BioAct WG, 1 X 10^{10} spores/gram (60 g/kg)

of *Purpureocillium lilacinum (syn. Paecilomyces lilacinus)* 251

Microbial pest control product against plant parasitic nematodes

Dossier according to OECD guidance for industry data submissions for microbial pest control products and their microbial pest control agents – August 2006

Summary documentation, Tier II

Annex IIIM, Section 6

Point IIIM 11: Summary and evaluation of environmental impact

Date: January 2016

Applicant

Bayer CropScience AG

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OWNERSHIP STATEMENT

Introduction

The company Bayer CropScience AG is submitting a dossier for the re-approval of the microorganism *Purpureocillium lilacinum* 251 as an active substance under regulation (EC) 1107/2009.

The Microbial Pest Control Agent *Paecilomyces lilacinus* strain 251 was included into Annex I of Directive 91/414/EEC on 01/08/2008 (Commission Directive 2008/44/EC) and then approved according to the Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, implementing Regulation (EC) No 1107/2009 of the European Parliament [1]. *P. lilacinus* strain 251 was notified and defended by Prophyta GmbH. The active ingredient has been evaluated in Belgium according to Uniform Principles. The representative formulated product for the initial evaluation was the experimental formulation PBP-01001-I, containing 2×10^9 spores/g. PBP-01001-I, is comparable to the commercial formulation BioAct WG, containing 1×10^{10} spores/g, and the only changes between both formulations were slight adjustments of the content of two co-formulants, without any impact on the performance or physical properties of the formulated product. The recommended rate in terms of spores per hectare remained exactly the same. The data on PBP-01001-I can therefore be extrapolated to the formulated product BioAct WG, a wettable granule formulation (WG), the representative formulation in the present application for the renewal.

In 2013 Bayer CropScience AG acquired Prophyta Biologischer Pflanzenschutz GmbH, now named Bayer CropScience Biologics GmbH. Bayer CropScience AG is the notifier for the renewal of *P. lilacinus* strain 251 in the procedure of AIR 3.

The microorganism has been previously classified as *Paecilomyces lilacinus* until 18S rRNA gene, internal transcribed spacer (ITS) and partial translation elongation factor 1-α (TEF) sequencing revealed that *P. lilacinus* is not related to *Paecilomyces.* The new genus name *Purpureocillium* has been proposed for *P. lilacinus* and the new species name was assigned: *Purpureocillium lilacinum.* Therefore the strain is now identified as *Purpureocillium lilacinum*. In this dossier *Paecilomyces lilacinus* 251 and *Purpureocillium lilacinum* 251 are used as synonyms: *Paecilomyces lilacinus = Purpureocillium lilacinum*.

It has to be taken into account that data on *Paecilomyces lilacinus* from the open literature stated before 2011 may not necessarily provide reliable information due to insufficient classification methods used in these studies, especially, if the strain identification is not provided and/or identification methods used were based solely on morphological characteristics. However, they may provide relevant information transferrable to *Purpureocillium lilacinum*.

Purpureocillium lilacinum 251 is a ubiquitous, saprobic filamentous fungus commonly isolated from soil, decaying vegetation, insects and nematodes. Strains of *P. lilacinum* are used in plant protection products due to their nematicide activity. The mode of action against plant pathogenic nematodes of *P. lilacinum* strain 251 is principally based upon parasitism of nematode eggs as well as the vermiform stages of the nematodes, leading eventually to their death. With regard to the results of toxicity and ecotoxicity studies of the active substance *P. lilacinum* strain 251, it can be concluded that *P. lilacinum* strain 251 shows no risk for exposed humans, animals and environment.

P. lilacinum 251 is intended to be used in plant protection products to control plant pathogenic nematodes. The representative use presented in this dossier comprises applications of the formulation BioAct WG in protected and non-protected vegetable crops to control root know nematode, *Meloidogyne* spp.

Here we submit data that were previously evaluated by RMS Belgium as well as new data and information based on literature searches and studies.

A summary of the GAP table is presented in **Table IIIM 10-1** below.

[1] OJEU L94/13 Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole as active substances

Table IIIM 6-1 Summary of critical Good Agricultural Practice for BioAct WG

Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled	Application			Application rate			PHI (days)
			Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications)	kg as/hL min max	water L/ha min max	kg as/ha min max	
Vegetables (tomatoes, cucurbits), soil decontamination against *Meloidogyne*	F/G	*Meloidogyne* spp.	1st application: Drip irrigation or Soil drench or Mechnical incorpo-ration	Pre-transplant	1	0.012 - 0.24 (4×10^{12} - 2×10^{13} spores/hL)	200 - 1,000	0.24 kg /ha (4×10^{13} spores/ha) 4 kg product/ ha	0
			Dipping (of seedlings) Drip irrigation or Soil drench	At transplant	1	0.006 - 0.24 (2×10^{12} - 2×10^{13} spores/hL)	200 - 1,000	0.12 - 0.24 kg /ha (4×10^{13} spores/ha) 4 kg product/ ha	0
			Drip irrigation or Soil drench	Post-transplant	4 (4-6 weeks)	0.012 - 0.24 (4×10^{12} - 2×10^{13} spores/hL)	200 - 1,000	0.24 kg /ha (4×10^{13} spores/ha) 4 kg product/ ha	0

Please note:
As worst case, the maximum number of six applications is considered for the risk assessment within the frame of the risk envelope approach.

IIIM 11 Summary and evaluation of environmental impact

IIIM 11.1 Distribution and fate of MPCP

In order to perform a risk assessment for non-target organisms the actual concentration of BioAct WG is calculated for soil, based on the single and the maximum application rate of 24 kg/ha, the latter being considered as worst case. For risk assessment the resultant load of active substance will be related to the top 5 cm of soil to achieve the highest theoretical soil concentration, although in practise incorporation will be performed within the top 10 to 15 cm of soil.

Based on the available data no significant accumulation of the fungus after repeated application to soil is anticipated.

To demonstrate what level of PEC_{soil} could theoretically result from the max. of applications possible, the calculation for this unrealistic case is also provided.

Assumptions:

- Single application of BioAct WG: 4 kg product/ha (= 240 g a.s./ha, equivalent to 4×10^{13} CFU/ha)
- The worst case assumption that a max. of six applications would accumulate: 24 kg product/ha (= 1.44 kg a.s./ha, equivalent to 24×10^{13} CFU/ha)
- Incorporation into the top 5 cm layer (= 50 L soil/ m^2)
- Soil density of 1.5 g/ cm^3 (= 75 kg soil/ m2)
- No plant interception due to direct incorporation into the soil by drip or drench irrigation

A summary of PEC_{Soil} calculation is presented in **Table IIIM 11.1-1**.

The calculation was based on the accumulated field rate of BioAct WG in vegetables, with a maximum of 6 applications.

Table IIIM 11.1-1 Summary of PEC_{Soil} calculations

Critical use	Vegetables, maximum of six applications with 4 kg BioAct WG/ha each
Single application rate	4 kg BioAct WG/ha, 240 g *P. lilacinum* 251/ha, 4×10^{13} CFU/ha
Accumulated application rate	24 kg BioAct WG/ha, 1.44 kg *P. lilacinum* 251/ha, 24×10^{13} CFU/ha
Soil density	1.5 g/ cm^3 (= 75 kg soil/ m^2)
Incorporation depth	5 cm layer (= 50 L soil/m^2)
Plant interception	No plant interception
Realistic PEC_{Soil}	5.33 mg BioAct WG/kg dry weight soil, 0.32 mg *P. lilacinum* 251/kg dry weight soil, 5.3×10^7 CFU/kg dry weight soil
Unrealistic worst case PEC_{Soil} (all applications accumulated)	32 mg BioAct WG/kg dry weight soil, 1.92 mg *P. lilacinum* 251/kg dry weight soil, 32×10^7 CFU/kg dry weight soil

Fate and behaviour in water

Water is not the natural habitat of the soil-born fungus *P. lilacinum*. Spores will be subject to sedimentation, and may persist for some time, but will not find conditions favourable for germination or growth. For more information please refer to Point IIM 7.1.2.

Predicted environmental concentrations in natural waters

Following Good Agricultural Practice (see Doc. D-1) *P. lilacinum* 251 will be applied directly onto the soil surface by soil irrigation (drip or drench) or by tray drench/dipping following watering to assure full incorporation into the soil. Spray drift can be excluded and further, no run-off is expected as the application intends full incorporation of *P. lilacinum* 251 into soil. Therefore, exposure to surface water can be excluded.

IIIM 11.2 Identification of non-target species at risk and extent of their exposure

According to the presented risk assessment, the use of BioAct WG at the proposed label rates according to good agricultural practice poses no risk to any of the non-target species. Please refer to Point IIIM 10 and the data presented in Annex II, Doc IIIM, Section 6.

IIIM 11.3 Identification of precautions necessary to minimize environmental contamination and to protect non-target species

The risk assessment proves that BioAct WG is not toxic to the tested aquatic and terrestrial species, and considering the expected environmental concentration will not be hazardous to natural populations upon applications according to Good Agricultural Practice. No hazard classification or specific labelling according to EC Directive 1107/2009 is required for BioAct WG.

References

No references are cited in this section.