	3565	Aderio	Potato and grapevine (table and for vinification)	180	3
Romania	11/04/2011	2102	Electis 75WG Fungicide (GF-GWN-1045)	Tomatoes, Potatoes, Cucumbers. Grapevines,	150	3
Slovakia						
Slovenia	5/5/2009	327-02-304/2003/15	Electis 75WG	Vines Potatoes	150	Not available
Spain	05/11/2013	ES-00007	Electis CX	Tomato, Eggplant Potato	150	3
Spain	05/25/05	23055	Electis	Potato Grapevine	166 150	3 2
Sweden						
UK	04/26/2012	MAPP 14200	Unikat 75WG	Potato Wine grapes	150	8 4
UK	03/30/2012	MAPP 14195	Electis 75WG	Potato Wine grapes	150	8 4
UK	04/26/2012	MAPP 14191	Roxam 75WG	Potato Wine grapes	150	8 4

ZOXIUM 240 SC (zoxamid, 240 g/l)

Uses supported for the renewal of authorisation of zoxamide are: potatoes and grapes.

Table 3.3-2 Summary of the representative uses of Zoxium 240 SC

Crop Zone	**Pests or Group of pests controlled**	**Application**				**Application rate per treatment**		**PHI** days
		method kind	growth stage & season	number min max	interval between applications (min)	water l/ha min max	kg as/ha min max	
Potato All zones	Foliar fungi Late blight	Foliar spraying	BBCH 20-80	Max. 5	8 days	1000	0.15 – 0.18	7
Table and wine grapes Central and Southern EU	Foliar fungi Downy mildew	Foliar spraying	BBCH 15-79	Max.5	8 days	1000	0.15 – 0.18	28

Table 1. ZOXIUM 240 SC: Details of harmful organisms against which protection is afforded

Crop	**Crop code**	**Disease / Organism**	**Disease / Organism code**
Potato	SOLTU	Late blight (*Phytophthora infestans*)	PHYTIN
Grapes	S	Downy mildew *(Plasmopara viticola)*	

Table 2. Good agricultural practices (GAP)

ZOXIUM 240 SC: CRITICAL USES – JUSTIFICATION AND GAP TABLES

PPP (product name/code)	**Zoxium 240 SC**	**Formulation type:**	**Soluble concentrate (SC)**
active substance 1	**Zoxamide**	**Conc. of as 1:**	**240 g/L**
active substance 2	**Not applicable**	**Conc. of as 2:**	**Not applicable**
safener	**None**	**Conc. of safener:**	**Not applicable**
synergist	**None**	**Conc. of synergist:**	**Not applicable**
Applicant:	**Gowan Comércio Internacional e Servicos Ltd**	**professional use**	☒
		non professional use	☐
Zone(s):	**All zones as indicated below**		

Verified by MS: j/n

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Zone(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)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	Central South	Wine grapes	F	grape downy mildew *Plasmopara viticola*	3-d broadcast with mist blower	BBCH 15-79	5 (8)	a) 0.75 b) 3.75	a) 180 b) 900	1000	28	Maximum 3 consecutive applications of PPP's containing zoxamide. Always apply product in mix with downy mildewcides having different target site and mode of Action
2	Central South	Table grapes	F	grape downy mildew *Plasmopara viticola*	3-d broadcast with mist blower	BBCH 15-79	5 (8)	a) 0.75 b) 3.75	a) 180 b) 900	1000	28	
3	North, Central South	Potato	F	potato late blight *Phytophtora infestans* Mont. De Bary	broadcast with spray boom	BBCH 20-80	5 (8)	a) 0.75 b) 3.75	a) 180 b) 900	1000	7	

B.3.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

Application rate

For both potatoes and grapevines the application rate is 0.15 – 0.18 kg zoxamide per hectare equivalent to 0.625 - 0.75 L Zoxium 240 SC / ha.

Concentration of active substance in applied spray

For both potatoes and grapevines, the product is applied in 1000 L water/ ha. The concentration of zoxamide in the applied spray is 0.15 – 0.18 g/L.

B.3.5. METHOD OF APPLICATION

Method of application:	Foliar spray application
Type of equipment used:	Potato: tractor mounted or drawn boom sprayer. Grapes: orchard/vineyard sprayer.
Volume of diluent per unit of area or volume:	Potato, grapes: 1000 L/ha

B.3.6. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION

Maximum number of applications and their timings:

Wine and table grapes

Up to 5 applications of Zoxium 240 SC can be made to a crop. The minimum spray interval is 8 days and no more than 3 consecutive applications can be made.

Potatoes

Up to 5 applications of Zoxium 240 SC can be made to a crop. The minimum spray interval is 8 days and no more than 3 consecutive applications can be made.

Growth stages of crops or plants to be protected:

Wine and table grapes

Applications of Zoxium 240 SC can be made from growth stage BBCH 15 (5 leaves unfolded) up to growth stage BBCH 79 (Majority of berries touching).

Potatoes

Applications of Zoxium 20 SC can be made from growth stage BBCH 20 (beginning of Principal growth stage 2) up to growth stage BBCH 80 (beginning of Principal growth stage 8).

Development stages of the harmful organism concerned:

Zoxium 240 SC should be applied as a preventative treatment before disease has established.

Duration of protection afforded by each application:

Duration of protection from a single fungicide application is dependent on disease pressure, the crop and prevailing environmental conditions. The last parameter is of particular significance when considering a molecule such as zoxamide. Zoxamide is initially sprayed on the leaf surface but it is highly lipophilic and has an affinity for leaf waxes. The majority of the zoxamide quickly moves to the epidermal leaf wax layer. It is

resistant to removal by rain or irrigation as it locks into the leaf waxes. Zoxamide has been found to be rain fast with in 1 hour after application to potato leaves. When used in accordance with label directions, Zoxium 240 SC offers 7 – 10 days protection, longer if disease pressure is low.

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:

The potential for adverse effects to exposed non-target plant species is negligible. No pre- or post emergent herbicidal activity was observed in a variety of broadleaf and grassy weeds and importantly, a wide variety of crops exposed to Zoxium 240 SC at rates up to 500 g as/ha (3.3 x the maximum application rate). Zoxamide is a protectant fungicide with no persistence issues and a very short half life in soil. No waiting periods or other precautions are necessary to avoid phytotoxic effects on succeeding crops.

Limitations on choice of succeeding crops:

None

B.3.8. PROPOSED INSTRUCTIONS FOR USE

Instructions for use are already reported on the label provided and are in accordance with the information provided in the GAP table:

- The product should be applied before disease attack (preventive applications),

"Start treatment when conditions are favorable for development of the disease and continue at intervals 8-10 days, using shorter intervals and larger doses in more favorable environmental conditions for development of the disease".

- Advices for resistance management are proposed (for more details, see in B 3.10).

"RESISTANCE MANAGEMENT:
Do not apply this or any other products containing zoxamide more than 5 times in a season and more than 3 consecutive times.
To avoid the occurrence of resistance always use the product at the recommended dose and mixed with fungicides with different modes of action".

B.3.9. EFFECTIVENESS

The active ingredient acts against fungus from the class of Oomycetes, especially against downy mildews (e.g. *Phytophtora infestans*). It works protective and needs to be applied before the disease attack.
Depending on the disease pressure, a good protection against the disease can be expected over a period of 7 to 10 days. The product will be used as a contact fungicide with the first application to be made when warning systems forecast significant disease attack situations.

B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

Zoxamide belongs to the chemical family of benzamides and works by disrupting mitosis and cell division (FRAC target site B3[1]) through inhibition of β-tubulin assembly (FRAC code 22[2]) and has specific biological activity on the oomycetes group of microorganisms, which include the proposed targets *Plasmopara viticola* and *Phytophtora infestans.* The Fungicide Resistance Action Committee (FRAC) considers that there is a low to medium risk of resistance developing and that resistance management is required for this group of chemistry. FRAC also consider that *Plasmopara viticola* and *Phytophtora infestans* are of high and medium risk

[1] http://www.frac.info/publication/anhang/FRAC%20Code%20List%202013-update%20April-2013.pdf
[2] http://www.frac.info/publication/anhang/FRAC%20Code%20List%202013-update%20April-2013.pdf

respectively of developing resistance to this chemistry[3]. The combined fungicide-pathogen risk is therefore considered to be medium.

For the first inclusion of zoxamide in Annex I to Directive 91/414/EEC, baseline responses of *Phytophtora infestans* to zoxamide were established which showed that the variation in sensitivity of naturally occurring and laboratory isolates was similar. **Note:** Although the potential for *Plasmopara viticola* to develop resistance to zoxamide was investigated, *Phytophtora infestans* was chosen to assess the possibility of fungicide resistance as it was considered to possess key attributes for the rapid development of resistance.

There was no indication of any cross-resistance between phenylamide resistance and sensitivity to zoxamide. In addition, no cross-resistance was found to other commonly used benzimidazoles which have a similar mode of action to zoxamide.

The *Phytophtora infestans* sensitivity study and lack of success at producing zoxamide cross-resistant strains in laboratory mutagenesis studies with *Phytophtora infestans*, suggest the risk of resistance development to zoxamide is low. However, it is considered that the disease has a high resistance risk because of its history, the life cycle of the disease and the large number of applications made to the crop.

As of January 2013, FRAC have stated that no resistance to zoxamide has been reported for any pathogen[4].

In light of the potential risk of resistance developing and to ensure the continued effectiveness of this active substance, the following risk management strategy is in place:

1. A limited number of repeated applications on the crop;
2. A program of disease management based on co-formulation with active substances with different modes of action and product alternation.
3. A respect of recommended product dose rate, timing and spray interval.
4. A rigorous program of stewardship

B.3.11. ADVERSE EFFECTS ON TREATED CROPS

The applicant informs that no adverse effects on treated crops have been observed.
Zoxamide based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

B.3.12. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

The applicant informs that no undesirable or unintended side-effects have ever been reported or observed.
Zoxamide based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

B.3.13. REFERENCES RELIED ON

None.

[3] http://www.frac.info/publication/anhang/FRAC_Pathogen_risk%20list.pdf
[4] http://www.frac.info/publication/anhang/List%20of%20resistant%20plant%20pathogenic%20organisms_February%202013%20updated.pdf