Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Chlorocresol

Product type: 3

ECHA/BPC/093/2016

Adopted

13 April 2016

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on the application for approval of the active substance chlorocresol 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 approval in product type 3 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 15 November 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 3 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 3 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 3. 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 3, 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 justification based on the absence exposure of food or feedstuffs is not acceptable. Analytical methods for the determination of CMK in potentially (directly or indirectly) exposed food and feedstuffs will be required when 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 used for veterinary disinfection (PT 3) by professionals. It is intended for the disinfection of pig barns and other intensive livestock farming installations, as bactericide, fungicide and as an anti-parasitic disinfectant. CMK is used by professionals as foam solution by spraying.

The data on CMK and the representative biocidal product have demonstrated sufficient efficacy against oocysts at the application rates ranged from 0.25 % 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 it 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**
Disinfection in intensive livestock farming installations (spraying solution of 0.5% w/w a.s. and 0.25% w/w a.s)	*Primary exposure: combined exposure (for systemic and local effects):* -mixing/loading -application by spraying (2 hours a day), -post-application of the biocidal product: spray equipment cleaning (20 min per day) with or without rinsing step	Professional	Acceptable (with goggles, gloves, impermeable coverall during mixing/loading, application and post application, and RPE during mixing/loading)
Re-entry following disinfection	*Secondary exposure* Re-entry of professional or workers following disinfection	Professional and workers	Unacceptable after re-entry when the surface is wet. Acceptable after drying of the spraying solution
Consumption of products of animal origin contaminated with active substance	*Secondary exposure* Exposure via food residues (Preliminary assessment of indirect exposure via food)	General public	Acceptable

Considering systemic effects for primary exposure, risk for professionals spraying surfaces is acceptable with gloves and impermeable coveralls during loading, application and post-application and RPE during application.

Considering systemic effects for secondary exposure, risk related to the reentry of professional in treated premises is considered as acceptable when the treated surface is dry. An unacceptable risk is identified for re-entry of professional or workers following disinfection when the surface is wet. If the risk cannot be reduced to an acceptable level by introducing a waiting time for drying before re-entry, re-entry is not acceptable.

The dietary exposure via ingestion of products of animals that have been reared in facilities disinfected with CMK is acceptable, based on experimental data, for chronic as well as for acute risk for the consumer.

Considering local effects, for the mixing and loading phase due to the classification of the representative product, risk for professionals spraying surfaces is acceptable with the wear of mask, goggles, gloves and coveralls.

The ready-for-use spraying solution is not classified for dermal route and inhalation, 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**
Disinfection in animal housings (emissions have been estimated for the 18 types of animal housings) Application of a solution with CMK at 0.25% w/w and at 0.5% w/w	The solutions are considered to be ultimately discharged *via* two pathways: - *via* the waste water leading to a potential for exposure of both the aquatic (sewage treatment plant (STP), surface water and sediment) and the terrestrial (soil and groundwater) compartments, the latter as a result of contaminated sewage sludge spreading on land. - *via* the manure or slurry leading to a potential for exposure of the terrestrial (soil and groundwater) compartments, following the spreading of contaminated slurry/manure on land.	Acceptable for all compartments except for the soil compartment for the following animal housing categories: - veal calves, sows in individual pens and in group, fattening pig and ducks in free range when releases are not directed to waste water for an application of a solution with CMK at 0.25% w/w - dairy cows, veal calves, sows in individual pens, sows in group, fattening pigs, laying hens in free range with litter floor (partly litter floor, partly slatted), laying hens in free range with grating floor (aviary system), parent broilers in rearing with grating floor, turkeys in free range with litter floor, ducks in free range with little floor, geese and ducks in free range with litter floor when releases are not directed to wastewater for an application of a solution with CMK at 0. 5% w/w

The environmental risk assessment has been carried out through a consumption approach for 18 different types of animal housings. For each type of animal housing, emissions to slurry/ manure are assumed and in the case of some poultries, emissions to waste water are taken into account.

At a CMK concentration of 0.25% v/w, risks are acceptable for disinfection of the following animal housing categories: dairy cows, beef cattle, laying hens in battery cages without treatment, laying hens in battery cages with aeration (belt drying), laying hens in battery cages with forced drying (deep pit, high-rise), laying hens in compact battery cages, laying hens in free range with litter floor (partly litter floor, partly slatted), broilers in free range with litter floor, laying hens in free range with grating floor (aviary system), parent broilers in free range with grating floor, parent broilers in rearing with grating floor, turkeys in free range with litter floor, ducks in free range with litter floor but only when releases are directed to wastewater and geese in free range with litter floor..

At a CMK concentration of 0.50% v/w, risks are acceptable for disinfection of the following animal housing categories: beef cattle, laying hens in battery cages without treatment, laying hens in battery cages with aeration (belt drying), laying hens in battery cages with forced drying (deep pit, high-rise), laying hens in compact battery cages, broilers in free range with litter floor, parent broilers in free range with grating floor, geese and ducks in

free range with litter floor but only when releases are directed to wastewater.

Overall conclusion
A safe use for human health and environment is identified for the following scenarios: disinfection of animal housings by spraying by professionals.

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 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 3

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:

        i. professional users;

        ii. soil compartment.

    c. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009[4] of the European Parliament and of the Council or Regulation (EC) No 396/2005[5] of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken into account to ensure that the applicable MRLs are not exceeded.

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), toxic to aquatic life of acute category 1 (Aquatic Acute 1).

[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)

2.4. 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 the soil compartment following disinfection of animal housing this use should not be authorised.

c. If an unacceptable risk is identified for professionals following disinfection of animal housings, labels, and where provided, safety data sheets should indicate that there should be no re-entry until treated surfaces are dry.

d. An updated 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 MRL for the active substance, analytical methods for the determination of CMK in potentially (directly or indirectly) exposed food and feedstuffs should be provided.

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