

***Purpureocillium lilacinum* 251**  
**Microbial pest control agent 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 IIM, Section 6**

**Point IIM 9: Summary and evaluation of environmental impact**

Date: January 2016

**Applicant**

**Bayer CropScience AG**



M-544187-01-3

*This document is the property of Bayer AG and/or any of its affiliated companies. It may be subject to rights of the owner and third parties. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution and use of this document or its contents without the permission of the owner of this document may therefore be prohibited and violate the rights of its owner.*

**Table of contents**

Introduction ..... Fehler! Textmarke nicht definiert.

IIM 9 Summary and evaluation of environmental impact .....5

IIM 9.1 Distribution and fate of MPCA .....5

IIM 9.2 Identification of non-target species at risk and extent of their exposure .....5

IIM 9.3 Identification of precautions necessary to minimize environmental contamination and to protect non-target species .....6

References.....6

*This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and third parties. Furthermore, this document may fall under a regulatory data protection regime and consequently, any publication, distribution, reproduction and/or publishing and any commercial exploitation, distribution, reproduction and/or publishing and without the permission of the owner of this document may therefore be prohibited and violate the rights of its owner.*

## OWNERSHIP STATEMENT

This document, the data contained in it and copyright therein are owned by Bayer CropScience. No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Bayer CropScience.

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and copy rights of the owner and third parties. Furthermore, this document may fall under a regulatory data protection regime and consequently, any publication, distribution, reproduction and/or publishing and any commercial exploitation, distribution, reproduction and/or publishing and without the permission of the owner of this document or its contents be prohibited and violate the rights of its owner.

## 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<sup>1</sup>. *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  $2 \times 10^9$  spores/g. PBP-01001-I, is comparable to the commercial formulation BioAct WG, containing  $1 \times 10^{10}$  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- $\alpha$  (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 transferable 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 knot 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.

<sup>1</sup> OJEU 2008/L13 Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiazalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole as active substances

## IIM 9 Summary and evaluation of environmental impact

### IIM 9.1 Distribution and fate of MPCA

#### Persistence and mobility in soil:

*P. lilacinum* strain 251 is a common soil saprophyte and soil is the original habitat of this fungus. Following application of *P. lilacinum* strain 251 to soil the number of viable cells or spores of *P. lilacinum* are expected to show a fast decline to very low percentages within a few weeks. However, depending on the prevailing environmental conditions of the relevant soil ecosystem, they may possibly approach a balance at a clearly lower population density compared to the initial concentration, in response to limiting abiotic and also counteracting biotic factors. On a long-term scale, without further applications of *P. lilacinum* strain 251, this saprophytic fungus may diminish completely, indicating the need for more than a single application to achieve nematode control. Therefore, since *P. lilacinum* strain 251 is naturally occurring in soil, neither an unlimited multiplication nor an accumulation is expected.

#### Persistence and mobility in water:

*P. lilacinum* strain 251 is a common soil saprophyte with ubiquitous distribution worldwide. Spores of this species may also be found and persist in natural waters, but will be subjected to sedimentation and does not find conditions favourable for germination and growth in this compartment.

#### Persistence and mobility in air:

Dispersal of spores via aerosols is not anticipated due to the nature of this preparation.

### IIM 9.2 Identification of non-target species at risk and extent of their exposure

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, with subsequent incorporation into the soil by watering. Therefore, exposure to birds, mammals, aquatic organisms, honey bees and leaf dwelling arthropods can be excluded. Nevertheless, exposure to soil dwelling organisms, earthworms and microorganisms is possible and a risk assessment was performed (see summary Table 9.2-1 below). The risk assessment states both, the TER related to the active substance on a weight basis and the relevant TER based on colony forming units, i.e. number of viable spores. The calculated TER exceeded the respective limit values for earthworms, collembolan and microorganisms indicating no risk for the intended field use.

Test organism	Test substance	NOEC	PEC <sub>Soil</sub>	TER	Trigger value	
<i>Folsomia candida</i>	BioAct WG	562 mg prod./kg d.w. soil	Single application: 5.33 mg product/kg d.w. soil	105	5	
			Multiple applications*: 32 mg/kg product/kg d.w. soil	17.6		
		6.8 x 10 <sup>9</sup> spores/kg d.w. soil	Single application: 5.3 x 10 <sup>7</sup> CFU/kg d.w. soil	105	5	
			Multiple applications*: 3.2 x 10 <sup>8</sup> CFU/kg d.w. soil	21.2		
<i>Eisenia fetida</i>	BioAct WG	≥400 mg prod./kg d.w. soil	Single application: 5.33 mg product/kg d.w. soil	≥75	5	
			Multiple applications*: 32 mg/kg product/kg d.w. soil	≥2.5		
		6 x 10 <sup>9</sup> spores/kg d.w. soil	Single application: 5.3 x 10 <sup>7</sup> CFU/kg d.w. soil	≥113	5	
			Multiple applications*: 3.2 x 10 <sup>8</sup> CFU/kg d.w. soil	≥18		
Soil micro-organisms	PBP-1001-r	60 kg prod./ha	Single application: 5.33 mg product/kg d.w. soil	≥15	1	
			Multiple applications*: 32 mg/kg product/kg d.w. soil	≥2.5		
		6.62 x 10 <sup>9</sup> spores/kg d.w. soil	Single application: 5.3 x 10 <sup>7</sup> CFU/kg d.w. soil	≥6.8		1
			Multiple applications*: 3.2 x 10 <sup>8</sup> CFU/kg d.w. soil	≥1.1		

Even in case 6 consecutive applications as described in the GAP for BioAct WG are applied, no significant accumulation is expected. To demonstrate that there is even no risk indicated under the unrealistic worst assumption that all six applications would completely accumulate, also a risk assessment for the six-fold PEC<sub>soil</sub> value is provided.

In conclusion, no hazard classification or specific labelling according to EC directive 67/548/EEC is required.

**IIM 9.3 Identification of precautions necessary to minimize environmental contamination and to protect non-target species**

The submitted study reports and the risk assessment prove that *P. lilacinum* strain 251 is non-toxic and considering the expected environmental concentration non-hazardous to the tested aquatic and terrestrial species. Therefore, no hazard classification or specific labelling is required.

**References**

No references are submitted in this dossier part.

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and copy rights of the owner and third parties. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction and/or publishing and any commercial exploitation, use of this document or its contents without the permission of the owner may therefore be prohibited and violate the rights of its owner.