EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11865/2017 ANNEX
(POOL/E4/2017/11865/11865-EN ANNEX.doc)
[…](2017) XXX draft

ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) …/...

approving PHMB (1415; 4.7) as an active substance for use in biocidal products of product-types 2 and 4

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 (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: CoPoly(bisiminoimidocarbonyl, hexamethylene hydrochloride),(iminoimidocarbonyl, hexamethylene hydrochloride) EC No: not available CAS No: 32289-58-0 and 1802181-67-4	943g/kg (calculated dry weight specification). The active substance as manufactured is an aqueous solution of 20% w/w of PHMB (1415; 4.7)	1st 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 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 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 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.
					4	PHMB (1415; 4.7) is considered a candidate for substitution in accordance with point (d) of Article 10(1) Regulation (EU) No 528/2012.

[1] 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.

						The authorisations of biocidal products are subject to the following conditions: 1) 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. 2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: a) professional users; b) non-professional users; c) secondary exposure of the general public; d) environment: surface water, sediment and soil. 3) 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. 4) 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 (1415; 4.7) 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:

[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).

						The person responsible for the placing on the market of a treated article treated with or incorporating PHMB (1415; 4.7) 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.