Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Dichlofluanid

Product type: 21

ECHA/BPC/120/2016

Adopted

11 October 2016

Opinion of the Biocidal Products Committee

on the application for approval of the active substance dichlofluanid for product type 21

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 21 of the following active substance:

Common name:	**Dichlofluanid**
Chemical name:	**N-(Dichlorofluoromethylthio)-N',N'-dimethyl-N-phenylsulfamide**
EC No.:	**214-118-7**
CAS No.:	**1085-98-9**
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 30 April 2006, the evaluating Competent Authority UK submitted an assessment report and the conclusions of its evaluation to ECHA on 22 October 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-17) and its Working Groups (WG III 2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the approval of the active substance dichlofluanid in product type 21 was adopted on 11 October 2016.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at:

http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that dichlofluanid in product type 21 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 dichlofluanid in product type 21. The biocidal activity of N-haloalkylthio compounds like dichlofluanid is based on the ability of the N-S bond to open and react with nucleophilic entities within the cell, such as SH groups of enzymes.

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, 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. The methods for analysis in environmental matrices, as appropriate for the areas of use assessed, have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

The proposed classification and labelling for dichlofluanid according to Regulation (EC) No 1272/2008 (CLP Regulation) is (agreed in RAC opinion on 3 June 2015, however the harmonised classification and labelling in Annex VI of CLP has not been amended yet):

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4, H332 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Acute 1, H400
Labelling	
Pictogram codes	GHS07 GHS09
Signal Word	Warning
Hazard Statement Codes	H332: Harmful if inhaled H319: Causes serious eye irritation H317: May cause an allergic skin reaction H400: Very toxic to aquatic life
Specific Concentration limits, M-Factors	M = 10 (acute)

Based on the available data, the evaluating Competent Authority proposes the following amendment of the existing harmonised classification:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4, H332 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictogram codes	GHS07 GHS09
Signal Word	Warning
Hazard Statement Codes	H332: Harmful if inhaled H319: Causes serious eye irritation H317: May cause an allergic skin reaction H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long-lasting effects
Specific Concentration limits, M-Factors	M = 10 (acute) M = 10 (chronic)

b) Intended use, target species and effectiveness

Anti-fouling products containing dichlofluanid are applied by brush or roller, by non-professionals, to pleasure craft to protect surfaces from algae, diatoms and other fouling organisms.

Regarding mode of action, the biocidal activity of N-haloalkylthio compounds like dichlofluanid is based on the ability of the N-S bond to open and react with nucleophilic entities within the cell such as SH groups of enzymes. Such reactions proceed by way of several steps and lead to disulphides.

The data on dichlofluanid and the representative biocidal products have demonstrated sufficient efficacy against the target species.

Regarding resistance, due to the unspecific mode of action the development of resistance is neither to be expected nor has been ever observed. In addition, a literature search on resistance with respect to dichlofluanid and wood preservation was negative. In addition, the rapid degradation of dichlofluanid in seawater after its release from the paints does not provide conditions, which would support developing resistances.

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

The overall conclusion from the evaluation of dichlofluanid for use in product type 21 (antifouling products) is that it may be possible for Member States to issue authorisations of products containing dichlofluanid in accordance with the conditions laid down in Regulation (EU) No 528/2012.

It should be noted that assessments carried out for human health and the environment for the limited number of substances under product type 21 (antifouling products) often indicate unacceptable risks to certain end users and/or environmental compartments exposed to these substances. These assessments also indicate the need for risk mitigation measures, such as technical controls and/or personal protective equipment (PPE), in order to protect end-users using these substances and minimise exposure of the relevant environmental compartments.

It was agreed at the 55th meeting of the representatives of Member State Competent Authorities for the implementation of the BPR to utilise generic conditions in approval regulations (as outlined in Section 2.3 below) for all product type 21 substances evaluated

as part of the EU Review Programme for exisiting active substances to reduce the risks for human health and for the environment from use of these substances[1].

Human health

Dichlofluanid is of low acute toxicity by the oral and dermal routes but has moderate acute toxicity by the inhalation route. Dichlofluanid is not classified as a skin irritant, but it does meet the criteria for classification as an eye irritant and there is evidence that dichlofluanid can cause some respiratory tract irritation. Dichlofluanid has skin sensitisation potential and meets the EU criteria for classification.

Following repeated oral administration of dichlofluanid, the most prominent finding was fluorosis, which resulted in skeletal osteosclerosis, observed in lifetime dietary studies in both rats and mice. Chronic nephropathy was also observed following repeated oral administration, but in dogs only.

Dichlofluanid does not meet the criteria for classification as a mutagen, carcinogen or reproductive toxicant.

The relevant information for the risk characterisation for exposure to dichlofluanid comes largely from oral studies, which are used to derive systemic AELs for dichlofluanid for inhalation and dermal exposure. For local effects, eye irritation and skin sensitisation are the most relevant dermal effects; a risk characterisation has been conducted using a qualitative approach.

The table below summarises the exposure scenarios assessed. The conclusion of the scenarios reflects the outcome of both local and systemic risk assessments.

[1] See document: Antifouling (PT21); the way forward for the management of active substances and the authorisation of biocidal products. (CA-March14-Doc.4.2 – Final).

Summary table: scenarios			
Scenario	**Primary or secondary exposure Description of scenario**	**Exposed group**	**Conclusion**
Brush and roller application	Primary exposure - an adult applies the product to the surface of the vessel using a brush and/or roller.	Non-professional	Acceptable (with gloves)
Washing out contaminated brushes	Primary exposure - an adult cleans out a brush contaminated with the product using an appropriate solvent.	Non-professional	Acceptable
Paint removal using high pressure water washing and/or abrasion techniques.	Primary exposure - an adult removes the dried paint from the surface of the vessel using high pressure water washing and/or abrasion equipment.	Non-professional	Acceptable
Laundering work clothing	Secondary exposure – an adult launders contaminated (from non-professional application of the product) clothing at home.	Bystanders (general public)	Acceptable
Contact with treated boat surface	Secondary exposure – a young child (toddler) touches a boat surface coated in the product.	Bystanders (general public)	a) Not acceptable (when wet) b) Acceptable (when dry)
Exposure via the environment	Secondary exposure - an individual may consume fish contaminated with dichlofluanid.	General Public	Acceptable

Acceptable risks were identified for non-professionals applying dichlofluanid in the representative products by brush and roller when long sleeved shirt, trousers and shoes (default clothing penetration value of 50 %) and gloves are worn.

An acceptable risk was identified for an adult washing clothes contaminated with dichlofluanid following use of the representative products.

An unacceptable risk is identified (from dermal and hand-to-mouth exposure) for a young child touching wet paint on a boat surface freshly treated with dichlofluanid in the representative products. However, an acceptable risk is identified for a young child touching dry paint (both dermal and hand-to-mouth exposure) from a boat surface treated with dichlofluanid in the representative products. Therefore, it is considered that this potential risk to children can be mitigated by suitable labelling of products containing dichlofluanid intended for non-professional use by adding the following additional warning on the label: "Keep children away until treated surfaces are dry".

An acceptable risk from combined exposure to dichlofluanid in the representative products is identified for a non-professional operator applying the representative product by brush and roller and cleaning out the paint brush/roller on the same day provided gloves are worn during the application phase.

With regard to local effects arising from primary exposure no unacceptable risks are identified when gloves are worn. Risks of local skin effects from secondary exposure, particularly skin sensitisation for a child touching a wet treated boat surface may occur. As for the systemic risks, it is considered that such skin sensitisation risks could be mitigated by an additional warning on the product label.

Dietary exposures to dichlofluanid do not pose an unacceptable risk to the consumer based on a preliminary dietary risk assessment.

Based on environmental monitoring and modelling relatively high concentrations of N,N-dimethylsulfamide, a persistent second degradation product of dichlofluanid, in freshwater cause concern in relation to surface water intended for production of drinking water and human health. Concentrations of N,N-DMS exceed the drinking water limit value of 0.1 µg/l. The main concern is related to water treatment and the possible formation of N-nitrosodimethylamine (NDMA) during ozonation of surface water containing N,N-dimethylsulfamide. NDMA is classified as carcinogenic (Carc. Cat. 1B).

Environment

Dichlofluanid hydrolyses rapidly in freshwater and seawater to N,N-dimethyl-N'-phenylsulfamide (DMSA). It is also inherently biodegradable and, in biologically active soils, is degraded to DMSA with a half-life of less than one day.

Leaching studies in soil showed that dichlofluanid was not mobile but was rapidly degraded under the conditions of the available studies, whereas DMSA was shown to be mobile and susceptible to degradation with time. Dichlofluanid and DMSA are unlikely to bioaccumulate.

Dichlofluanid, DMSA and N,N-DMS have low vapour pressures which together with the intended use suggest that exposure of the air compartment is unlikely.

Dichlofluanid is extremely toxic to aquatic organisms, whereas DMSA has a low toxicity. A short term toxicity test submitted for the terrestrial toxicity endpoint demonstrates that dichlofluanid has a relatively low toxicity to earthworms.

The metabolite N,N-DMS shows a low toxicity to aquatic and terrestrial organisms compared to the parent compound dichlofluanid. However, it is persistent and highly mobile.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Environmental compartments**	**Conclusion**
Application (maintenance and repair)	Aquatic, soil	Acceptable risk
Removal (maintenance and repair)	Aquatic, sediment, soil	Acceptable risk Unacceptable risk to soil from direct exposure
In service		
Within saltwater marina (OECD-EU)	Aquatic, sediment	Unacceptable risk- aquatic Acceptable risk - sediment
Adjacent to saltwater marina (OECD-EU)	Aquatic, sediment	Acceptable risk
Within freshwater marina (Swiss)*	Aquatic, sediment	Unacceptable risk -aquatic Acceptable risk - sediment
Adjacent to freshwater marina (Swiss)*	Aquatic, sediment	Acceptable risk

Maintenance cycle (i.e. removal followed by application on successive days)	Soil	Unacceptable risk
Cumulative exposure – application plus in-service losses		
Within marina (OECD-EU)	Aquatic	Unacceptable risk
Adjacent to marina (OECD-EU)	Aquatic	Acceptable risk
For all scenarios evaluated the exposure is estimated within the marina as well as adjacent to the marina (defined as the wider environment). In addition, worst case and typical case situations were evaluated. * The freshwater marina is not a harmonised scenario.		

An acceptable risk to STPs, groundwater, and the atmosphere from all typical case scenarios was identified following use of dichlofluanid in the representative products. An unacceptable risk to soil was identified in the immediate area where removal processes occur. Labels and/or safety data sheets shall advise users to protect the soil during application and removal and prevent direct losses to soil and water, and that any losses must be collected for disposal. The risk to the wider terrestrial environment from application of sludge was acceptable.

An acceptable risk to the wider marine environment represented by the area adjacent to the saltwater marina was also identified. This acceptable risk is identified for the cumulative exposure scenario that combines in-service and application or removal losses where those losses are based on the worst case OECD ESD defaults.

The risk is unacceptable within the saltwater marina from in-service use alone and cumulative exposure.

There was also an unacceptable risk within the Swiss freshwater marina from the concentration of the metabolite N,N-DMS where the PECwater value of 3.46 µg/L exceeded the drinking water standard of 0.10 µg/L by a large margin. Concentrations of N,N-DMS reported in monitoring studies also breached this limit. The drinking water limit value of 0.10 µg/L should be used in the risk assessment of N,N-DMS as it is a precursor of the relevant metabolite NDMA. On this basis the use of dichlofluanid as an antifoulant on pleasure craft in freshwater bodies should be excluded.

Overall conclusion

All risks from primary exposure are acceptable risks when normal clothing and gloves are worn for non professional application by brush and roller. Overall risks from secondary exposure to dichlofluanid are acceptable; however, the risks are unacceptable for a young child touching a treated boat surface when the paint is still wet.

There is an acceptable risk to STPs, groundwater, and the atmosphere from all typical case scenarios; however there is an unacceptable risk to soil in the immediate area where removal processes occur. There is an acceptable risk to the wider marine environment represented by the area adjacent to the saltwater marina. The risk is unacceptable within the saltwater marina and the Swiss freshwater marina from in-service use alone and cumulative exposure. On this basis the use of dichlofluanid as an antifoulant on pleasure craft in freshwater bodies should be excluded.

Dichlofluanid degrades to the persistent substance N,N-DMS which may form N-

nitrosodimethylamine (NDMA) when surface water containing N,N-DMS is extracted for the production of drinking water and ozonated. Due to this concern dichlofluanid can only be applied for use in antifouling products for marine-going vessels.

Overall an acceptable risk is identified for non-professional use on marine going vessels where appropriate risk management measures are in place (i.e. gloves and prevention of soil exposure).

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>Not C</td><td rowspan="3">Dichlofluanid does not fulfil criterion (a), (b) and (c) of Article 5(1)</td></tr>
<tr><td>Mutagenicity (M)</td><td>Not M</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>Not R</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>Not P or vP

(DMSA and N,N-DMS - vP)</td><td rowspan="3">Dichlofluanid 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

(DMSA and N,N-DMS – not B or vB)</td></tr>
<tr><td>Toxic (T)</td><td>T

(DMSA and N,N-DMS – not T)</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">Dichlofluanid is not considered to have endocrine disrupting properties. Dichlofluanid does not fulful criterion (d) of Article 5(1).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. Dichlofluanid does not fulfil criterion (b) of Article 10(1).</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">Dichlofluanid does not fulfil criterion (e) of Article 10(1).</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">Dichlofluanid does not fulfil criterion (f) of Article 10(1).</td></tr>
</table>

Consequently, the following is concluded:

Dichlofluanid does not meet the exclusion criteria laid down in Article 5 or the substitution criteria laid down in Article 10 of Regulation (EU) No. 528/2012.

Dichlofluanid 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"[2] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] 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

Dichlofluanid is not persistent and therefore does not fulfill the criteria for being a POP. The degradation products DMSA and N,N-DMS are both very persistent but neither are bioaccumulative or toxic criteria and so do not fulfill the criteria for being a POP.

2.3. BPC opinion on the application for approval of the active substance dichlofluanid in product type 21

In view of the conclusions of the evaluation, it is proposed that dichlofluanid 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: 96 % w/w

2. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by the application for authorisation but not addressed in the Union level risk assessment of the active substance.

3. Products shall not be authorised to control the growth and settlement of fouling organisms on freshwater going vessels.

Authorisations are subject to the following condition(s):

1. For industrial or professional users, safe operational procedures and appropriate organisational 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.

2. Persons making products containing dichlofluanid available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves. Labels and, where provided, instructions for use shall indicate whether other personal protective equipment shall be used. Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry.

3. Labels, and where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area, on an impermeable hard standing with bunding or on soil covered with an impermeable material to prevent direct losses and minimise emissions to the environment, and that any losses or waste containing dichlofluanid shall be collected for reuse or disposal.

4. For products that may lead to residues in food or feed, the need to set new or to

[2] 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)
[3] 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)

amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[4] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[5] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

5. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance, dichlofluanid, shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

Dichlofluanid gives rise to concern for both human health and the environment i.e. it is classified with Skin Sens. 1 (H317) and Aquatic Acute 1 (H400). Consequently, according to Article 28(2) (a) of Regulation (EU) 528/2012, inclusion in Annex I of Regulation (EU) 528/2012 is not acceptable.

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:

1. Dichlofluanid can be applied to be used in antifouling products for marine-going vessels only due to the concern related to use of surface water in production of drinking water and human health. Dichlofluanid degrades to the persistent substance N,N-DMS which may form N-nitrosodimethylamine (NDMA) when surface water containing N,N-DMS is extracted for production of drinking water and ozonated. Based on environmental monitoring and modelling data N,N-DMS concentrations in surface water can be relatively high. For dichlofluanid containing antifouling products authorised for marine going vessels the following information may be provided on the label: "Do not sail in inland (freshwater) water bodies. Do not sail upstream river harbours or marinas adjacent to estuarine mouth with your boat treated with dichlofluanid containing antifouling products".

2. Because of deficiencies in the dermal absorption studies, new studies would be needed at product authorisation. However, for approval of the active substance, it would not be reasonable to require new dermal absorption studies before harmonised guidance for PT 21 dermal absorption studies is developed.

3. Labels, and where provided, safety data sheets of biocidal products should indicate that users should wear long-sleeved shirt, long trousers and shoes and that children should be kept away until treated surfaces are dry.

4. Safe uses for the environment have been identified for scenarios representative of the wider environment (i.e. areas adjacent to marinas). A risk has been identified within marinas. These areas may need additional consideration at national level and the available best practices shall be applied to mitigate these risks.

5. With regard to the environment, the need to address any specific national conditions and protection goals and/or undertake regional assessments should be considered at product authorisation stage, as environmental risk assessments in this evaluation have been based on generic EU scenarios.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance,

[4] OJ L 152, 16.6.2009, p. 11.
[5] OJ L 70, 16.3.2005, p.1

permitting the proposal for the approval of dichlofluanid. However, further data shall be required as detailed below:

- Analytical methods for the determination of dichlofluanid residues in fish and seafood should be provided to the evaluating Competent Authority (UK) as soon as possible but no later than 6 months before the date of approval of the active substance.

- In order to address a potentially severe underestimation of the risk to sediment dwelling organisms from exposure via suspended matter, caused by the fact that sorption data (Koc) has only been studied at concentrations that are not fully relevant in the marine environment, a new study on sorption at environmentally relevant conditions (concentrations µg/l to ng/l, pH ~8, DOC not too high, etc.) is to be performed before the antifouling active substances are evaluated for a potential renewal of the approval.

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