Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Chlorophene

Product type: 2

ECHA/BPC/165/2017

Adopted

3 October2017

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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 BPC (BPC-22) and its Working Groups (WG III 2017). 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 https://echa.europa.eu/potential-candidates-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.

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 3 October 2017.

Chlorophene fulfils the interim criteria as an active substance with endocrine disrupting (ED) properties as laid down in Article 5(3) of the BPR due to the classification as Carc. Cat. 2 and Repr. Cat. 2. The two draft legal acts setting the criteria to identify endocrine disruptors under the BPR and PPPR, respectively, are currently in the adoption process according to their relevant procedures, which in both cases involve Parliament and Council (see https://ec.europa.eu/health/endocrine_disruptors/next_steps_en). The adoption of the criteria may impact the approval process after the adoption of the BPC opinion[1].

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. 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.

[1] See document: Implementation of scientific criteria to determine the endocrine–disrupting properties of active substances currently under assessment (CA-July17.Doc.7.4b)

Detailed BPC opinion and background

1. Overall conclusion

Since chlorophene fulfils the criteria set in Article 5(1) of Regulation (EU) No 528/2012, the overall conclusion of the BPC is that chlorophene in product type 2 should normally not be approved, unless one of the conditions for derogation in Article 5(2) is met. The process related to the demonstration of whether the conditions for derogation set in Article 5(2) are met, is not in the remit of the BPC[2]. 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 required and available for the relevant matrix water. Analytical methods for soil and air are deemed not satisfactory and further validation of the methods are required at product authorisation.

A CLH dossier was submitted to the Agency (ECHA) on 30 June 2014, as no harmonised classification was available, and there were data that indicated that the substance might fulfil the exclusion and substitution criteria in article 5(1) and 10(1) of Regulation (EU) No 528/2012. This procedure was also in line with the guidance document agreed by the CA meeting[3]. A Committee for Risk Assessment (RAC) opinion was adopted on 12 March 2015 and a harmonised classification according to Regulation (EC) No 1272/2008 is now available.

[2] See document CA-Nov14-Doc.4.5-Final: Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2)

[3] See document referred to in footnote 2, and document CA-Sept13-Doc.8.3–Final: Review programme of active substances: Establishment of a work programme to meet the 2024 deadline.

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. Chlorophene fulfils the interim criteria according to Article 5(3) of the BPR as an active substance with endocrine disrupting properties. However, with the information currently available, it is not possible to conclude on the possible ED mode of action of the substance.

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	Acceptable 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	Acceptable 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. Non-professional users cannot use the example product safely, but must be provided with a significantly less concentrated product, or preferably, a ready-to-use formulation in order to achieve safe use.

For professional cleaning personnel, the described use was found acceptable, provided that coated coveralls and gloves are worn during the application phase. For professional health care workers, the use of gloves and cotton workwear is necessary for safe use.

For non-professional users, a risk was identified. A marginal risk would still persist if the mixing and loading phase of the use is omitted as is the case with the use of ready-to-use formulation.

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

Overall, a safe use has been identified for both human health and the environment when ready to use (RTU) products containing chlorophene is used by professionals to treat institutional areas and adequate PPE are considered.

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 meet the exclusion criteria laid down in Article 5(1)(d)
	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	Chlorophene fulfils the interim criteria according to article 5(3) of the BPR as an active substance with endocrine disrupting properties due to the classification as Carc. 2 and Repr. 2. Hence, it fulfils the exclusion criteria given in Article 5(1)(d) of the BPR.		
Respiratory sensitisation properties	No classification required. Chlorophene does not fulfil criterion (b) of Article 10(1)		
Concerns linked to critical effects	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)		

Consequently, the following is concluded:

Chlorophene does meet the exclusion criteria laid down in Article 5(1)(d) of Regulation (EU) No 528/2012 as it fulfils the interim criteria as an active substance with endocrine disrupting properties due to the classification as Carc. 2 and Repr. 2.

Chlorophene does meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, as criteria given in 10(1)(a) are fulfilled, and is therefore 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"[4] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[5] 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).

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.

2.2.3. Public consultation for potential candidates for substitution and alternative substances or technologies

A public consultation was carried out to determine if any chemical or non-chemical alternatives are available for the intended use of chlorophene.

The applicant has argued that chlorophene has an essential use and is an important disinfection management tool for disease prevention, and that only a limited number of other active substances could cover similar use conditions as chlorophene. They have compiled a comparison with other evaluated substances and concluded that not all intended uses have identified alternatives that could be used.

Three Member States and Norway responded to the public consultation regarding possible use of chlorophene in PT2 and alternatives. None of the responses indicated any essentiality of the use of chlorophene for general disinfection or against any specific organism as the substance seems not to be on the market in several MS and Norway, or is only used in cleaning products. Alternative substances or methods seem to exist to prevent the effect of the indicated target organisms, e.g. *Escherichia coli, Pseudomonas aeruginosa, Aspergillus species* and *Mycobacteria* in these countries.

As the number of respondents in the consultation is small, an in-depth evaluation of alternative substances and methods is not possible, and no clear conclusion can be drawn on the need of chlorophene for use in PT2. However, there is no clear indication of the essentiality of the substance.

[4] See document CA-March14-Doc.4.1–Final: Note on the principles for taking decisions on the approval of active substances under the BPR

[5] See document: CA-Nov14-Doc.4.4–Final: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR

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

As the exclusion criteria are met, chlorophene should normally not be approved unless one of the conditions for derogation set in Article 5(2) of BPR is met.

If chlorophene is approved and included in the Union list of approved active substances, the approval shall be subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 966 g/kg
2. Chlorophene is considered a candidate for substitution in accordance with Article 10(1)(a) of Regulation (EU) No 528/2012.
3. The authorisations of biocidal products are subject to the following condition(s):
    a. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.
    b. 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.
    c. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
        i. Professional users;
        ii. Non-professional users;
        iii. Surface water and sediment.
4. The placing on the market of treated articles is subject to the following condition:
    a. The person responsible for the placing on the market of a treated article treated with or incorporating chlorophene shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

The active substance does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012 as it is classified as skin sensitiser (Skin Sens. 1, H317), carcinogenic (Carc. 2, H351), reprotoxic (Repr. 2, H361f), specific target organ toxicant (STOT RE 2, H373) and toxic to aquatic life (Aquatic Acute 1, H400) and as it is meeting the exclusion and substitution criteria.

2.4. Elements to be taken into account when authorising products

1. The active substance chlorophene is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for national authorisation.
2. 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. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment.

b. An unacceptable risk for non-professional users is identified. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

c. Unacceptable risks have been identified for surface water and sediment following the general scenarios for sanitary purposes in hospitals and households. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the non-approval of chlorophene for product-type 2. However, if it is decided that chlorophene should be approved, further data on the active substance are required and must be provided as soon as possible, but no later than 6 months before the date of approval to the evaluating Competent Authority (NO):

– Fully validated confirmatory methods for detection of chlorophene in air and soil.

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