Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

***Pythium oligandrum* Strain M1**

Product type: 10

ECHA/BPC/30/2014

Adopted

2 December 2014

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance *Pythium oligandrum* Strain M1 for product type 10

In accordance with Article 90(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 10 of the following active substance:

Common name:	***Pythium oligandrum* Strain M1**
Chemical name(s):	**not applicable**
EC No.:	**not applicable**
CAS No.:	**not applicable**
New active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Biopreparáty s.r.o on 12 July 2005, the evaluating Competent Authority the Czech Republic submitted an assessment report and the conclusions of its evaluation to the Commission on 8 November 2011. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and the Commission via the Biocides Technical Meetings. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC Member for the Czech Republic.

The BPC opinion on the approval of the active substance *Pythium oligandrum* STRAIN M1 in product type 10 was adopted on 2 December 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the *Pythium oligandrum* STRAIN M1 in product type 10 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of *Pythium oligandrum* Strain M1 in product type 10. *Pythium oligandrum* Strain M1 acts by mycoparasitism mediated by intimate hyphal interactions and competition for space and nutrients. Specifications for the reference strain are established. *Pythium oligandrum* Strain M1 orginates form wild *Pythium oligandrum* strain. It has not been genetically modified nor is it the result of an induced mutation.

The strain is not a human pathogen and is not related to known human pathogens. The strain is not able to grow at 37 °C and above.

The biological and physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Adequate analytical methods for the identification at the strain level are available for the active substance. Quality management ensures that no toxins or pathogens relevant for human health are present in the technical grade active ingredient.

The classification and labelling for *Pythium oligandrum* Strain M1 according to Regulation (EC) No 1272/2008 (CLP Regulation) is not required as the active substance is a living microorganism not covered by this regulation. It is not biohazardous according to Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work[1]. However, based on the precautionary principle all microorganisms should be considered to have the potential to provoke sensitising reactions.

b) Intended use, target species and effectiveness

Pythium oligandrum Strain M1 is a fungicide intended to control moulds on masonry. It is intended for both curative and preventive treatment.

The data on *Pythium oligandrum* Strain M1 have demonstrated sufficient efficacy against representative saprophytic molds including monoculture of *Aspergillus terreus* or mixture of *A. niger*, *A. terreus* and *A. auranogriseum*.

Development of resistance has not been observed and is not expected due to the *Pythium oligandrum* Strain M1 mode of action. Pythium oligandrum is a mycoparasite. With its hyphae, Pythium oligandrum penetrates cells of the target organisms (mould or yeast), drawing from it necessary substances for its nourishment. As soon as the

[1] OJ L 262, 17.10.2000 p.21

nourishment source is exhausted, the microorganism will transform into a spore stage and wait for more favourable conditions.

c) Overall conclusion of the evaluation including need for risk management measures

Human health
The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
Manufacture of biocidal product	Primary exposure	industrial users
Mixing and loading	Primary exposure	Professional and non-professional users
Brush and roller application	Primary exposure, indoor	Professional and non-professional users
Infant playing next to a treated wall	Secondary exposure	General public

In the absence of a reliable test on sensitisation or a scientifically sound justifcation *Pythium oligandrum, like other microorganism,* should be, as a general precautionary measure, regarded as a potential sensitizer. Therefore, prior to authorising products based on Pythium oligandrum strain M1 for non-professional users, it shall be ensured that the human exposure to the active substance is reduced to an acceptable level. The recommended risk mitigation measures include water soluble packaging for the product and a sufficiently high dilution rate of the application solution.

Exposure to *Pythium oligandrum* Strain M1 brings about no systemic adverse effects. Thus, though an exposure assessment was conducted it is only provided for information. *Pythium oligandrum* Strain M1 is, as well as all micro-organisms, by precaution considered to be a potential sensitiser. For this reason, industrial users and professionals exposed to TGAI or the undiluted product are required to wear appropriate personal protective equipment (PPE) including gloves, cotton coveralls and respiratory protection equipment (e.g. a dust mask). For the brush and roller application where professionals may be exposed to the diluted product repeatedly, the wearing of appropriate PPE is recommended.

The use by non-professionals is considered as safe as only occasional, short term, limited exposure to the application solution of low concentration is envisaged and there is no information indicating that the naturally occurring Pythium oligandrum exerts senzitising effects. However, exposure to powder formulations, or undiluted TGAI should be avoided by the application of RMMs other than the use of PPE, e.g. by the use of water dissolvable sachet formulation.

No concern is foreseen from secondary exposure to *Pythium oligandrum* Strain M1.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Disposal of unused biocidal product after treatment via the sewer	Release to waste water and subsequently to a sewage treatement plant (STP), surface water and sediment and soil after application of sewage sludge on agricultural or grassland. Qualitative assessment as no quantitative methods are available.

Pythium oligandrum Strain M1 is intended for preventive and curative treatment of walls indoors. Most of the applied *Phythium oligandrum* Strain M1 is left on the wall even after the mould has been destroyed. Should the conditions under which humidity and hence moulds re-occur *Phythium oligandrum* Strain M1 will become active again due to sporulation. For this reason the walls affected shall not be rinsed after the application. Hence the emissions of *Phythium oligandrum* Strain M1 to the environment will be very low. Exposure to the environment may occur due to disposal of unused biocidal product via the sewer system. The resulting exposure was compared with the results from effects studies, although no effects were observed in fish in a short term toxicity study. No unacceptable risks were identified for surface water.

Pythium oligandrum Strain M1 is a mycoparasite and does not adversely affect sludge bacteria in an STP, nor does it produce any toxins which could affect bacteria in the wastewater treatment plants. Moreover, the water phase in an STP is not a favourable environment for *Pythium oligandrum* Strain M1 to survive in an active state. If *Pythium oligandrum* Strain M1 however remains in sludge, it will probably be removed during the sludge treatment due to starvation or high temperatures.

Pythium oligandrum Strain M1 is a naturally occurring soil micro-organism and occurs in relatively high densities in many agricultural soils using soil fungi as a food source.

Overall it is expected that exposure to the environment is low and as no adverse effects were observed in the available studies, no unacceptable risks are expected to occur in any of the relevant environmental compartments.

2.2. Exclusion, substitution and POP criteria

For microorganisms the assessment of exclusion criteria is not relevant. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[2] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the substitution criteria is based on Article 10(1)(a, b, d, e and f). Of these Article 10(1)(b) may be relevant although micro-organisms are not covered by CLP

[2] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)
[3] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

as all microorganisms are considered as potential sensitizers. In the absence of data indicating respiratory sensitization *Pythium oligandrum* Strain M1 does not meet Article 10(1)(b). The other criteria (Article 10(1)(a, d and f) are not applicable for microorganisms or are not met (Article 10(1)(e). Therefore, Pythium oligandrum does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution.

For microorganisms the assessment of POP criteria is not relevant.

2.3. BPC opinion on the application for approval of the active substance *Pythium oligandrum* Strain M1 in product type 10

In view of the conclusions of the evaluation, it is proposed that *Pythium oligandrum* Strain M1 shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: *Pythium oligandrum* Strain M1 and "no relevant impurities".
2. The product assessment shall pay particular attention to the exposure, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed at the Union level risk assessment of the active substance.
3. For industrial and professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment.

As all microorganisms are considered as potential sensitizers, based on the precautionary principle, the active substance may not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

1. Considering that all microbials should be regarded as potential sensitisers, the agreed warning phrase on the product label is "Microorganisms may have the potential to provoke sensitising reactions".
2. The possibility of sensitisation from products containing *Pythium oligandrum* M1 should be addressed by a qualitative risk assessment covering all potential exposure routes at product authorisation since the active substance is a microorganism which may cause sensitization reactions. Products for non-professionals shall normally not be authorised if the wearing of PPE/RPE is the only mitigation measure to reduce exposure to an acceptable level. Other elements leading to a reduction of exposure like design should be considerd.
3. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of *Pythium oligandrum* Strain M1.