Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Chlorophene

Product type: 2

ECHA/BPC/238/2020

Adopted

4 March 2020

Opinion of the Biocidal Products Committee

on the application for approval of the active substance chlorophene 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 application for approval in product type 2 of the following active substance:

Common name:	**Chlorophene**
Chemical name:	**2-benzyl-4-chlorophenol**
EC No.:	**204-385-8**
CAS No.:	**120-32-1**

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 The Chlorophene Task Force (later supported by LANXESS Deutschland GmbH only) on 31 July 2007, the evaluating Competent Authority Norway submitted an assessment report and the conclusions of its evaluation to ECHA on 22 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-22) and its Working Groups (WG III 2017). The BPC opinion was adopted on 3 October 2017. Due to the entry into force of Regulation (EU) 2017/2100[1] the Commission returned the BPC opinion to the Agency on 26 April 2018 with the request to revise the opinion already adopted by the Biocidal Products Committee (BPC), related to the application of the criteria for endocrine disrupting properties as laid down in this regulation.

However, after the finalisation of the CA-report, the eCA was informed by the US EPA that the key 90 day dog study in the dossier was deemed invalid by the US EPA as the study had been conducted at a testing laboratory having falsified data reports on several chemicals. The study was therefore not included in the Registration Review Draft Risk Assessment performed by the US-EPA. The study was also considered invalid in the EU submission. Removing the study from the dossier resulted in a datagap for the subchronic toxicity study in the second animal species (dog).

[1] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

Given that the data gap was identified at a very late stage (i.e. after the BPC discussion), the eCA suggested to apply an additional AF in the AEL setting to compensate for the incomplete data package in order to be able to finalise the risk assessment for chlorophene. The revised risk assessment was discussed at the Human Health WG V 2019 where $AEL_{medium\ term}$ and $AEL_{long\ term}$ were re-established. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly at the BPC-34.

Chlorophene did meet the interim criteria for endocrine-disrupting properties according to Article 5(3) of the BPR as it is classified as a carcinogen category 2 and toxic for reproduction category 2. Consequently, the information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at https://echa.europa.eu/potentialcandidates-for-substitution-previous-consultations on 10 February 2017, 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 2017. An evaluation of the information was presented in the opinion adopted at BPC-22. However, as the conclusion of the BPC is now that chlorophene cannot be approved in product type 2 this information is removed from the opinion and presented in the Assessment Report in section 2.2.3.

Adoption of the BPC opinion

Rapporteur: Norway

The BPC opinion on the application for approval of the active substance chlorophene in product type 2 was adopted on 4 March 2020.

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 chlorophene in product type 2 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 chlorophene in product type 2. 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 available for the relevant matrix water. Analytical methods for soil and air are deemed not satisfactory.

A harmonized classification according to Regulation (EC) No 1272/2008 is available for chlorophene. The current classification and labelling for chlorophene according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Carc. 2 Repr. 2 Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Eye Dam. 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS05 GHS07 GHS08 GHS09
Signal Word	Danger
Hazard Statement Codes	H351 Suspected of causing cancer. H361f Suspected of damaging fertility. H332 Harmful if inhaled. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H373 May cause damage to kidneys through prolonged exposure H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.

Specific Concentration limits, M-Factors	M=1 (acute) M=100 (chronic)

b) Intended use, target species and effectiveness

The active substance chlorophene is intended to be used as a heavy-duty disinfectant for both professional and private use. Professional use includes several uses in hospitals while private use of chlorophene is limited to disinfection of objects, such as washbasins and toilet facilities.

Chlorophene is a multi-site bactericide and fungicide with basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of the cytoplasmic membrane.

For the active substance chlorophene, efficacy towards bacteria and mycobacteria has been demonstrated. The evaluated representative product has shown bactericidal and fungicidal efficacy. However, in the representative product the active substance chlorophene is combined with three other biocidal active compounds.

Due to the unspecific mode of action (multi-site activity), the development of resistance towards chlorophene has not been observed and is not expected.

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

Human health

Chlorophene is classified as harmful by inhalation, but has low acute oral and dermal toxicity. It causes eye damage, is irritating to the skin and is a skin sensitizer. The kidneys were identified as the target organ in all species in the repeated dose studies, and chlorophene may cause damage to kidneys through prolonged exposure. No classification for genotoxicity is justified, however, it is suspected of causing cancer. Chlorophene is suspected of damaging fertility, but no potential for developmental toxicity were identified

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**
Mixing & loading	Pouring a concentrate from a 1-litre container into a small bucket. Exposure is limited to the hands and forearms	Professional users	Acceptable with PPE (gloves)
Mixing & loading and application by wiping	Professional user diluting disinfectant in a bucket and wiping surfaces using a wrung cloth or a mop.	Professional cleaning personnel	Unacceptable with PPE (gloves, footwear, coated coverall)
Mixing & loading and application by wiping	Professional user diluting disinfectant in a bucket and wiping surfaces using a wrung cloth or a mop.	Professional health care workers	Unacceptable with PPE (gloves, cotton workwear)
Mixing & loading and application by wiping	Mixing and loading of a concentrate and application of the water-diluted solution by wiping with a mop.	Non-professional user	Unacceptable
Secondary exposure - Exposure to vapour	The scenario assesses inhalation exposure of a toddler breathing saturated vapour concentration of chlorophene for 24 hours (worst-case scenario)	General public	Acceptable
Secondary exposure – infant crawling	Secondary exposure to an infant crawling on a carpet which has been cleaned using a carpet powder, including inhalation, dermal and oral exposure.	General public	Acceptable

Due to the corrosive and sensitising properties of the undiluted representative product, all operations with a risk of exposure to the undiluted product exert a risk for local effects. The corrosive property of the product is most likely caused by a co-formulant, and chlorophene is not classified as corrosive to skin.

Professional users can be protected from local effects by prescribing PPE such as gloves, apron and protective goggles when handling the undiluted product. For professional cleaning personnel as well as professional health care workers the described use was found unacceptable. No further refinement was considered possible as realistic PPE is already included in the risk assessment.

Non-professional users cannot use the representative product safely (unacceptable risk due to local effects). For non-professional users, an acceptable risk was identified in the systemic risk assessment.

Secondary exposure was assessed, both for toddlers being exposed by inhalation, and to an infant crawling on a treated surface having dermal, oral (through mouthing) and inhalation exposure. No risks for secondary exposure were identified for any of the groups assessed.

Environment

Chlorophene is not expected to accumulate in air. It is considered hydrolytically stable, but photolysis will significantly contribute to the degradation. Chlorophene is shown to be readily biodegradable but failing the 10 day window requirement, and it is aerobically degraded in soils. Anaerobic degradation is not expected. The K_{oc} value is 3398, indicating a potential for binding to soils and sediments. The log K_{ow} is 4.28, but based on the experimentally determined steady-state BCF for fish (whole body and lipid-normalised: 110 L/kg and 55 kg/L, respectively), bioaccumulation in the environment is not expected.

Aquatic organisms are the most sensitive to chlorophene, and the lowest NOEC (0.58 µg/L) is identified for fish.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Professional use, Tier 1: Disinfectants used for sanitary purposes in hospitals	Emission based on the standard assumed amount of disinfectant solution used per hospital per day, i.e. 50 L. Direct emission to sewage treatment plants (STPs). Indirect emission to surface water, sediment and soil.	Unacceptable risk to surface water and sediment.
Professional use, Tier 2: Ready to use (RTU) disinfectants in institutional areas	Emission based on a treated surface of 25 m^2. Direct emission to sewage treatment plants (STPs). Indirect emission to surface water, sediment and soil.	Acceptable
Non-professional use, Tier 1: Disinfectants used for sanitary purposes (general and lavatory) in households	Emission based on the standard assumed average consumption of disinfectant solution, i.e. 0.007 L per capita per day. Direct emission to sewage treatment plants (STPs). Indirect emission to surface water, sediment and soil.	Unacceptable risk to surface water and sediment.
Non-professional use, Tier 2: Disinfectants used for sanitary purposes (lavatory only) in households	Emission based on the standard assumed average consumption of disinfectant solution for lavatories only, i.e. 0.002 L per capita per day. Direct emission to sewage treatment plants (STPs). Indirect emission to surface water, sediment and soil.	Unacceptable risk to surface water and sediment.

The assessment of the use of chlorophene in the representative biocidal products as a general PT 2 disinfectant in hospitals (professional use), i.e. according to the Tier 1 assessment for professional users, resulted in identified risks to the aquatic environment (surface water and sediment). However, risks were not identified from the assessment of the use of chlorophene in ready to use (RTU) products.

When used in private households, the assessment resulted in risks for the aquatic environment (surface water and sediment) both when considering the use as a general disinfectant and the use on lavatories only.

The only acceptable use identified in this environmental risk assessment is hence the professional use of RTU products for small scale applications (up to 25 m^2).

Overall conclusion

An unacceptable risk (even when relevant PPE is taken into account) was identified for human health when chlorophene is used by professionals to treat institutional areas. An acceptable risk was identified for the environment only for the professional RTU scenario.

An unacceptable risk to human health was identified for small scale sanitary non-professional use (e.g. use in lavatories) due to the local effects of the representative product. In addition, an unacceptable risk was identified for the environment.

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, H351 Suspected of causing cancer	Chlorophene does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification	
	Toxic for reproduction (R)	Repr. 2, H361f Suspected of damaging fertility	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP	Chlorophene 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)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	An assessment of the endocrine disrupting properties according to Regulation (EU) 2017/2100 was not conducted. Consequently, no conclusion can be drawn whether Chlorophene fulfils criterion (d) of Article 5(1) for human health or criterion (e) of Article 10(1) for the environment.	
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms		
	Article 57(f) and 59(1)		

	of REACH	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	
Respiratory sensitisation properties	No classification required. Chlorophene does not fulfil criterion (b) of Article 10(1)	
Concerns linked to critical effects other than those related to endocrine disrupting properties	Chlorophene does not fulfil criterion (e) of Article 10(1)	
Proportion of non-active isomers or impurities	Chlorophene does not fulfil criterion (f) of Article 10(1)	

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"[2], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] and "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[4] agreed at the 54th, 58th and 77th 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).

Consequently, the following is concluded:

Chlorophene does not meet the exclusion criteria laid down in Article 5(a, b, c and e) of Regulation (EU) No 528/2012.

Chlorophene does not meet the conditions laid down in Article 10 (b, d and f) of Regulation (EU) No 528/2012.

The endocrine disruptor properties have not been assessed as defined in Regulation (EU) No 2017/2100 and it is therefore not possible to finally conclude on the exclusion criteria related to Article 5(1)(d) and 10(1)(a), and on whether chlorophene shall be considered a candidate for substitution related to Article 10(1)(e). This is in line with paragraph 16 of the "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[4].

[2] 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)

[3] 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)

[4] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

2.2.2. POP criteria

Chlorophene does not meet the P/vP and B/vB criteria. It also does not meet the criteria for long-range transport in the environment. Consequently, it can be considered that chlorophene does not meet the POP criteria.

2.3 BPC opinion on the application for approval of the active substance chlorophene in product type 2

In view of the evaluation, it is concluded that biocidal products containing chlorophene as an active substance used for heavy-duty disinfection for both professional and private use may not be expected to meet the criteria laid down in points (b)(iii) and (b)(iv) of Article 19(1) of Regulation (EU) 528/2012. Consequently, it is proposed that chlorophene shall not be approved and included in the Union list of approved active substances.

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