

BioAct WG, 1×10^{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 5

Point IIIM 9: Fate and behaviour in the environment

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Applicant

Bayer CropScience AG



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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 Parliament¹. *P. lilacinus* strain 251 was notified and defended by Prophyta GmbH. The active ingredient has been evaluated in Belgium according to Uniform Principle. 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 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 transferable to *Purpureocillium lilacinum*.

Purpureocillium lilacinum 251 is a ubiquitous saprotrophic 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.

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 IIM 9-1 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 <i>Meloidogyne</i>	F/G	<i>Meloidogyne</i> spp.	1 st application: Drip irrigation or Soil drench or Mechanical incorporation	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	0.012 - 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
			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

BioAct WG is a biological nematicide for field and glasshouse use based on the soil born fungus *Purpureocillium lilacinum* strain 251. BioAct WG is to be applied immediately after mixing with water. In tomatoes and cucumbers BioAct WG has to be applied at least three times: as pre-planting, seedling and post-planting treatment. More applications may be necessary as post-planting treatments.

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It is referred to the information submitted for *P. lilacinum* in Doc M, Annex IIM, Section 5, Point 7. Apart from active spores, the preparation BioAct WG contains to >99 % of formulators of food-grade quality as carrier (see Doc. J), which will be metabolised by micro-organisms immediately. All ingredients degrade completely. As no impurities are present, no hazards to the environment are expected. Therefore, studies and information on the microbial pest control agent, *P. lilacinum* 251, are considered applicable and relevant with regard to the evaluation of the formulated product. Any specific studies on the preparation BioAct WG were not conducted. The predicted environmental concentrations in soil and water are stated in Doc. M, Annex IIM, Section 6, Point 11.

References

No references are cited in this section.

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