COMMISSION IMPLEMENTING REGULATION (EU) 2016/1088

of 5 July 2016

approving copper flakes (coated with aliphatic acid) as an existing active substance for use in biocidal products of 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. That list includes copper, to be named copper flakes (coated with aliphatic acid) as a result of its evaluation.

(2) Copper flakes (coated with aliphatic acid) has been evaluated for use in products of product-type 21, antifouling products, as described in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as evaluating competent authority and submitted the assessment report together with its recommendations on 31 October 2014.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 9 December 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 21 and containing copper flakes (coated with aliphatic acid) may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.

(6) The acceptability of the risks related to the use of antifouling products, as well as the suitability of the proposed risk mitigation measures, should however 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 all those substances should be the same.

(7) It is therefore appropriate to approve copper flakes (coated with aliphatic acid) for use in biocidal products of product-type 21, subject to compliance with certain specifications and conditions.

(8) 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.

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

([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).

HAS ADOPTED THIS REGULATION:

Article 1

Copper flakes (coated with aliphatic acid) is approved as an active substance for use in biocidal products of 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, 5 July 2016.

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	Conditions
Copper flakes (coated with aliphatic acid)	IUPAC Name: Copper EC No: 231-159-6 CAS No: 7440-50-8	95,3 % w/w	1 January 2018	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. In the event that products containing copper flakes (coated with aliphatic acid) are subsequently authorised for use by non-professional users, persons making products available on the market for non-professional users shall ensure that the products are supplied with appropriate gloves. For biocidal products, authorisations are subject to the following conditions. (1) For industrial or 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 shall be used with appropriate personal protective equipment. (2) Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry. (3) 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, on an impermeable hard standing with bunding or on soil covered with an impermeable material to prevent losses and minimise emissions to the environment, and that any losses or waste containing copper flakes (coated with aliphatic acid) shall be collected for reuse or disposal.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Conditions
						(4) 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 89(1) of Regulation (EU) No 528/2012. 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).