COMMISSION IMPLEMENTING REGULATION (EU) 2015/1610

of 24 September 2015

approving Pythium oligandrum strain M1 as an active substance for use in biocidal products for product-type 10

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (1), and in particular Article 90(2) thereof,

Whereas:

- (1) The Czech Republic received on 12 July 2005 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council (²), for the inclusion of the active substance *Pythium oligandrum* strain M1 in its Annex I for use in product-type 10, masonry preservatives, as defined in Annex V to that Directive, which corresponds to product-type 10, as defined in Annex V to Regulation (EU) No 528/2012.
- (2) Pythium oligandrum strain M1 was not on the market on 14 May 2000 as an active substance of a biocidal product.
- (3) The Czech Republic submitted an assessment report, together with its recommendations, to the European Chemicals Agency on 8 November 2011 in accordance with Article 11(2) of Directive 98/8/EC.
- (4) The opinion of the European Chemicals Agency was formulated on 2 December 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products used for product-type 10 and containing *Pythium oligandrum* strain M1 may be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve *Pythium oligandrum* strain M1 for use in biocidal products for product-type 10 subject to compliance with certain specifications and conditions.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Pythium oligandrum strain M1 is approved as an active substance for use in biocidal products for product-type 10, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

^(?) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 September 2015.

For the Commission The President Jean-Claude JUNCKER

Common name	IUPAC name Identification numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
Pythium oligandrum strain M1	Not applicable	No relevant impurities	1 January 2016	31 December 2025	10	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following condition: For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

ANNEX

⁽¹) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 16(2) of Directive 98/8/EC. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.