Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Chlorocresol

Product type: 2

ECHA/BPC/092/2016

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 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:	**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 2 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 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 chlorocresol (CMK or p-chloro-m-cresol) in product type 2. Chlorocresol 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 chlorocresolate in product type 2, 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 private area and public health area disinfectants and other biocidal products for both professionals and non-professional uses.

It is intended for use in industrial premises, institutional and private areas, including lavatories. The disinfection in hospitals and the use as laundry disinfectant have been intended but not evaluated for the approval of the active substance.

The data on CMK and the representative biocidal product have demonstrated sufficient efficacy against bacteria and yeasts, after dilution in water to achieve the end-use concentration, at the application rate of 0.1% w/w a.s considering application by dipping and 0.1% w/w (bacteria, yeasts) to 0.4% w/w a.s (fungi) considering surface application.

Literature shows that especially if the concentration of CMK is in the efficient range 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/loading and wiping surfaces with disinfection product (i.e. diluted biocibal representive product)	*Primary exposure* Mixing/loading and wiping surfaces - Dilution of the concentrate product in a bucket with water - application of the diluted product on surface to be disinfected	Professional	Acceptable with diluted product of 0.1% (with gloves and coated coverall)
Mixing/loading and wiping surfaces with disinfection product (i.e. diluted representative product)	*Primary exposure* Mixing/loading and wiping surfaces - Dilution of the concentrate product in a bucket with water - application of the diluted product on surface to be disinfected	Non-professional	Acceptable with diluted product of 0.1%)
Infant crawling on treated surface	*Secondary exposure* Chronic dermal exposure to surface disinfected with product containing 0.4% and 0.1% of CMK.	General public: infant	Not acceptable

Considering systemic effects for primary exposure, the risk for professionals and non-professionals wiping or mopping surfaces with a detergent diluted at 0.4% w/w a.s is considered to be unacceptable.

However, the risk during wiping or mopping surfaces with a detergent diluted at 0.1% w/w a.s is considered to be acceptable for systemic effects for professionals with gloves and coated coverall and for non-professional without PPE.

Considering systemic effects for secondary exposure, the risk for infant crawling on a surface cleaned with CMK based product is considered to be unacceptable.

Considering local effects, given the classification of the representative product for serious eye irritation (H319), goggles should be worn during the dilution phase for profesionals and non professional. However, it is considered that eyes exposure will happen only in accidental occasions. Consequently the risk for professionals and non-professionals is considered acceptable without goggles.

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**
Disinfection of surfaces in industrial premises, institutional and private areas Approaches : - consumption approach - tonnage approach	After surface disinfection, the product is rinsed off with water and released to wastewater which will be discharged to a sewage treatment plant (STP), being the primary residues receiving environmental compartment. Soils and surface water bodies are indirect targets for emissions.	Acceptable

The environmental risk assessment of CMK used for PT 2 purposes is based on its use for disinfection of private and public health areas (hospital excluded).

Risk assessment for the environment was based on a consumption approach for surface disinfection in industrial premises and through consumption and tonnage approaches for disinfection of institutional/privates areas.

Whatever the approach considered, acceptable risks for the environment are predicted for the use of CMK as surface disinfectant at a concentration of 0.4% w/v a.s.

Overall conclusion
A safe use for human health and environment is identified for the following scenarios: disinfection of surfaces in industrial premises, institutional and private areas. However, the risk for infant crawling on a surface treated with CMK based product is considered to be unacceptable.

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).

[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)

2.2.2. POP criteria

CMK does not fulfil criteria for being a persistent organic pollutant (POP). CMK is readily 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 2

In view of the conclusions of the evaluation, it is proposed that CMK 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.

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

        i. industrial and professional users;

        ii. children for products used in private and institutional areas.

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

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 for industrial professionals is identified, then safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

b. If an unacceptable risk is identified for children following secondary exposure in institutional areas, labels, and where provided, safety data sheets should indicate that products used in institutional areas shall be restricted to areas not accessible to children.

c. If an unacceptable risk for children following secondary exposure in private areas (households) is identified, this use 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 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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