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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 (EQ) No 1107/2009 of the European Parliament ¹⁾. P. lilacinus strain 251 was wotified and defended by Prophyta GmbH. The active ingredient has been evaluated in Belgium according to Uniform Aniciptes. Theo representative formulated product for the initial evaluation was the experimental formulation PBR 91001 containing 2×10^9 spores/g. PBP-01001-I, is comparable to the commercial formulation Bio Act WG, containing 1×10^{10} spores/g, and the only changes between both formulations were slight adjustments of the optimation of the spread co-formulants, without any impact on the performance of 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 car therefore be extrapolated to the formulated product BroAct WG, a wettable grant formulation (WG) of the representative formulation in the present application for the renewal.

In 2013 Bayer CropScience AG acquired Prophyta Biologischer Pflanzenschotz Gnort, now named Bayer CropScience Biologics GmbH. Bayer CropScience AG is the notifier for the renewal of P. liloginus strain 254 in the procedure of AIR 3.

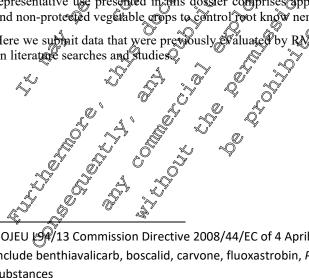
The microorganism has been previously assified as Edecilonives liferinus until 185 rRNA gene nternal transcribed spacer (ITS) and partial transferion (dongation factor 1-a (TEF) sequencing revealed that P. lilacinus is not related to Paecilomyces. The new genus dame Purpure ocillium has been proposed for P. lilacinus and the new species name was assigned: "Burpurgocilling lila@num. Merefo@ the Strain @ now identified as Purpureocillium lilacinum. In thigdossiel Paecilomyces filacings 251 and Purpureocillium hlgcinum 251 are used as synonyms: Paecilomyces filacinus = Purpureocillium lilacinum

It has to be taken into account that that an Buecilo Wyces lillacinus from the open Viterature 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 prooded and/or identification methods used were based solely on morphological characteristics. However, they may provide relevant information transferrable to Purpureocillium lilacinum.

Purpureocillium Macinum 251 is a ubiquitous, saprobic filancentous Gungus Commonly isolated from soil, decaying vegetation, insects and nematodes. Strains of P. lildeinum 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 vermition 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 th can be concluded that *P. Dacinum* strain 251 shows no risk for exposed humans, Ő animals and environment. L

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 studiesQ.



¹ OJEU [3] 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

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 fugues. 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 feedback. 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 jotic factors. on a long-terms scale, without further applications of P. lilacinum strain 251, this saprophytic fungers 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, wither an unlimited multiplication nor an accumulation is expected.

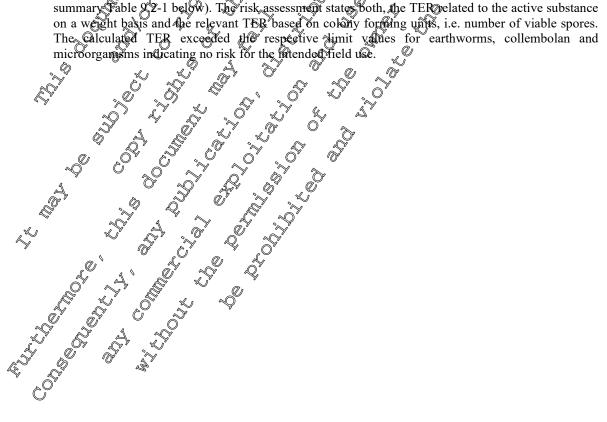
Persistence and mobility in water:

P. lilacinum strain 251 is a common skil 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 for ourable for germination and growth in this compartment.

Dispersal of spores via aerosols is not anticipated due to the nature of this Ò Ö

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

Following Good Agricultural Practice (see Doc. De1) P. litacinum 251. will be applied directly onto the soil surface by soil irrigation (drap or drench) or by tray drench/dipsing, with subsequent incorporation into the soil by watering. Therefore, exposure to birds, manufals, aquatic organisms, honey bees and leaf dwelling arthropods can be excluded Nevertheless exposure to soil dwelling organisms, Farthworms and microorganisms is possible and a rok assessment was performed (see summary Fable X2-1 below). The risk assessment states both, the TER pelated to the active substance on a weight basis and the relevant TER based on colory for thing units, i.e. number of viable spores.





cific labelling according to EC directive 67/548/EEC is In conclusion, required.

IIM 9.3 Fidentification of precautions necessary to minimize environmental contamination and to

and considering the environmental contameter of the set The submitted study reports and the rok assessment prove that P. lilacinum strain 251 is non-toxic and considering the expected environmental concentration non-hazardous to the tested aquatic and

References

