

## **Biocidal Products Committee (BPC)**

Opinion on the application for approval of the active substance:

**Chlorocresol**

**Product type: 13**

ECHA/BPC/096/2016

Adopted

13 April 2016



## Opinion of the Biocidal Products Committee

### on the application for approval of the active substance chlorocresol for product type 13

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 13 of the following active substance:

<b>Common name:</b>	<b>chlorocresol</b>
<b>Chemical name:</b>	<b>4-chloro-3-methylphenol</b>
<b>EC No.:</b>	<b>200-431-6</b>
<b>CAS No.:</b>	<b>59-50-7</b>
<b>Existing active substance</b>	

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 Commission on 24<sup>th</sup> of July 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 on the approval of the active substance chlorocresol in product type 13 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 13 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 13. 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 13, 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:

<b>Classification according to the CLP Regulation</b>	
Hazard Class and Category Codes	Acute Tox. 4* Eye Dam. 1 Skin Sens 1 Aquatic acute 1
<b>Labelling</b>	
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.
<b>Specific Concentration limits, M-Factors</b>	-

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

<b>Classification according to the RAC opinion adopted at the 36<sup>th</sup> RAC meeting</b>	
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
<b>Labelling</b>	
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.
<b>Specific Concentration limits, M-Factors</b>	
	M factor = 1 (acute)

#### **b) Intended use, target species and effectiveness**

CMK is intended to be used for preservation of Metalworking (MWF) fluid (PT 13) by professional users. It is intended for the preservation of water based emulsifiable metal working fluids, as antimicrobial.

The data on CMK and the representative biocidal product have demonstrated sufficient efficacy against bacteria and fungi at the application rate range of 0.25 – 0.30% w/v active substance.

Literature shows that especially if the concentration of CMK is in the efficient range no acquired resistance occurs. In addition, 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
Professional use of metal working fluids (MWF)	<i>Primary exposure</i> to the biocidal product Mixing and loading: - Preparation of CMK solution at 6% (unloading of big bag)	professionals	Acceptable (with gloves, protective coverall, goggles and mask and automatic big bag loading)
	<i>Primary exposure</i> CMK solution at 6% Mixing and loading: - Addition of CMK solution at 6% to the metalworking fluid circuit manual, semi-automated or automated.	professionals	Acceptable (manual: with gloves and cotton coverall, semi-automated and automated: without PPE)
	<i>Primary exposure to MWF:</i> Application: - Operating the machines, handling objects wetted with MWF, cleaning the wetted tools and surfaces (manual or automated).	professionals	Acceptable (the metalworking machinery maintenance tasks (7 hours) are done with the wearing of gloves and impermeable coverall and when direct metalworking on the machinery (60 min/day) is completely automated)
	<i>Primary exposure to MWF:</i> post application: - Fluid monitoring,	professionals	Acceptable (without PPE)
	<i>Primary exposure to MWF:</i> post application: - Sump maintenance, disposal and recycling of MWF.	professionals	Acceptable (with the wear of gloves and cotton coverall)

	<p><i>Primary exposure to the biocidal product and MWF:</i></p> <p>Combined exposure of all daily tasks:</p> <ul style="list-style-type: none"> <li>- Mixing and loading when addition of CMK solution into the circuit is automated,</li> <li>- Application,</li> <li>- Post application.</li> </ul>	professionals	<p>Acceptable</p> <p>1) the preparation of 6%-CMK solution is done wearing gloves, coverall and mask and automatic unloading of big bag,</p> <p>2) the addition of 6%-CMK solution in the MWF circuit is manual with gloves and impermeable coverall,</p> <p>3) the metalworking machinery maintenance tasks (7 hours) are done with the wearing of gloves and impermeable coverall and when direct metalworking on the machinery (60 min/day) is completely automated</p> <p>4) the monitoring task is done without PPE.</p>
Professional use of metal working fluids (MWF)	<p><i>Secondary exposure to MWF</i></p> <ul style="list-style-type: none"> <li>- Cleaning surfaces and equipment, collecting shaving storage, used fluid and empty drums for recycling or disposal and transferring worked pieces to storage.</li> </ul>	professionals	Acceptable

Considering systemic effects for primary exposure, the risk is considered to be acceptable when the following tasks are done:

- preparation of 6%-CMK solution unloading of big bag, with the wear of gloves, coverall, goggles and mask for local effects;



- addition of 6%-CMK solution in the MWF circuit, when this task is manual (with PPE: gloves and cotton coveralls ) or semi-automated (without PPE) or when this task is completely automated (without PPE);
- application, the metalworking machinery maintenance tasks are done with the wearing of gloves and impermeable coverall and when direct metalworking on the machinery (60 min/day) is completely automated or which the task is completely automated in order to reduce exposure;
- sump maintenance with gloves and coverall;
- fluid monitoring, without PPE.

For systemic effects for combined exposure, the risk is considered to be acceptable for operators during:

- preparation of 6%-CMK solution, with the wear of gloves, goggles and protective coverall;
- manual addition of 6%-CMK solution in the MWF circuit, with gloves and impermeable coverall;
- application, the metalworking machinery maintenance tasks are done with the wearing of gloves and impermeable coverall and when direct metalworking on the machinery (60 min/day) is completely automated or this task is completely automated in order to reduce exposure;
- post application, without PPE.

The secondary exposure *via* residues on surfaces and objects is anticipated to be lower than the exposure by handling worked pieces and operating the machines: systemic risk is considered to be acceptable.

Considering local effects for primary exposure, the risk is considered to be acceptable when the following tasks are done:

- preparation of 6%-CMK solution automated unloading of big bag, with the wear of gloves, coverall, goggles and mask,
- addition of 6%-CMK solution in the MWF circuit, when this task is manual (with PPE: gloves, goggles and impermeable coveralls) semi-automated (with PPE: gloves, goggles) or when this task is completely automated (without PPE).

For others tasks, workers will be exposed to the in-use concentration of the product that doesn't lead to classification for local effects. So no local effect is expected at this concentration.

## **Environment**

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	Description of scenario including environmental compartments	Conclusion
Preservative for water-based emulsifiable lubricant running in a circulation system during metalworking processes	Emission to sewage treatment plant (STP), surface water, sediment, soil, groundwater by end-users of metal working fluid who treat their waste on-site	Acceptable
	Emission to sewage treatment plant (STP), surface water, sediment, soil, groundwater by waste management companies who receive waste from smaller companies who do not treat their fluids directly on site.	Acceptable

Risk assessment for the environment is based on the assumption that used metalworking fluids, which were treated with CMK, are sent either to on-site plant or to waste management companies which receive waste from smaller companies.

For both approaches, the risk for the environment is considered to be acceptable when CMK is used in emulsifiable metalworking fluids.

### Overall conclusion

A safe use for human health and environment is identified for the following scenarios: preservation of water-based emulsifiable metal working fluids.

## 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"<sup>1</sup> and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"<sup>2</sup> agreed at the 54<sup>th</sup> and 58<sup>th</sup> 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 13

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:  $\geq 99.8\%$ . 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 possible risks identified for the uses assessed, the product assessment shall pay particular attention to:

<sup>1</sup> 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>)

<sup>2</sup> 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](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.

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 loading of the biocidal products into pre-metalworking fluids at 6% CMK, this process shall be automated unless it can be demonstrated at product authorization that risks to professional users can be reduced to an acceptable level by other means.
- c. If an unacceptable risk is identified for working on turning machines, labels and where provided safety data sheets for products should indicate that metalworking on turning machines shall be automated unless it can be demonstrated at product authorization that risks to professional users can be reduced to an acceptable level by other means.

#### **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.