Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

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)

Product type: 9

ECHA/BPC/063/2015

Adopted

17 June 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance PHMB (1600; 1.8) for product type 9

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the non-approval in product type 9 of the following active substance:

Common name:	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)
Chemical name:	CoPoly(bisiminoimidocarbonyl, hexamethylene hydrochloride), (iminoimidocarbonyl, hexamethylene hydrochloride)
EC No.:	None
CAS No.:	27083-27-8 and 32289-58-0

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Lonza (previously Arch Chemicals Ltd) on 29 October 2008, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the European Chemicals Agency on 8 October 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations on 9 February 2015, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 10 April 2015.

Adoption of the BPC opinion

Rapporteur: BPC member of France

The BPC opinion on the non-approval of the active substance 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) in product type 9 was adopted on 17 June 2015.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the 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) in product type 9 may not be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of PHMB (1600; 1.8) (polyhexamethylene biguanide hydrochloride which is identified and characterised with a mean number-average molecular weight (Mn) of 1600 and a mean polydispersity (PDI) of 1.8) in product-type 9. PHMB (1600; 1.8) is a polymer that is directly manufactured as an aqueous solution, at a concentration. Specifications for the reference source are established.

The physico-chemical properties of the active substance as manufactured are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. Not all impurities have been identified or quantified. Validated analytical methods that were required have not been submitted for some impurities and the active substance as well as for the determination of residues in drinking water, body fluids and tissues and food stuff.

A harmonised classification is available and is given below. The current harmonised classification and labelling for PHMB (according to Regulation (EC) No 1272/2008 (CLP Regulation)) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 4; H302 Skin Sens. 1B; H317 Eye Dam. 1; H318 Carc. 2; H351 STOT RE 1; H372 (respiratory tract) (Inhalation) Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Labelling	
Pictograms	GHS07, GHS09, GHS05, GHS08
Signal Word	Dgr
Hazard Statement Codes	H302: Harmful if swallowed. H317: May cause an allergic skin reaction. H318: Causes serious eye damage. H351: Suspected of causing cancer. H372 (respiratory tract) (Inhalation): Causes damage to organs through prolonged or repeated exposure by inhalation. H410: Very toxic to aquatic life with long lasting effects.

Specific Concentration limits, M-Factors	M = 10 (acute, chronic)

An opinion of the Risk Assessment Committee (RAC) was adopted in March 2014 for acute toxicity by inhalation:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 2; H330
Labelling	
Hazard Statement Codes	H330: Fatal if inhaled.

b) Intended use, target species and effectiveness

The intended use is the preservation of textiles (PT9). The active substance is applied on textile by padding (foulard).

The lethal action of PHMB (1600; 1.8) is an irreversible loss of essential cellular components as a direct consequence of cytoplasmic membrane damage. It is concluded that cytoplasmic precipitation is a secondary event to the death of the bacterial cell.

The data on PHMB (1600; 1.8) and the representative biocidal product (containing 20% w/w of active substance) have demonstrated sufficient efficacy against bacteria at the concentration of 1 to 5% w/w of active substance in solution, in order to reach 2% w/w (0.4% w/w of active substance) on dry textile.

The evaluation of the literature studies provided by the applicant does not show particular resistance to PHMB (1600; 1.8) with bacteria. Nevertheless, cross resistances and modifications of the expression of genes as a mechanism of tolerance to sublethal concentrations of PHMB (1600; 1.8) are described in the literature and should be taken into account if needed in a strategy of resistance management at product authorisation stage.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

PHMB (1600; 1.8) is harmful if inhaled and may cause an allergic skin reaction. By inhalation, it causes damage to organs through repeated exposure and is also suspected of causing cancer. It has no irritant properties and is not genotoxic or reprotoxic.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusions**

Mixing and loading	*Primary exposure* Dosing the mixing vessels with the product (manual pouring): dermal exposure • tier 1: without personal protective equipment (PPE) • tier 2: with gloves and protective clothes	Industrials and professionals	Acceptable
Application of product on textiles by padding (foulard)	*Primary exposure* Immersion of textile in the foulard dipping baths, recycling of surplus water from foulard bath into storage tank, oven drying of textile and final rolling of fabric. These processes are automated and no exposure is expected. Rinsing/cleaning of foulard chassis/pipelines and discarding waste water is covered by post-application scenario.	Industrials and professionals	Acceptable
Post-application	*Primary exposure* Cleaning of dispersing pumps: dermal exposure • tier 1: without PPE • tier 1b: with previous rinse before pump cleaning phase, without PPE • tier 2: with gloves and impermeable coverall	Industrials and professionals	Acceptable
Combined exposure (mixing/loading and post-application)	*Primary exposure* Mixing and loading and post-application during a day: dermal exposure • tier 1: without PPE • mixing and loading tier 2, post-application tier 1b as described above • mixing and loading tier 2, post-application tier 2 as described above	Industrials and professionals	Acceptable
Dermal contact with treated textile during service life	*Secondary exposure* Dermal contact with treated textile during service life: • 100% cotton unwashed • 100% cotton washed • 50/50 cotton/polyester unwashed • 50/50 cotton/polyester washed	General public: infant	Not acceptable
Mouthing on the textile	*Secondary exposure* Mouthing on 1.3 g of textile crumpled into a sphere	General public: infant	Not acceptable

Concerning primary exposure, the risk is considered to be acceptable for professionals during manual pouring and post-application, with the wear of gloves and protection clothes during mixing and loading, and with a previous rinse step before pump cleaning.

Concerning secondary exposure, the risk is considered to be unacceptable for systemic effects for infant mouthing and wearing washed or unwashed textile.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusions**
Releases of PHMB (1600; 1.8) by use of the product as preservative for textile in the finishing step of wet processing with foulard machines. This use is in accordance with the scenario described for padding processes, printing, and coating in the ESD on textile finishing industry (OECD, 2004, section 10.1.3.), considering the intended use of PHMB (1600; 1.8) as PT09 at the finishing step during the process of immersion or dipping that take place by continuous "padding" (impregnating and pressing out again).	The product ultimately be discharged to drain and will enter a municipal sewage treatment plant (STP). As a result of this, there will be potential for exposure of both the aquatic (surface water and sediment) and the terrestrial (soil and groundwater) compartments, the latter as a result of contaminated sewage sludge spreading on land.	Not acceptable
Releases of PHMB (1600; 1.8) during service life of articles treated with the product based on a tonnage approach.		Acceptable

The risk is unacceptable for freshwater, sediment, and soil when PHMB (1600; 1.8) is used during the finishing step of wet processing in foulard baths for textile preservation.

The risk is acceptable for groundwater when PHMB (1600; 1.8) is used during the finishing step of wet processing in foulard baths for textile preservation.

The risk is acceptable for all relevant compartments during service life of articles treated with PHMB (1600; 1.8).

General conclusion

It is concluded that the use of PHMB (1600; 1.8) for the preservation of textiles (application by padding/foulard) gives rise to concerns for human health, when considering secondary exposure of the general public, and for the aquatic compartment (including sediment) and terrestrial compartment when considering the application phase.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions
CMR properties	Carcinogenicity (C)	Carc 2
	Mutagenicity (M)	No classification required
	Toxic for reproduction (R)	No classification required

PBT and vPvB properties	Persistent (P) or very Persistent (vP)	P and vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB
	Toxic (T)	T
Endocrine disrupting properties	PHMB (1600; 1.8) is not considered to have endocrine disrupting properties.	
Respiratory sensitisation properties	No classification required	
Concerns linked to critical effects	PHMB (1600; 1.8) does not fulfil criterion (e) of Article 10(1).	
Proportion of non-active isomers or impurities	With regard to the proportion of non-active isomers or impurities, PHMB (1600; 1.8) is put on the market as a 20 % aqueous solution of the active substance which has a minimum purity of 95.6% w/w. Given this, PHMB (1600; 1.8) does not fulfil criterion (f) of Article 10(1).	

Consequently, the following is concluded:

PHMB (1600; 1.8) does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

PHMB (1600; 1.8) meets the conditions laid down in Article 10(1)(d) of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution. PHMB (1600; 1.8) fulfils the P, vP and T criteria.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[1] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[2] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

During public consultation, three confidential and eleven non-confidential comments were received from third parties. Comments included information on the availability of alternative active substances, on the essentiality of the active substance PHMB (1600; 1.8) for the control of bacteria, viruses and other pathogens, and on the properties of PHMB (1600; 1.8). There are several other active substances intended for use in the same product type already approved, or currently being reviewed under Regulation (EU) No 528/2012.

2.2.2. POP criteria

PHMB (1600; 1.8) does not fulfil criteria for being a persistent organic pollutant (POP). PHMB (1600; 1.8) does not have potential for long-range transboundary atmospheric transport.

[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc).
2 See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc).

2.3. BPC opinion on the application for approval of the active substance PHMB (1600; 1.8) in product type 9

In view of the conclusions of the evaluation, the use of PHMB (1600; 1.8) for the preservation of textiles (application by padding/foulard) gives rise to concerns for human health, when considering secondary exposure of the general public, and for the aquatic compartment (including sediment) and terrestrial compartment when considering the application phase.

The overall conclusion from the evaluation of PHMB (1600; 1.8) for use in product type 9 is that biocidal products containing PHMB (1600; 1.8) as an active substance may not be expected to meet the criteria laid down in point (iii) and (iv) of Article 19(1)(b). Subsequently, it is proposed that PHMB (1600; 1.8) shall not be approved and included in the Union list of approved active substances.

According to Article 28(2) of Regulation (EU) No 528/2012, PHMB (1600; 1.8) gives rise to the following concerns: it is classified as skin sensitizer (Skin Sens. 1B), carcinogenic of category 2 (Carc. 2), specific target organ toxicant by repeated exposure by inhalation (STOT RE 1), toxic to aquatic life of acute category 1 (Aquatic Acute 1). In addition, it fulfils the substitution criteria vP and T. Therefore inclusion in Annex I of Regulation (EU) No 528/2012 is not acceptable.

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