COMMISSION IMPLEMENTING REGULATION (EU) 2015/984

of 24 June 2015

approving copper pyrithione as an existing active substance for use in biocidal products for product-type 21

(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 the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products.

(2) That list includes copper pyrithione.

(3) Copper pyrithione has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council ([3]) for use in product-type 21, antifouling products, as defined in Annex V to that Directive, which correspond to product-type 21, as defined in Annex V to Regulation (EU) No 528/2012.

(4) Sweden was designated as evaluating competent authority and submitted an assessment report, together with its recommendations, to the Commission on 28 January 2011 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([4]).

(5) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 3 October 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products used for product-type 21 and containing copper pyrithione may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain conditions concerning its use are complied with.

(7) It is therefore appropriate to approve copper pyrithione for use in biocidal products for product-type 21 subject to compliance with the specific conditions in the Annex.

(8) The acceptability of the risks related to the use of antifouling products, as well as the suitability of the proposed risk mitigation measures, needs to be further confirmed. In order to facilitate, at the time of the renewal of the approvals of existing antifouling active substances, the review and comparison of the risks and benefits of those substances as well as of the risk mitigation measures applied, the expiry date of approval of those substances should be the same.

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) 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).

([4]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

HAS ADOPTED THIS REGULATION:

Article 1

Copper pyrithione is approved as an active substance for use in biocidal products for product-type 21, 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*.

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

Done at Brussels, 24 June 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

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
Copper pyrithione	IUPAC Name: bis(1-hydroxy-1H-pyridine-2-thionato-O,S) copper EC No: 238-984-0 CAS No: 14915-37-8	950 g/kg	1 October 2016	31 December 2025	21	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 conditions: (1) Products containing copper pyrithione shall not be authorised for or used by non-professional users. (2) 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. (3) Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry. (4) Labels and, where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area and on impermeable hard standing with bunding to prevent direct losses and minimise emissions to the environment, and that any losses or waste containing copper pyrithione shall be collected for reuse or disposal. (5) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council [2] or Regulation (EC) No 396/2005 of the European Parliament and of the Council [3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

[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.

[2] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).