Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Chlorocresol

Product type: 6

ECHA/BPC/094/2016

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 6

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 6 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 18 December 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 6 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 6 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 6. 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 chlorocresolate in product type 6, 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. Analytical methods for the determination of CMK in potentially (directly or indirectly) exposed food and feedstuffs will be required when a MRL will be set.

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 intended to be used as an an antimicrobial preservative for aqueous manufactured products in cans, tanks or other closed containers during storage. CMK is used by professional users against potentially harmful and spoilage microorganisms (bacteria and fungi).

It is intended to be used as preservatives for detergents used in many applications (e.g. liquid for manual/machine dishwashing, floor waxes, car polishes, detergents, laundry softeners, etc.) and as preservatives for fluids used in paper production.

The data on CMK and the representative biocidal product have demonstrated sufficient efficacy against bacteria and fungi at the application rate ranged from 0.3 % w/w to 0.5 % w/w active substance, after dilution in water to achieve the end-use concentration.

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**
Formulation of product to be preserved			
Formulation of product to be preserved (mixing and loading)	*Primary exposure to the biocidal product* *(for systemic and local effects)* Mixing and loading phase: - Preparation of pre-mix 25% CMK solution - Addition of the pre-mix in the product to be preserved - Combined exposure Preparation of pre-mix and Addition of the pre-mix into detergent product	Professional	Acceptable (with respiratory protection equipment) Acceptable (with gloves and impermeable coverall) Acceptable (with respiratory protection equipment during preparation of the pre-mix and with gloves and impermeable coverall during adition of the pre-mix into biocidal product)
Application in paper production (concentration : 0.5% w/w a.s)			
In-can preserved paper additives used in paper production	*Primary exposure to preserved paper additives* - *(for systemic and local effects)* Addition of the preserved additive in the system - Post-application:Pump cleaning - Combined exposure:mixing loading and post application	Professional	Acceptable (with gloves and impermeable coverall) Acceptable (without PPE) Acceptable (with gloves and impermeable coverall during adition of the pre-mix into biocidal product and without PPE during post application)

	Secondary exposure to preserved paper additives Dermal exposure from handling dry paper	Professional	Acceptable (without PPE)
	Secondary exposure to preserved paper additives Oral exposure to paper by an infant (accidental ingestion of paper)	General public	Acceptable
Liquid detergents (concentration : 0.3% w/w and 0.5% w/w a.s)			
Liquid detergent for hand wash or machine laundry	*Primary exposure to preserved liquid detergent (for systemic and local effects)* Mixing and loading detergent Application phase (washing) : - manual wash - machine wash Combined exposure (mixing/loading and hand-washing)	Professional	Acceptable (without PPE)
		Non-professional	Acceptable (without PPE)
	Secondary exposure to preserved liquid detergent Dermal exposure from wearing clothes washed with preserved product	General public	Acceptable
Liquid detergent for pre-treatment of clothes	*Primary exposure to preserved liquid detergent (for systemic and local effects)* Use of liquid detergent for clothes as pre-treatment Combined exposure (hand washing clothes and spot pre-treatment)	Professional	Acceptable (without PPE)
		Non-professional	Acceptable (without PPE)
Liquid detergent for hand or machine dishwashing	*Primary exposure to preserved liquid detergent (for systemic and local effects)* Mixing and loading detergent Application phase (dishwashing): - manual wash - machine wash Combined exposure (mixing/loading and hand dishwashing)	Professional	Acceptable (without PPE)
		Non-professional	Acceptable (without PPE)
	Secondary exposure Dermal exposure from dish/utensils washed with	General public	Acceptable

	preserved product		
Liquid detergent for surface cleaning (household)	*Primary exposure to preserved liquid detergent (for systemic and local effects)* Wiping surfaces with preserved product	Professional	Acceptable (without PPE)
		Non-professional	Acceptable (without PPE)
	Secondary exposure to preserved liquid detergent Oral and dermal exposure for an infant crawling on surface cleaned with preserved product (i.e. floor)	General public	Acceptable (only for 0.3% CMK into liquid detergent)
Indirect exposure via food (concentration : 0.3% w/w and 0.5% w/w a.s)			
Combined scenario (indirect exposure via food)	*Secondary exposure* Combined exposure to food in contact with dish/utensils cleaned with preserved product, to food in contact with surface cleaned (surfaces other than floor) with preserved product and to food in contact with paper	General public	Acceptable (except when cleaned surfaces in contact with food with a 0.5% CMK w/w detergent are not rinsed).

- Formulation of preserved products:

Considering systemic effects for primary exposure, the risk for combined systemic exposure of professionals during formulation of preserved products (preparation of the pre-mix and addition in the system) is considered acceptable without PPE and with the wearing of gloves and impermeable coverall during addition of the pre-mix to the biocidal product.

Considering the local effects, due to the classification of the product and the 25% premix, a risk assessement is needed.

- During the preparation of the 25% premix, risk is acceptable if automated big bag loading is used combined with gloves, goggles, protective overalls and RPE.
- During the addition of the pre-mix into the product, the risk is acceptable for professionals with the wear of respiratory protection equipment and the risk of skin sensitization and eye damage is readily controllable through the use of proper risk mitigation measures when handling formulations such as gloves, goggles, protective overalls.

- Preservatives for fluids used in paper production:

Considering systemic effects for primary exposure, the risk for the addition of the pre mix in the product is considered acceptable with the wearing of gloves and impermeable coverall and without PPE for post application.

Considering the local effects, the risk is acceptable for professionals without respiratory protection equipment. The risk of skin sensitization and eye damage is readily controllable through the use of proper risk mitigation measures when handling formulations such as gloves, goggles, protective overalls.

Considering the secondary exposure, the systemic and local risk is acceptable when considering professionals handling processed (dry) paper, the ingestion of paper by an infant and the exposure via food in contact with wrapping paper.

- Liquid detergents:

Considering systemic effects for primary exposure, the risk is considered acceptable for professionals and non-professionals when using preserved detergent without PPE, for manual laundry washing, manual dishwashing, spot pre-treatment of clothes, separately and combined. The risk is also considered acceptable without PPE for the use of preserved surface cleaner.

Considering systemic effects for secondary exposure, the risk is acceptable when considering the dermal contact with residues on dish/utensils and surfaces cleaned with preserved detergent, the wear of clothes washed with preserved detergent, and the exposure via food in contact with residues of the active substance on dish/utensils and surfaces cleaned with 0.5% w/w CMK preserved detergent when cleaned surface are rinsed. The systemic risk for an infant crawling on surface cleaned is acceptable only if the preserved product contains 0.3 % of CMK.Considering local effects for primary and secondary exposure, the in-use concentration in liquid detergent will not lead to classification so no local effect is expected.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Preservative in detergents Exposure and risk were assessed considering tonnage and consumption approaches for the formulation phase (professional); the use phase (professional and amateur) and aggregated disopersive uses in PT6 concentration : 0.3% w/w and 0.5% w/w a.s in the detergent	In all cases, the STP is the primary compartment of exposure for the proposed uses.	Acceptable
Preservative in products used in the paper industry (dry-end paper operations, during coating operations) Exposure and risk were assessed considering tonnage and consumption approaches concentration : 0.3% w/w and 0.5% w/w a.s in the fluid		Acceptable

- Preservation of detergents :

Based on the consumption and the tonnage approach, the risk is considered acceptable for the environment for both concentrations of 0.3% w/w and 0.5% w/w a.s CMK in the detergents.

- Preservative in paper processing fluids :

Whatever the approach and the market share considered, the risk is considered acceptable for the environment for both concentrations 0.3% w/w and 0.5% w/w a.s of CMK in paper processing fluids.

- Aggregative assessment for dispersive uses in PT 6:

Acceptable risks are predicted for all the environmental compartments, for the aggregated known dispersive uses (detergents, paints and coatings and glues and adhesives). Risks for the environment are also acceptable when a general dispersive scenario is applied to the total provided tonnage, to assess the exposure of the environment based on the global known tonnage of CMK for PT 6 applications.

Overall conclusion
A safe use for human health and environment is identified for the following scenarios: preservation of processing fluids in paper production at a concentration up to 0.5% w/w a.s. and preservation of liquid detergents at a concentration up to 0.3% w/w a.s due to risk for children crawling on cleaned surfaces such as the floor.

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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>No classification required</td><td rowspan="3">CMK does not fulfil criterion (a), (b) and (c) of Article 5(1).</td></tr>
<tr><td>Mutagenicity (M)</td><td>No classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>No classification required</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>not P or vP</td><td rowspan="3">CMK does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1).</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>not B or vB</td></tr>
<tr><td>Toxic (T)</td><td>not T</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">CMK is not considered to have endocrine disrupting properties.</td></tr>
</table>

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 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 6

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.

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

[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)

i. professional users for the formulation of product to be preserved and application of the preserved product in paper production;

ii. infant crawling on surface cleaned with preserved product.

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 professional users 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 should be used with appropriate personal protective equipment.

b. If an unacceptable risk for an infant crawling on a surface cleaned with a preserved detergent is identifiedlabels and where provided safety data sheets should contain that the biocidal products should not be used to preserve detergents for surface cleaning.

c. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.

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;

- in case of setting a MRL for CMK, analytical methods for the determination of CMK in potentially (directly or indirectly) exposed food and feedstuffs should be provided.

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