Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Triclosan

Product-type: 1

ECHA/BPC/066/2015

Adopted

17 June 2015

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 triclosan 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 non-approval in product-type 1 of the following active substance:

Common name:	**Triclosan**
Chemical name(s):	**5-Chloro-2-(2,4-dichlorophenoxy)-phenol**
EC No.:	**222-182-2**
CAS No.:	**3380-34-5**
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 by Ciba Inc (during the evaluation taken over by BASF SE in 2009) the evaluating Competent Authority Denmark submitted an assessment report and the conclusions of its evaluation to the Commission on 8 April 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.

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/public-consultation-on-potential-candidates-for-substitution on 16 June 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 15 August 2014.

Adoption of the BPC opinion

Rapporteur: BPC member for Denmark

The BPC opinion on the non-approval of the active substance triclosan in product-type 1 was adopted on 17 June 2015.

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 triclosan in product type 1 may not 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 triclosan in product-type 1. Triclosan is a bacterial active ingredient. The triclosan molecule kills the bacterial cell by disturbing the function of the cell membrane. Specifications for the reference source are established.

A data gap has been identified for the water solubility and partition coefficient endpoints and information would still be required. The other 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 significant impurities. Validated analytical methods are required and are available for the relevant matrices soil and water, but additional validation data would still be required.

The harmonised classification and labelling for triclosan according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Eye Irrit. 2 Skin Irrit. 2 Aquatic acute 1 Aquatic chronic 1
Labelling	
Pictograms	GHS07 GHS09
Signal Word	Warning
Hazard Statement Codes	H319 Causes serious eye irritation H315 Causes skin irritation H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 100 (for both acute and chronic aquatic toxicity)

Concerning the physico-chemical properties, triclosan does not fulfil the criteria for a classification according to regulation (EC) No 1272/2008. Therefore no labelling is required for physico-chemical hazards.

No changes are proposed to the already existing harmonised classification and labelling under CLP.

b) Intended use, target species and effectiveness

Triclosan is a bactericidal active ingredient for use in liquid soap formulations for hand disinfection. Triclosan may also have virucidal and fungicidal activity. In the case of active substance approval, full efficacy against these organisms or other organisms claimed would still need to be demonstrated.

The exemplary product for which the exposure and risk characterisation is presented in this dossier contains 0.7% triclosan by weight. This triclosan-containing bactericidal soap is only intended for use by special professional health care personnel of e.g. surgical operations. 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 for approximately 1 minute and then rinsed off with tap water.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against potentially harmful bacteria, e.g. *Staphylococcus aureus, Staphylococcus epidermitis, Enterococcus hirae, Escherichia coli, Pseudomonas aeruginosa* and *Enterococcus faecalis*. Disinfectants containing triclosan may also have virucidal and fungicidal activity.

Triclosan has been the most studied biocide with respect to its anti-bacterial activity. Low concentrations of triclosan can trigger the expression of resistance and cross-resistance mechanisms in bacteria in vitro. However, investigations concerned mainly laboratory experiments and only very few studies are available to date on bacterial resistance to Triclosan in situ. Thus additional in situ information is needed to provide a definitive opinion.

Tests were submitted by the Applicant with a Triclosan concentration of 0.1%, but the Efficacy Working Group concluded that sufficient efficacy was not demonstrated. Efficacy was demonstrated only for gram-positive bacteria and not against gram-negative bacteria, which was considered insufficient for active substances used in disinfectants. In this case the efficacy should have been demonstrated for at least the representative bacteria in the EN Phase 1 test.

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

Human health

Pharmacokinetic data in hamsters indicate that Triclosan is well-absorbed following oral administration. Oral absorption in rats is 70 %. Two C_{max} values are seen in mice and rats (at 1 and 4 hours), indicating enterohepatic recirculation, which does not occur in hamsters or humans. In hamsters, the C_{max} occurs after 1 hour following administration of Triclosan. There is no evidence of bioaccumulation/bioretention of triclosan in rats and hamsters. A dermal absorption of 13% is taken forward to the risk assessment.

Triclosan is not acutely toxic to animals *via* the oral, dermal or inhalation routes of administration. Pure Triclosan is irritating to skin and eyes, whereas the low concentrations used in personal hygiene products do not pose an irritant hazard. Triclosan is not sensitising to skin.

The critical effects of Triclosan in rats were determined in a two-year carcinogenicity study. NOAEL was determined to be 40 mg/kg bw/day based on reduced white blood cell (WBC) counts in female rats and increased clotting time/decreased monocyte count in male rats. Tumour induction was reported in the mouse, but no effects of these types were seen in rats and hamsters, and it was concluded that the mouse is uniquely sensitive to Triclosan in the liver due to peroxisome proliferation as inducer of liver tumours in mice.

No genotoxic or foetal effects were observed.

There is a growing number of studies from the open literature showing potential problems with Triclosan concerning endocrine disruption. This is however subject to further evaluation under REACH where Triclosan has been included in the Community Rolling Action Plan (CoRAP) and will undergo substance evaluation. It is considered appropriate to postpone the assessment on endocrine disrupting properties until the evaluation under REACH has been finalised.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
Hand wash (ready-to-use formulation)	Primary exposure: application of 7 g product (0.7%) in-use solution Tier 2: 4 uses per day (for surgical hand disinfection)	Professionals
Exposure via mother's milk	Infant (0-1 month) consuming 207 g breast milk per kg bw per day	General public

At 4 uses per day an acceptable exposure is established. The application is therefore of acceptable risk for human health.

In a recent publication, a risk assessment based on Triclosan levels measured in human milk from Breast Milk Banks in California and Texas is presented. Therefore a risk assessment of the exposure via breast milk has been performed. Potential indirect exposure via breast milk, albeit mostly from non-biocidal sources of Triclosan, has however been shown to be of acceptable levels. Thus health risks of Triclosan exposure via breast milk are unlikely.

Environment

One scenario is considered for the environmental risk assessment: the consumption-based approach.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
The consumption-based approach	Use as antimicrobial hand soaps (restricted to surgical operations). The exemplary soap is a model formulation which contains 0.7% Triclosan by weight and the number of disinfection events/day is 4.
Environmental compartments for the consumption based approach.	The following environmental compartments might be exposed from the use of triclosan in liquid disinfectant soap: • Sewage Treatment Plants (STP) After use the remaining Triclosan will be disposed of down the drain. Thus, sewage treatment plants (STP) will be the receiving compartment. • Surface water and sediment Due to the use pattern of Triclosan, there are no direct emissions of Triclosan to surface water and sediment. The aquatic environment will be exposed via effluents of STPs. • Soil, Groundwater Due to the use pattern of Triclosan, potential direct contamination of the environment via the pathways soil and ground water is considered negligible. However, sludge from STP might be applied to agricultural land. Therefore, the concentrations in soil after one year and 10 years of sludge application are calculated. • Air Air will not be an environmental compartment of concern. • Biota The PECoralpredator (predicted exposure concentration) is calculated from the PEC for surface water.

Risk characterisation for the environment for the consumption-based approach:

No risk for the micro-organisms in STP due to the evaluated use of Triclosan is expected.

For the surface water, realistic worst-case assumptions are used (a predicted no effect concentration (PNEC) for Triclosan of 0.05 µg a.s./L, derived from data consisting of long-term no observed effect concentrations (NOECs) for the three trophic levels). A PEC/PNEC relation for surface water is 6.4, indicating a risk for surface water due to the evaluated use of Triclosan.

A PEC/PNEC relation for the sediment compartment indicateno risk for sediment dwelling organisms is expected due to the evaluated use of Triclosan.

A PEC/PNEC relation for Triclosan in the soil compartment (regarding the exposure via sludge) indicates no risk for soil organisms due to the evaluated use of Triclosan. Also for the metabolite methyl triclosan the PEC/PNEC ratio is below 1, indicating no risk.

The PEC/PNEC ratio concerning groundwater is below 1 indicating no potential risk for ground water.

Non compartment specific effects relevant to the food chain (secondary poisoning).
Based on the $NOEC_{birds}$ obtained from feeding studies with birds, the $PNEC_{oral}$ of 1.67 mg a.s./kg food was derived. Because birds are more sensitive predators than mammals, the PNEC of birds is used in the risk characterisation.

To assess the risk for fish eating birds, the $PNEC_{oral,\ mammals}$ is compared with the $PEC_{oral,\ predator}$ (27.8 at pH 6).

As the PECpredator is higher than the PNECoral (16.6), a risk from non-compartment specific exposure relevant to the food chain due to the proposed use of Triclosan is identified. However, the wide range of bioconcentration factor (BCF) values in fish raises some uncertainty regarding the actual bioaccumulation potential of triclosan. This PEC value is based on a BCF of 8700 which is the highest value identified (pH = 6). The BCF varies strongly with the pH of the media and decrease at higher pH values; however these values are considered as representing a realistic worst case. Furthermore, it should be noted that an assessment factor of 3000 has been used for the PNECoral, birds as no chronic data was available therefore this value also represent a realistic worst case situations. Furthermore, there are several other factors that might influence the effects on fish eating predators due to bioaccumulation via the food chain. The depuration half-life in fish is short (1-2 days) and Triclosan is excreted in fish via the bile as inactive glucuronides. However, during the review process it was concluded that the PEC/PNEC ratio for secondary poisoning was 16.6 and a risk was identified.

Therefore based on the consumption-based approach, a risk is identified for both surface water and for the non compartment specific effects relevant to the food chain (secondary poisoning). Based on the specific evaluated use no possibilities for any risk mitigation measures seem to be realistic.

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
	Mutagenicity (M)	No classification required
	Toxic for reproduction (R)	No classification required
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Triclosan is not P; The metabolite methyl triclosan may be P or even vP; however further evaluation is necessary
	Bioaccumulative (B) or very Bioaccumulative (vB)	vB Methyl triclosan seems to fulfill B and probably also vB; however further evaluation is necessary

	Toxic (T)	T
Endocrine disrupting properties	An assessment of endocrine disruptor properties has been carried out for Triclosan according to the interim criteria, described in Article 5.3 of Regulation (EU) No 528/2012. According to these interim criteria, Triclosan shall not be considered as having endocrine-disrupting properties. However, as Triclosan and its metabolites will be subject to further evaluation under REACH where it has been included on the Community Roling Plan (CoRAP) and will undergo substance evaluation in which two identified areas of concern are targeted: PBT and endocrine disruption, a further evaluation of these properties will take place under REACH. 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) However, an appeal has been launched by the applicant to ECHA with regard to the decision. At present there is a stay of action from ECHA.	
Respiratory sensitisation properties	No classification required	
Proportion of non-active isomers or impurities	Active substance does not fulfill this criterion	

Consequently, the following is concluded:

- Triclosan does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012. However, depending on the results of the REACH evaluation for triclosan, the active substance might fulfil the exclusion criteria as triclosan might be P or the metabolite methyl-triclosan might be vB and vP.

- Triclosan does meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution as it fulfils 2 of the 3 PBT criteria. 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). There was no information from the public consultation.

[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

According to Triclosan's atmospheric half-life (1 day), Triclosan does not demonstrate the potential for long-range transport. In this view, Triclosan does not meet the criteria for being a persistent organic pollutant.

2.3. BPC opinion on the application for approval of the active substance triclosan in product-type 1

In view of the conclusions of the evaluation, it is proposed that Triclosan shall not be approved, as no safe use could be demonstrated. A risk is identified for both surface water and for the non compartment specific effects relevant to the food chain (secondary poisoning). The only possible risk mitigation measure would be to decrease the concentration of Triclosan in the soap or to collect and dispose the wastewater as hazardous waste after use. However, a suggestion to decrease the concentration of Triclosan in the soap was not taken into account as sufficient efficacy could not be demonstrated. A collection and disposal of wastewater after hand washing by special professional health care personnel of e.g. surgical operations in hospitals is not normal practice. Therefore, based on the evaluated use, there are no realistic possibilities for risk mitigation measures.

It is concluded that biocidal products containing Triclosan as an active substance may not be expected to meet the criteria laid down in point (b) of Article 19(1)(b)(iv). Consequently, it is proposed that Triclosan shall not be approved and included in the Union list of approved active substances.

Triclosan meets the criteria for classification according to Regulation (EC) 1272/2008 as toxic to aquatic life of acute category 1 and fulfills the substitution criteria set out in Article 10(1). Therefore, Triclosan does not meet the conditions in Article 28(2) to allow inclusion in Annex I of Regulation (EU) 528/2012.

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