Commission Implementing Regulation (EU) 2016/125 of 29 January 2016 approving PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-types 2, 3, 11 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/125

of 29 January 2016

approving PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-types 2, 3, 11

(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 for use in product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, product-type 3, veterinary hygiene, and product-type 11, preservatives for liquid-cooling and processing systems, as defined in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, on 8 October 2013 and 14 November 2013.

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

(5) According to those opinions, biocidal products used for product-types 2, 3, and 11 and containing PHMB (1600; 1.8) may be expected to satisfy the requirements of 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 PHMB (1600; 1.8) for use in biocidal products for product-types 2, 3, and 11 subject to compliance with certain specifications and conditions.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/125. (See end of Document for details)*

(7) The opinions conclude 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[3].

(8) PHMB (1600; 1.8) meets the conditions set out in point (d) of Article 10(1) of Regulation (EU) No 528/2012 and should therefore be considered a candidate for substitution.

(9) Pursuant to Article 10(4) of Regulation (EU) No 528/2012, the approval of an active substance that is considered as a candidate for substitution should be for a period not exceeding 7 years.

(10) 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.

(11) 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.

(12) 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-types 2, 3, and 11, 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

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(iminoimidocarbonyl, iminoimidocarbonyl, hexamethylene hydrochloride) (iminoimidocarbonyl, iminoimidocarbonyl, hexamethylene hydrochloride) EC No: n.a. CAS No: 27083-27-8 and 32289-58-0	956 g/kg (calculated on dry weight basis, as specification). The active substance as manufactured is an aqueous solution of 20 % w/w of PHMB (1600; 1.8)	1 July 2017	30 June 2024	2	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

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						are subject to the following conditions. (1) 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. (2) In view of the risks identified for human health and the environment, products

							shall not be authorised for the treatment of swimming pools, unless it can be demonstrated that risks can be reduced to an acceptable level.
						(3)	In view of the risks identified for human health and the environment, products shall not be authorised for disinfection of medical equipment by dipping, unless it can be demonstrated