Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

5-Chloro-2-(4-chlorophenoxy)-phenol (DCPP)

Product type: 1

ECHA/BPC/34/2014

Adopted

4 December 2014

Opinion of the Biocidal Products Committee

on the application for approval of the active substance DCPP 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:	**DCPP**
Chemical name(s):	**5-Chloro-2-(4-chlorophenoxy)-phenol**
EC No.:	**429-290-0**
CAS No.:	**3380-30-1**

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 originally by Ciba Spezialitätenchemie Grenzach GmbH, in the context of the acquisition of Ciba by BASF, BASF SE continued to act as applicant. On 19 February 2013 the evaluating Competent Authority Austria submitted an assessment report and the conclusions of its evaluation to the Commission. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and the Commission via the Biocides Technical Meetings. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations/-/substance/5801/search/+/term on 11 April 2014, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 10 June 2014.

Adoption of the BPC opinion

Rapporteur: BPC Member for Austria

The BPC opinion on the approval of the active substance DCPP in product type 1 was adopted on 04 December 2014.

No comments were received from interested third parties during the public consultation in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the DCPP 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 5-Chloro-2-(4-chlorophenoxy)-phenol (common name: DCPP) in product type 1. DCPP has several mechanisms of action including membrane destabilization and inhibition of fatty acid synthesis. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use and materials suitable for storage and transport 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 and water.

DCPP is structurally closely related to the antibacterial active substance triclosan. The evaluation is partially based on read across from triclosan to DCPP.

A harmonised classification is available: Eye Damage, Category 1, (H318 – causes serious eye damage), Aquatic Acute 1 (H400 - Very toxic to aquatic life) and Aquatic Chronic 1 (H410 - Very toxic to aquatic life with long lasting effects). A CLH dossier was submitted to ECHA on 5 July 2013 to include M-Factors for acute and chronic environmental classification.

The classification and labelling for DCPP according to Regulation (EC) No 1272/2008 (CLP Regulation) including the Austrian proposal regarding the M-Factor for Environment hazards is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Eye damage, Category 1 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictograms	GHS 05 GHS 09
Signal Word	Danger
Hazard Statement Codes	H318 – causes serious eye damage H410: Very toxic to aquatic life with long lasting effects.
Specific Concentration limits, M-Factors	M = 10 for Aquatic Acute 1* M = 10 for Aquatic Chronic 1*
***: proposal submitted to ECHA**	

b) Intended use, target species and effectiveness

DCPP is used in liquid soap formulations for hand disinfection. The covered product contains 0.2% technical DCPP by weight. DCPP-containing soaps are intended for use by professional health care personnel. Non-professional use is not intended. The assessed soaps are designed and used as rinse-off products. Both hands and forearms are washed with soap and water; the suds are left on skin and then rinsed off with tap water.

The bactericidal efficacy of DCPP was shown in tests according to EN 1040 and EN 1276. According to these tests bactericidal efficacy was achieved against *Staphylococcus aureus*, *Pseudomonas aeruginosa* and/or *Escherichia coli* and *Enterococcus hirae* respectively.

Based on available literature information on triclosan showing that resistance in laboratory tests may be associated with changes in antibiotic susceptibility, resistance against DCPP and cross resistance with antibiotics cannot be excluded.

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

Human health

DCPP is classified for eye damage category 1. It is not classified for skin irritation, skin sensitization or acute toxicity. Genotoxicity was concluded as negative. Carcinogenicity and reproductive toxicity was evaluated on the basis of respective standard animal studies read across from triclosan and concluded as negative. The read across was supported by structural similarity, toxicokinetic studies and available toxicological data for both substances.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
Antimicrobial active ingredient in soaps for use by professional health care only (primary)	DCPP-containing soap will be used by health care professionals in hospitals or for surgical applications. The covered product contains 0.2% technical DCPP by weight. The individual use frequency and duration may vary substantially from user to user. Antimicrobial hand soap will be applied to both hands and forearms; the suds are left on skin for some time and then rinsed off with tap water. Surgical hand disinfection involves a more intensive scrubbing than the use by general population. 5 min treatment before rinse-off was considered as reasonable worst-case assumption. 7 g product per application, 10 applications per day and exposure of hands and forearms were applied as key parameters for the performed risk assessment.	Professionals

DCPP-containing antimicrobial soap is intended for use by professional health care personnel. These soaps are designed as rinse-off products. The suds are left on the skin for a short period of time and then rinsed off with water. Due to the intended use, dermal exposure is expected. Inhalation exposure is considered to be not relevant due to

the low volatility of the substance and as formation of aerosols can be disregarded due to the intended use. Oral exposure can be neglected due to the intended use as liquid antimicrobial soap for professionals. Secondary exposure and exposure via the environment are expected to be low in comparison to the exposure levels of users.

The risk for systemic effects for professionals from the exposure appears clearly acceptable.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Antimicrobial active ingredient in soaps for use by professional health care only	According to the Emission Scenario Document (ESD) for PT1 the model hospital has 400 beds, 75% of them are occupied. It is assumed that one nurse is responsible for one bed with 10 applications per day and nurse with an application rate of 7 g per event. Antimicrobial soaps are used as rinse-off products, which are left on skin for a short time and then rinsed off with water. The sewage treatment plant (STP) is the only directly receiving compartment. Indirectly receiving comparments are surface water, sediment, soil and groundwater. The risk assessment was conducted for the active substance DCPP and its metabolite methyl-DCPP. In case of lack of data, data from read-across to triclosan and methyl-triclosan were used.

DCPP and its metabolite methyl-DCPP in PT1 pose in a higher tier calculation no unacceptable risks neither for microorganisms in STP, aquatic organisms in surface water and sediment, soil organisms nor for groundwater. Therefore, no unacceptable risks for any environmental compartment and in the food chains (secondary poisoning) are expected.

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)	Data available, evidence not sufficient for classification
	Mutagenicity (M)	Data available, evidence not sufficient for classification
	Toxic for reproduction (R)	Data available, evidence not sufficient for classification
PBT and vPvB properties	Persistent (P) or very	DCPP and its metabolite, methyl-DCPP are not

	Persistent (vP)	considered to fullfill the P or vP criterion.
	Bioaccumulative (B) or very Bioaccumulative (vB)	DCPP itself is not B, but its metabolite methyl-DCPP fulfils the vB-criterion.
	Toxic (T)	DCPP as well as its metabolite methyl-DCPP fulfil the T-criterion.
Endocrine disrupting properties	DCPP is not considered to have endocrine disrupting properties according to the interim criteria.	

Consequently, the following is concluded:

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

DCPP does meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution by being a substance for which two of the three PBT criteria are met (the metabolite methyl-DCPP fulfils the T-criterion and the vB-criterion). However, further data is required to conclude on the P criterion (see 2.4 and 2.5). 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).

No comments were received during public consultation.

2.2.2. POP criteria

The POP criteria are listed in Annex D of the Stockholm Convention. One important element of these criteria is long-range transport. No monitoring data distant from source regions are available for DCPP. The half-life of DCPP in the troposphere was calculated to be 0.821 days. For the metabolite methyl-DCPP the calculated half-life is 1.17 days according to the AOP Program (v1.92) (24-hr day; 5x10^5 OH/cm^3). DCPP and methyl-DCPP are not considered to undergo long-range transport.

Therefore it can be concluded that DCPP will not fullfill the Annex D POP screening criteria of the Stockholm Convention.

2.3. BPC opinion on the application for approval of the active substance DCPP in product type 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)

In view of the conclusions of the evaluation, it is proposed that 5-Chloro-2-(4-chlorophenoxy)-phenol (DCPP) 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: 995 g/kg.

2. The active substance contains polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/F) as relevant impurities. The maximum limit for PCDD/F is set to 2 pg TEQWHO-2005/g.

3. DCPP is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012.

4. 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)(a) and 28(2)(b) to enable inclusion in Annex I of Regulation (EU) 528/2012.

The following provision was proposed for treated articles by some members of the BPC to be added in the decision making process in Article 9(1) of the BPR: "*DCPP must not be used in treated articles unless the efficacy and the benefits of the treated articles can be clearly demonstrated*."

2.4. Elements to be taken into account when authorising products

1. The active substance DCPP is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for either national or Union authorisation.
2. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage. Efficacy should be tested under relevant practical conditions (e.g. realistic contact time, high level soiling conditions), both in phase 2/step 1 tests and in phase 2/step 2 tests. If relevant, tests to prove long lasting antimicrobial activity have to be submitted
3. A qualitative local risk assessment will be necessary if the biocidal product is classified for local effects.
4. The potential resistance of bacteria to DCPP could be of concern and, as such, resistance management measures should be included in the authorisation of products. These could include (but should not be restricted to) the following factors:
5. an indication in the accompanying leaflet of the biocidal products warning:" Microbial resistance to DCPP and cross resistance with antibiotics can not be excluded"
6. and recommendation for a resistance management strategy such as: "Alternate DCPP containing products with other products which contain an active substance with a different mode of action, to prevent development of resistance due to prolonged use. Sub-inhibitory DCPP concentrations – which may originate through dilution effects- should be avoided".
7. The results of the substance evaluation according to REACH for triclosan with the special concerns of endocrine disrupting properties and PBT/vPvB properties as well as other relevant upcoming data have to be taken into account: According to

the decision on substance evaluation persuant to Article 46(1) of Regulation (EC) No 1907/2006 the Registrant(s) shall submit to ECHA by 26 September 2016 an update of the registration dossier containing the information required by this decision (pursuant to Article 46(2) of the REACH Regulation, see http://echa.europa.eu/documents/10162/0fe59e36-9bdb-4e08-a9ef-7cb01c8a4477).

After receiving the data the evaluating Member State (the Netherlands) has one year to assess the data. In this time period of one year the PBT EG or ED EG can be asked for advice.

8. Based on the available information it cannot be excluded that resistance against DCPP and cross resistance with antibiotics may occur. Therefore the occurrence of resistance of microorganisms against DCPP should be assessed. Periodic monitoring for resistant/less susceptible microorganisms to DCPP should be carried out, especially in health care areas, within the framework of routine hygiene controls in order to ensure that the target organisms remain susceptible to in-use concentrations of DCPP.

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 DCPP. However, further data shall be required as detailed below:

1. At the product authorisation stage validation data should be submitted showing that the analytical methods for active substance residues in water and soil are able to satisfy the required LOQ, i.e. 0.1 µg/L for water and 1µg/kg for soil. The data should be provided as soon as possible and at the latest 6 months before the date of approval to the evaluating Competent Authority (Austria).
2. The submitted photolysis studies did not identify all degradation products. Having in mind the structure of DCPP, formation of dioxins represents a potential concern. Referring to the found formation pathways of metabolites of DCPP, most relevant reactions are considered to be: dechlorination, condensation and ring opening of DCPP. Some of the detected unidentified degradation products were photolytically instable and were degraded shortly after formation. They are not considered to be relevant. Referring to the 2 more stable and unidentified metabolites reaching their maxima at the end of testing, evaluation of available data led to the conclusion that in this case it is very unlikely that they could be higher chlorinated dioxins. Nevertheless, the missing identity of the unidentified degradation products needs to be clarified. This information needs to be provided as soon as possible and at the latest 6 months before the date of approval to the evaluating Competent Authority (Austria).
3. The applicants used "dummy" products as part of their submission. Further data may be required, in particular regarding the physical and chemical properties, efficacy and dermal absorption of the products and should be provided by applicants at the product authorization stage..

In addition, further data will need to be provided at renewal of the active substance approval:

1. The applicant for the active substance should keep up to date with the scientific progress concerning development and spread of microbial resistance related to DCPP and cross resistance with antibiotics. This is considered necessary, because DCPP is used in healthcare systems and on the other hand the wide-spread diffuse use of the active substance may have an impact on the transfer of resistance to healthcare areas. At active substance renewal stage the applicant should submit an updated literature review and respective monitoring data for

resistant/less susceptible microorganisms to DCPP, if available. In addition information about Triclosan is also considered relevant and should be included.

2. As Triclosan including its metabolite methyl-Triclosan is currently assessed under substance evaluation according to REACH with the special concerns of endocrine disrupting properties and PBT/vPvB properties and many data are from read across studies to Triclosan, the results of this substance evaluation according to REACH have to be taken into account. In any case, at the renewal stage for the re-evaluation of the persistence criterium of the metabolite methyl-DCPP at least a surface water simulation test (OECD Test Guideline No. 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test, performed at 12°C) with methyl-DCPP or the read across substance methyl-triclosan or a water sediment study (OECD Test Guideline No. 308: Aerobic and anaerobic transformation test in aquatic sediment systems surface water simulation test (OECD Test Guideline No. 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test) with methyl-DCPP needs to be available at the time point of re-evaluation. The applicant needs to consult with the eCA in due time prior the renewal stage on this issue: The eCA needs to have enough time to potentially consult the PBT expert group on this matter.

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