Commission Implementing Regulation (EU) No 1033/2013 of 24 October 2013 approving copper sulphate pentahydrate as an existing active substance for use in biocidal products for product-type 2 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1033/2013

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(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 Regulation (EC) No 1451/2007[(2)] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council[(3)]. That list includes copper sulphate.

(2) Copper sulphate has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 2, private area and public health area disinfectants and other biocidal products, as defined in Annex V to that Directive, which corresponds to product-type 2 as defined in Annex V to Regulation (EU) No 528/2012.

(3) The data submitted for the purpose of the evaluation allowed conclusions to be drawn only regarding a certain form of copper sulphate, i.e. copper sulphate pentahydrate CAS No 7758-99-8. The evaluation did not allow conclusions to be drawn regarding any other substance complying with the definition of copper sulphate CAS 7758-99-7 in the abovementioned list of active substances in Regulation (EC) No 1451/2007. Therefore, only copper sulphate pentahydrate should be covered by the approval.

(4) France was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 5 April 2011 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(5) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 27 September 2013, in an assessment report.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1033/2013. (See end of Document for details)*

(6) It appears from that report that biocidal products used for product-type 2 and containing copper sulphate pentahydrate may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC.

(7) It is therefore appropriate to approve copper sulphate for use in biocidal products for product-type 2.

(8) Since the evaluation did not address nanomaterials, the approval should not cover such materials pursuant to Article 4(4) of Regulation (EU) No 528/2012.

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit Member States, interested parties, and the Commission where appropriate, to prepare themselves to meet the new requirements entailed.

(10) 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

Copper sulphate pentahydrate shall be approved as an active substance for use in biocidal products for product-type 2, 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 October 2013.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1033/2013. (See end of Document for details)*

ANNEX

Common Name	**IUPAC NameIdentification Numbers**	**Minimum degree of purity of the active substance**[a]	**Date of approval**	**Expiry date of approval**	**Product type**	**Specific conditions**[b]
Copper sulphate pentahydrate	IUPAC Name: copper sulphate pentahydrate EC No: 231-847-6[c] CAS No: 7758-99-8	999 g/kg	1 July 2015	30 June 2025	2	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. Authorisations are subject to the following condition: For industrial or professional users, safe operational

a 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 8 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

b For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

c Only copper sulphate pentahydrate should be considered under this EC number