Commission Implementing Regulation (EU) 2018/613 of 20 April 2018 approving PHMB (1415; 4.7) as an existing active substance for use in biocidal products of product-types 2 and 4 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/613

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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 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 (1415; 4.7).

(2) PHMB (1415; 4.7) has been evaluated for use in products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, and product-type 4, food and feed area, as described 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 13 December 2016.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 4 October 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 2 and 4 containing PHMB (1415; 4.7) 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) It is therefore appropriate to approve PHMB (1415; 4.7) for use in biocidal products of product-types 2 and 4, subject to compliance with certain specifications and conditions.

(7) The opinions conclude that PHMB (1415; 4.7) meets the criteria for being a very persistent (vP) and toxic (T) substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(3)]. PHMB (1415;

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

(8) Pursuant to Article 10(4) of that Regulation, the approval of an active substance that is considered as a candidate for substitution should be for a period not exceeding 7 years.

(9) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing PHMB (1415; 4.7) 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[(4)]. 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.

(10) Since PHMB (1415; 4.7) 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 (1415; 4.7) 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 (1415; 4.7) is approved as an active substance for use in biocidal products of product-types 2 and 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, 20 April 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/613. (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 (1415; 4.7) (polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1415 and a mean polydispersity (PDI) of 4.7)	IUPAC Name: Poly(iminoimidocarbonyl iminoimidocarbonyl hexamethylene hydrochloride), (iminoimidocarbonyl iminoimidocarbonyl hexamethylene hydrochloride) EC No: not available CAS No: 32289-58-0 and 1802181-67-4	943g/kg (calculated on dry weight basis, specification). The active substance as manufactured is an aqueous solution of 20 % w/w of PHMB (1415; 4.7)	1 November 2019,	31 October 2026	2	PHMB (1415; 4.7) is considered a candidate for substitution in accordance with point (d) of Article 10(1) Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: (1) the product assessment shall pay particular attention to the exposures, the risks

a The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

b 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).

c 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).

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/613. (See end of Document for details)*

							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;
						(2)	in view of the risks identified for the uses assessed, the product assessment shall pay particular

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						attention to: (a) professional users; (b) non-professional users; (c) secondary exposure of the general public and toddlers; (d) environment: surface water, sediment and soil.	
						The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating PHMB (1415; 4.7) shall ensure	

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