Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

2-Phenoxyethanol

Product type: 2

ECHA/BPC/191/2018

Adopted

6 March 2018

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance 2-Phenoxyethanol for product type 2

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 approval in product type 2 of the following active substance:

Common name:	**2-Phenoxyethanol**
Chemical name:	**2-Phenoxyethanol**
EC No.:	**204-589-7**
CAS No.:	**122-99-6**

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 BASF SE on 30 July 2007, the evaluating Competent Authority, United Kingdom, submitted an assessment report and the conclusions of its evaluation to ECHA on 31 December 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-24) and its Working Groups (WG IV 2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the approval of the active substance 2-phenoxyethanol in product type 2 was adopted on 6 March 2018.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that 2-phenoxyethanol in product type 2 may 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 2-phenoxyethanol in product type 2. 2-Phenoxyethanol is a glycol ether and acts as a bactericide and a yeasticide. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are missing and required at product authorisation for water, air and food and feedstuffs (see section 2.5).

The classification and labelling for 2-phenoxyethanol according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Toxicity 4 Eye Irritation 2
Labelling	
Pictogram codes	None
Signal Word	Warning
Hazard Statement Codes	H302: Harmful if swallowd H319: Causes serious eye irritation
Specific Concentration limits, M-Factors	N/A

b) Intended use, target species and effectiveness

2-Phenoxyethanol is an active substance to be used in biocidal products for small scale surface disinfection in public and private places by professionals (eg hospitals).

2-Phenoxyethanol acts by a non-specific mode of action eg disruption of the cell membrane or inactivation of a broad range of enzymes affecting a multitude of intracellular targets.

The data on 2-phenoxyethanol and the representative biocidal product have demonstrated sufficient efficacy against the target species (bacteria and yeast). No data on the resistance of microorganisms against 2-phenoxyethanol are reported up to now. Nevertheless, the development of resistance is possible for such uses, therefore, at the stage of product authorisation, strategies of resistance management will be reviewed if needed.

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

Human health

2-Phenoxyethanol is well-absorbed by oral administration, extensively metabolised, and rapidly excreted. It is harmful by the oral route following acute exposure but is of low toxicity by the acute dermal and inhalation routes. It is not a skin irritant but is an eye irritant. It is not a skin sensitiser.

Following repeated exposure by the oral and dermal routes, haemolytic anaemia is identified as the principal and most sensitive indicator of toxicity. Following repeated inhalation exposure, the key effects observed are those arising as a result of local irritation.

2-Phenoxyethanol is not mutagenic, carcinogenic or a reproductive toxicant. There is no evidence that it is neurotoxic or immunotoxic.

An assessment of endocrine disruptor activity as defined in Regulation (EU) No 2017/2100 has not been conducted.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Disinfection of small surfaces – Application of biocidal product by trigger spray	Primary exposure by the dermal and inhalation routes. Ready-to-use product. In use concentration: 3 % Gloves	Professionals	Acceptable with PPE
Disinfection of small surfaces – Application of biocidal product by applying to a cloth and wiping of hard surfaces	Primary exposure by the dermal and inhalation routes. Ready-to-use product. In use concentration: 3 % Gloves and coveralls	Professionals	Acceptable with PPE
Disinfection of small surfaces	Secondary exposure by the dermal route following contact with wet treated surfaces.	Adults	Acceptable
Disinfection of small surfaces	Secondary exposure by the dermal and oral (hand to mouth) routes following contact with wet treated surfaces. Surface rinsed with 90 % cleaning efficiency.	Toddler	Accetable

For professional users, all primary exposure scenarios show acceptable risks for local and systemic toxicity if appropriate PPE is worn.

With regard to secondary exposure, acceptable risks are identified for adults touching wet surfaces. For toddlers, an acceptable risk is identified if the treated surface is rinsed with a 90 % cleaning efficiency.

A qualitative local risk assessment was performed as the representative product is classified for eye irritation in category 2 (H319) due to the presence of 2-phenoxyethanol and one co-formulant. The representative product is a free flowing liquid to be used as a surface disinfectant. Although it can be used in a spray, this occurs indoors and the spraying is directed away from the face/eye; the potential for eye exposure is considered minimal. In addition, the eye irritation effects are slight and reversible (Category 2). Overall, the potential risks of eye irritation are considered to be acceptable.

A dietary risk assessment was not undertaken as exposure to food from the use pattern is not expected.

Environment

2-Phenoxyethanol is stable to hydrolysis under environmental conditions. It does not fulfil the P criterion. Due to rapid and significant levels of mineralisation, it is assumed that metabolites and parent will be transient so their presence in environmental compartments will be short-lived. As a consequence, no further assessment of metabolites has been undertaken.

There is no indication of bioaccumulation potential for 2-phenoxyethanol. Additionally, it does not fulfil the T criterion.

2-Phenoxyethanol has a low vapour pressure and an estimated atmospheric half-life of < 12 h. This suggests that long-range transport is unlikely to be of concern.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Small scale surface disinfection e.g in hospitals - Rinsing/washing of treated objects/surfaces after application	Direct exposure to STP via drains. Indirect exposure to surface water (including sediment) via STP effluent; to soil (including groundwater) via STP sludge application to land; and biota via surface water and soil.	Acceptable

No unacceptable risks to environmental compartments are identified.

An aggregated exposure assessment has not been undertaken as all product types for which 2-phenoxyethanol has been supported have not yet been assessed.

Overall conclusion

A safe use for human health and the environment is identified for professionals for small scale surface disinfection via a ready-to-use product when appropriate risk mitigation measures are in place.

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)	No classification required.	2-Phenoxyethanol does not fulfil criterion (a), (b) and (c) of Article 5(1)]
	Mutagenicity (M)	No classification required.	
	Toxic for reproduction (R)	No classification required.	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP	2-Phenoxyethanol does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)]
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB	
	Toxic (T)	Not T	
Endocrine disrupting properties	An assessment according to the ED criteria as defined in Regulation (EU) No 2017/2100 has not been undertaken. However, there was no evidence of specific effects on endocrine tissues and organs. A decision on whether or not 2-phenoxyethanol fulfils criterion (d) of Artcile 5(1) cannot be made.		
Respiratory sensitisation properties	No classification required. 2-Phenoxyethanol does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	2-Phenoxyethanol is not considered to have concerns linked to critical effects and therefore it does not filfil criterion (e) of Article 10 (1).		
Proportion of non-active isomers or impurities	2-Phenoxyethanol does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

2-Phenoxyethanol does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012. However the endocrine disruptor properties have not been assessed as defined in Regulation (EU) No 2017/2100 and it is not possible to finally conclude on the exclusion criteria.

2-Phenoxyethanol does not currently meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. 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). However, the exclusion criteria were not assessed in line with the criteria laid down in the Annex of Regulation (EU) No 2017/2100 which apply as of 7 June 2018.

2.2.2. POP criteria

2-phenoxyethanol does not fulfil the criteria for being "vP" / "P" and does not demonstrate the potential for long range transport. In view of this, the compound does not meet the criteria for being a persistent organic pollutant.

2.3. BPC opinion on the application for approval of the active substance 2-phenoxyethanol in product type 2

In view of the conclusions of the evaluation, it is proposed that 2-phenoxyethanol shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 98.5 % w/w (985 g/kg)

   Relevant impurity: Ethylene oxide, maximum content: ≤0.001% w/w (≤0.01 g/kg)

2. The authorisations of biocidal products are subject to the following condition(s):

   a. 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.

[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)

b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

    i. Professional users;

    ii. Secondary exposure of toddlers.

The active substance fulfills the criteria according to Article 28 (1) to enable inclusion in Annex I of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

a. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational 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.

b. An unacceptable risk for children following secondary exposure with wet treated surfaces is identified. The risk can be mitigated if treated surfaces are thoroughly rinsed and drained after treatment and children are kept away from the wet surfaces until they are rinsed. Labels, and/or safety data sheets, should include this mitigation. However, if the risk cannot be reduced to an acceptable level by this risk mitigation measure or by other means, uses of the product should not be authorised.

c. Confirmatory data for the rinsing efficiency have to be requested at product authorisation stage, if rinsing is needed to provide a safe use.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of 2-phenoxyethanol.

However, further data on the active substance are required and should be provided to the evaluating Competent Authority (UK) as soon as possible but no later than 6 months before the date of approval:

Chemistry:

A monitoring method for 2-phenoxyethanol in water and air.