II

(Non-legislative acts)

REGULATIONS

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)

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.

([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).
([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
([4]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

(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.

(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 ([1]).

(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 ([2]). 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*.

([1]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

([2]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

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 Name Identification Numbers	Minimum degree of purity of the active substance (1)	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: CoPoly(bisiminoimidocarbonyl, hexamethylene hydrochloride), (iminoimidocarbonyl, hexamethylene hydrochloride) EC No: n.a. CAS No: 27083-27-8 and 32289-58-0	956 g/kg (calculated dry weight 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, products shall not be authorised for use as disinfectant of utensils by dipping, 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 aquatic compartment, products shall not be authorised for surface disinfection by mopping, unless it can be demonstrated that risks can be reduced to an acceptable level. (4) In view of the risks identified for human health, labels, and where provided, safety data sheets of ready-to-use wipes shall indicate that the use is restricted to areas not accessible to the general public, unless it can be demonstrated that risks can be reduced to an acceptable level by other means. (5) 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.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
						(6) Products shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of PHMB (1600; 1.8) into food or it has been established pursuant to that Regulation that such limits are not necessary. 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 (1600; 1.8) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

(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 16(2) of Directive 98/8/EC. 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).