Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Chlorocresol

Product type: 1

ECHA/BPC/091/2016

Adopted

13 April 2016

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance chlorocresol for product type 1

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 1 of the following active substance:

Common name:	**chlorocresol**
Chemical name(s):	**4-chloro-3-methylphenol**
EC No.:	**200-431-6**
CAS No.:	**59-50-7**
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 LANXESS Deutschland GmbH on *27* July 2007, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the Agency (ECHA) 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.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the approval of the active substance chlorocresol in product type 1 was adopted on 13 April 2016.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that chlorocresol in product type 1 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 chlorocresol (CMK or p-chloro-m-cresol) in product type 1. CMK acts by the disruption of membrane potentials, with basic activity at the cell wall and general membrane permeability of cytoplasmic membrane. CMK has a multi-site mode of action. At high concentrations, CMK also has an effect on cytoplasm by general coagulation.

Specifications for the reference source are established. One relevant impurity is identified: m-cresol (<0.1 %)

This evaluation covers the use of chlorocresol in product type 1, but it does not cover sodium p-chloro-m-cresolate.

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 matrices: soil, water, air.

The harmonised classification and labelling for CMK according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4* Eye Dam. 1 Skin Sens 1 Aquatic acute 1
Labelling	
Pictograms	GHS05 GHS07 GHS09
Signal Word	Danger, warning
Hazard Statement Codes	H302 Harmful if swallowed. H312 Harmful in contact with skin. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H400 Very toxic to aquatic organisms
Specific Concentration limits, M-Factors	-

According to the conclusion of the 36th RAC meeting (March 2016), amendment to the harmonised classification according to Regulation (EC) No 1272/2008 was adopted for CMK:

Classification according to the RAC opinion adopted at the 36th RAC meeting	
Hazard Class and Category Codes	Acute Tox. 4 STOT SE 3 Skin Corr. 1C Eye Dam. 1 Skin Sens 1B Aquatic acute 1 Aquatic chronic 3
Labelling	
Pictogram codes	GHS05 GHS07 GHS09
Signal Word	Danger
Hazard Statement	H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H335 May cause respiratory irritation. H400 Very toxic to aquatic organisms. H412 Harmful to aquatic life with long lasting effects.
Specific Concentration limits, M-Factors	M factor = 1 (acute)

b) Intended use, target species and effectiveness

CMK is used for hygienic hand disinfection. It is intended for use in hospitals, medical practices by professional users (adults only) and for personal hygiene purposes by non-professionals.

The representative product contains 4% w/w of active substance. The product, after dilution in water to achieve the end-use concentration of 0.2% m/m CMK, would be supplied in a container into which a small finger operated pump is integrated. Operating the pump dispenses 6 mL of product directly onto the hand. The hand washing is followed by a rinsing step with water.

The data on CMK and the representative biocidal product have demonstrated sufficient efficacy against bacteria at the application rate of 6 mL of the product containing 0.2% w/w of active substance.

Literature shows that especially if the concentration of CMK is in the efficient range (for PT 1: ca. 0.2 % w/w; in-use concentration) no acquired resistance occurs. In addition, using bactericidal concentrations, the risk of development of cross-resistance or co-resistance is in general low, considering the multi-site activity of CMK. Since it interacts with many different targets of the bacterial cell wall, the risk of developing resistance mechanisms is minimal.

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

Human health

CMK is harmful if swallowed and has a low toxicity in respect to acute inhalation and dermal toxicity. CMK is irritating to eye and skin and it is a skin sensitiser. Moreover, CMK may cause respiratory irritation. It is not genotoxic. CMK is not considered as carcinogenic or reproductive toxicant and did not shown endocrine disrupting properties.

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 and loading of biocidal product	*Primary exposure* Dermal exposure The biocidal product is diluted in a container to obtain a 0.2% CMK solution then reconditioned to dispenser bottles.	Professional users	Acceptable
Hygienic hand wash	*Primary exposure* Dermal exposure 6 mL of diluted product at 0.2% is dispensed onto the hand via a small finger operated pump. The hands are rubbed together and then rinsed with water.	Professional users in a health care setting (10 washes/day) and non-professional users in a domestic setting (5 washes/day)	Acceptable
Toddler mouthing on hands	*Secondary exposure* Oral exposure via residues of CMK on hands	General public	Acceptable
Combined exposure for toddler	*Primary and secondary exposure combined:* dermal exposure via hand washing and oral exposure via residues on hands	General public	Acceptable

Considering systemic effects for primary exposure, the risk during the preparation of the 0.2% solution (dilution and reconditioning of the washing product) is considered to be acceptable for professional users. The risk related to hand washing with CMK based products is considered as acceptable for professional and non-professional users.

Considering systemic effects for secondary exposure, the risk related to exposure via residues of CMK is considered as acceptable for toddlers.

A systemic combined exposure of toddler was estimated considering exposures after hand washing and via residue transferred from hand to mouth: the risk via oral and dermal route is considered to be acceptable.

Considering local effects, given the classification of the representative product for serious eye irritation (H319), goggles should be worn during the dilution phase for professionals. However, it is considered that eye exposure will happen only in accidental occasions. Consequently the risk for professionals is considered acceptable without goggles. Non-professionals doesn't handle the product they only use the diluted formulation.

No local risk assessment has been conducted for the diluted representative biocidal product, as it is not classified for local effects.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Hand disinfection by professionals in hospitals and by the general public in private areas based on: - annual tonnage approach	The total tonnage has been applied for both the professional and the private uses as a worst case. Considering the uses, sewage treatment plants are the only compartment for direct CMK emissions, whereas surface water bodies (water and sediment) and soils are indirect targets via STP effluents or the application of sewage sludge to agricultural fields.	Acceptable
Hand disinfection by professionals in hospitals and by the general public in private areas based on: - average consumption approach	For the consumption approach, market shares of 0.5 and 1 have been used for private and professional uses respectively. Considering the uses, sewage treatment plants are the only compartment for direct CMK emissions, whereas surface water bodies (water and sediment) and soils are indirect targets via STP effluents or the application of sewage sludge to agricultural fields.	Acceptable

Risk assessment for the environment based on the consumption approach has been performed considering professional and private use separately and cumulated exposures, as emissions from both uses could occur in the same sewage treatment plant (STP).

For the tonnage approach, the total tonnage has been applied for both the professional and the private uses as a worst case.

Whatever the approach considered (consumption or tonnage) risks for all the environmental compartments are acceptable for the use of CMK as hand disinfectant by professional in hospitals and by public in private area at a concentration of 0.2% w/v.

Overall conclusion
A safe use for human health and environment is identified for the following scenarios: Hand disinfection by professional in hospitals and by public in private area.

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	CMK 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	CMK 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	CMK is not considered to have endocrine disrupting properties.		
Respiratory sensitisation properties	No classification required. CMK does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	CMK does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	CMK does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

CMK does not 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).

2.2.2. POP criteria

CMK does not fulfil criteria for being a persistent organic pollutant (POP). CMK is readily

[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)

biodegradable, not bioaccumulative and degrades fast in air.

2.3. BPC opinion on the application for approval of the active substance chlorocresol in product type 1

In view of the conclusions of the evaluation, it is proposed that chlorocresol 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: ≥ 99.8%. Relevant impurity: m-cresol (<0.1 %).

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.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012. CMK gives rise to the following concerns: it is classified as skin sensitizer (Skin Sens. 1B), corrosive (Skin Corr. 1C), specific target organ toxicant by single exposure (STOT SE 3), and toxic to aquatic life of acute category 1 (Aquatic Acute 1).

2.4. Elements to be taken into account when authorising products

Not relevant.

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 CMK. However, further data should be provided to the evaluating Competent Authority (France) as soon as possible but no later than 6 months before the date of approval of the active substance:

- confirmatory data to support the log Pow.

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