Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Chlorophene

Product type: 3

ECHA/BPC/166/2017

Adopted

3 October 2017

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance chlorophene for product type 3

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 3 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 3 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 PPP, 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

The overall conclusion of the BPC is that chlorophene in product type 3 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 3. 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. Analytical methods for animal tissue and human body fluids, food and feed are missing and are required at product authorisation. Please refer to the section 2.5.

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[2]. 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), 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 in biocidal products to control pathogenic micro-organisms in poultry barns and similar facilities by professionals. Disinfection may be performed by the farmers themselves, or it may be performed by contractors who provide cleaning services for animal 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 and also efficacy against coccidian oocysts. However, in the representative product the active substance chlorophene is combined with three other biocidal active substances.

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 was 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 concentrated product and diluting 10-fold with water.	Professional user	Acceptable with PPE (gloves)
Application by handheld spray with medium pressure	Spray application indoors or outdoors in an over-head and downwards direction with hand held equipment with medium pressure (4-7 bar), generating a medium/coarse spray for broadcast application.	Professional user	Not acceptable with PPE (impermeable coveralls, RPE, gloves and footwear)
Cleaning of spray equipment	Cleaning of spray equipment. As the in-use solution is an aqueous solution, the cleaning consists of flushing of the spray equipment with water. Exposure is mainly to the hands, but splashes to other parts of the body may occur.	Professional user	Acceptable with PPE (impermeable coveralls, RPE, gloves and footwear)
Secondary exposure – Entry into treated premises	The model describes a person entering a treated poultry barn being exposed to inhalation to a saturated vapour concentration of chlorophene for 8 hours and having dermal contact with treated surfaces.	General public	Acceptable
Secondary exposure – Intake of broiler chicken with residues of chlorophene	Reverse calculation of the amount of chicken with worst case potential residues of chlorophene that must be consumed in order to exceed the ADI.	General public	Acceptable

Due to the corrosive and sensitising properties of undiluted representative product, all operations with a risk of exposure to this product exert a risk for local effects. The corrosive property of the representative product is most likely caused by chlorocresol (CMK), another active substance present and not by chlorophene. CMK is, in contrast to chlorophene, classified as corrosive to skin, and is present in the representative product in a concentration that triggers a classification for skin corrosion of the product. Professional users can be protected by prescribing PPE like gloves, apron and protective goggles when handling the undiluted representative product.

The application results in a relatively high level of exposure, and the exposure assessment identified that a protection level of double coveralls (99% protection factor) was needed in order to demonstrate safe use of chlorophene. Double coveralls are regarded as a specialised type of PPE, where it is of great importance that the coveralls are correctly fitted and used in order to function properly and to avoid leaks. The use of double coveralls is regarded not feasible for poultry farmers and farm employees as a user group. In general, this user group cannot reasonably be expected to have sufficient competence to ensure that this kind of PPE is used, or is used correctly. The protection level provided by impermeable coveralls (95% protection factor) is deemed more realistically achievable for this user group. Based on this, no safe use could be identified for chlorophene.

Secondary exposure was assessed in the case that an employee or a family member enters the treated premises, thus being exposed through inhalation and through dermal contact. No risks were identified for this group.

Secondary exposure through intake of chicken meat containing residues of chlorophene was also assessed. A reverse calculation of the amount of chicken containing a worst case level of chlorophene residues that must be consumed in order to exceed the ADI was made. The results showed that an unrealistically high amount of chicken must be consumed, thus this potential exposure pathway was deemed safe.

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**
Disinfectants used for disinfection of animal housing, Laying hens (animal sub-category i11), Tier 1	One disinfection event per year. Two exposure routes: 1) emission via the application of manure to arable land (one annual manure application) and grassland (four annual manure applications) - direct emission to soil, indirect to surface water and sediment 2) emission via release to STPs. - direct emission to STPs, indirect to surface water, sediment and soil	Unacceptable risk to surface water and sediment for exposure route 1), manure application to grassland. Acceptable for exposure route 1), manure application to arable land. Unacceptable risk to surface water and sediment for exposure route 2), release to STPs.
Disinfectants used for disinfection of animal housing, Laying hens (animal sub-category i11), Tier 2	One disinfection event per year. Emission via the application of manure to grassland (four annual manure applications to land). $PEC_{surface\ water}$ modelled in FOCUS SWASH, $PEC_{sediment}$ calculated based on partitioning properties (Equilibrium Partitioning Method)	Acceptable
Disinfectants used for disinfection of animal housing, Broilers (animal sub-category i12), Tier 1	Seven disinfection events per year. Two exposure routes: 1) emission via the application of manure to arable land (one annual manure application) and grassland (four annual manure applications) - direct emission to soil, indirect to surface water and sediment 2) emission via release to STPs. - direct emission to STPs, indirect to surface water, sediment and soil	Acceptable for exposure route 1), manure application to arable and grassland. Unacceptable risk to surface water and sediment for exposure route 2), release to STPs.

The assessment of the use of the representative biocidal product as a disinfectant for animal housing, sub-category i11 (laying hens) and sub-category i12 (broilers), resulted in unacceptable risk for surface water and sediment following release to STPs. The release to the environment from application of manure to land was found acceptable.

Overall conclusion

Overall, no safe use has been identified for human health when a chlorophene containing product is used by professional workers to control pathogenic micro-organisms in poultry barns. Safe use for the environment has been identified, provided that there is no release of the product to STPs.

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"[3] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[4] 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 actives could cover similar use conditions as chlorophene. Specifically, the applicant pointed out the need to combat *Mycobacterium avium* in animal premises. The applicant compiled a comparison with other evaluated substances and concluded that not all intended uses have identified alternatives that could be used.

The importance of chlorophene in breeding rabbits has been indicated by one national veterinary society. However, they are concerned regarding use of chlorophene due to the substance's CMR property and indicate that chlorophene could be substituted.

Two member states and Norway have indicated that chlorophene is not known to be used nationally as a disinfectant in animal housings.

As the number of respondents is small and an in-depth evaluation of alternative substances and methods is not possible based on the consultation, no clear conclusion can be drawn on the need of chlorophene for use in PT3. However, there is no clear indication of the essentiality of the substance.

[3] See document CA-March14-Doc.4.1–Final: Note on the principles for taking decisions on the approval of active substances under the BPR
[4] 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 3

In view of the conclusions of the evaluation, the use of chlorophene as a disinfectant in product type 3 gives rise to concerns for human health when considering exposure to professional users.

The overall conclusion from the evaluation is that biocidal products in product type 3 containing chlorophene as an active substance may not be expected to meet the criteria laid down in point (iii) of Article 19(1)(b). Subsequently, it is proposed that chlorophene shall not be approved and included in the Union list of approved active substances.

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.

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