Commission Implementing Regulation (EU) 2016/124 of 29 January 2016 approving PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-type 4 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/124

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approving PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-type 4

(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 PHMB (1600; 1.8).

(2) PHMB (1600; 1.8) 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 4, food and feed area disinfectants, as defined in Annex V to that Directive, which corresponds to product-type 4 as defined 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, to the Commission on 10 April 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007[(4)].

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 17 June 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products used for product-type 4 and containing PHMB (1600; 1.8) may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain conditions concerning its use are complied with.

(6) It is therefore appropriate to approve PHMB (1600; 1.8) for use in biocidal products for product-type 4 subject to compliance with certain specifications and conditions.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/124. (See end of Document for details)*

(7) The opinion concludes that the characteristics of PHMB (1600; 1.8) render it very persistent (vP) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(5)].

(8) Since, pursuant to Article 90(2) of Regulation (EU) No 528/2012, substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved in accordance with Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.

(9) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, PHMB (1600; 1.8) meets the conditions of Article 10(1)(d) of that Regulation and should therefore be considered a candidate for substitution.

(10) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing PHMB (1600; 1.8) in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[(6)]. Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of Regulation (EC) No 1935/2004. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.

(11) Since PHMB (1600; 1.8) meets the criteria for being very persistent (vP) according to Annex XIII to Regulation (EC) No 1907/2006, treated articles treated with or incorporating PHMB (1600; 1.8) should be appropriately labelled when placed on the market.

(12) 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.

(13) 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

PHMB (1600; 1.8) is approved as an active substance for use in biocidal products for product-type 4, 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, 29 January 2016.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/124. (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
PHMB (1600; 1.8) (polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1600 and a mean polydispersity (PDI) of 1.8)	IUPAC Name: Poly(bisiminocarbonyl, hexamethylene hydrochloride), (iminoimidocarbonyl, hexamethylene hydrochloride) EC No: n.a. CAS No: 27083-27-8 and 32289-58-0	956 g/kg (calculated on dry weight basis, specification). The active substance as manufactured is an aqueous solution of 20 % w/w of PHMB (1600; 1.8)	1 July 2017	30 June 2027	4	PHMB (1600; 1.8) is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012. 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) For 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. (2) In view of the risks identified for human health and the aquatic and soil compartments,