Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Tolylfluanid

Product type: 21

ECHA/BPC/007/2014

Adopted

17 June 2014

Opinion of the Biocidal Products Committee

on the approval of the active substance tolylfluanid 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:	**Tolylfluanid**
Chemical name(s):	**N-(Dichlorofluoromethylthio)-N',N'-dimethyl-N-p-tolylsulfamide**
EC No.:	**211-986-9**
CAS No.:	**731-27-1**
	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 by Lanxess Deutschland GmbH on 30 March 2006, the evaluating Competent Authority Finland submitted an assessment report and the conclusions of its evaluation to the Commission on 18 September 2012. 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.

Adoption of the BPC opinion

Rapporteur: BPC member for Finland

The BPC opinion on the approval of the active substance tolylfluanid in product type 21 was adopted on 17 June 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the tolylfluanid in product type 21 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. Opinion

2.1. 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 tolylfluanid in product type 21 (antifouling products). The biocidal activity of N-haloalkylthio compounds like tolylfluanid 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 tolylfluanid as manufactured and for the determination of impurities. Further validation data are required at product authorisation for the analytical methods of in seawater, residues in fish and shellfish, and in body fluids and tissues.

The current harmonised classification and labelling for Tolylfluanid containing < 0.1% (w/w) of particles with an aerodynamic diameter below 50µm (Index No 613-116-01-4) according to Regulation (EC) No 1272/2008 (CLP Regulation) is presented below. In addition, Aquatic Chronic 2 classification is proposed according to Regulation (EC) No 286/2011.

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Eye Irrit. 2; H319 STOT SE 3; H335 Skin Irrit. 2; H315 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 2; H411[§]
Labelling	
Pictograms	GHS07, GHS09
Signal Word	Danger
Hazard Statement Codes	H410:Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 10 (Aquatic Acute 1)
Justification for the proposal	
[§]Based on a NOEC of 0.04 mg/l for algae	

The current harmonised classification and labelling for Tolylfluanid containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm (Index No 613-116-00-7) according to Regulation (EC) No 1272/2008 (CLP Regulation) is presented below. In addition, Aquatic Chronic 2 classification is proposed according to Regulation (EC) No 286/2011.

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 2*; H330 STOT RE 1**; H372 Eye Irrit. 2; H319 STOT SE 3; H335 Skin Irrit. 2; H315 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 2; H411[§]
Labelling	
Pictograms	GHS07, GHS09
Signal Word	Danger
Hazard Statement Codes	H410:Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 10 (Aquatic Acute 1)
Justification for the proposal	
[§] Based on a NOEC of 0.04 mg/l for algae * minimum classification ** possible exclusion of exposure routes	

Tolylfluanid is already approved for product type 8 (Directive 2009/151/EC) where it was agreed that the assessment covered both entries of tolylfuanid, as the distintion between the two classifications is relevant only in exceptional situations in which the dry form of the substance is available. For product type 21 the dry forms have no special significance either so therefore the same approach can be followed as for product type 8.

Under the CLP Regulation a distinction can be made between category 1A and 1B for the classification as a skin sensitizer. This was not required under the previous dangerous substances legislation under which tolylfluanid was classified sensitizer R43. Tolylfluanid is not a highly potent sensitizer. Based on information available, there is no certainty on whether tolylfluanid could be classified other than category 1. In the single high-reliability compliant key study (Buehler assay) tolylfluanid was negative for skin sensitizing properties. The two other studies suggesting category 1A (GPMT) or a significant sensitizing property (open epicutaneous test, a key study) are of lower reliability or based with a non-compliant guideline according to current Guidance on the Application of the CLP criteria, respectively. Based on the Buehler assay and other information, including human data, the sub-category is proposed to be at least 1B.

b) Intended use, target species and effectiveness

The intended use of tolylfluanid in product type 21 is application by non-professionals and professionals via airless spray, brush or roller in a paint that can be applied to hulls of marine-going pleasure craft and professional application of marine going commercial ships.

The data on the active substance and the representative biocidal product (Interspeed Ultra) have demonstrated sufficient efficacy against soft fouling (e.g. bacteria, algae) and hard fouling organisms (barnacles and other invertebrates). Resistance has not been recorded due to the broad spectrum of algal and animal species controlled by the product and the general nature of the mode of action of active substance.

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

The overall conclusion from the evaluation of tolylflanid for use in product type 21 (antifouling products) is, that it may be possible for Member States to issue authorisations of products containing tolylfluanid 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 Regulation (EU) No 528/2012 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 existing active substances to reduce the risks for human health and for the environment from use of these substances[1].

Human health

The table below summarises the exposure scenarios assessed.

[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: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
professional mixing/loading	**Primary exposure**: mixing and loading antifouling product into reservoirs for airless spraying	professionals (potman)
professional spray application	**Primary exposure**: spray application of antifouling product via airless sprayer	professionals (sprayman)
professional brushing and rolling	**Primary exposure**: application of antifouling product by brush and roller	professionals
professional cleaning of a brush	**Primary:** cleaning of a brush	professionals
professional paint removal	**Primary exposure**: removal of antifouling paint by hydroblasting or grit blasting	professionals
non-professional brushing and rolling	**Primary exposure**: application of antifouling product by brush and roller	non-professionals
non-professional cleaning of a brush	**Primary:** cleaning of a brush	non-professionals
non-professional paint removal	**Primary exposure**: removal of antifouling paint by hydroblasting or grit blasting	non-professionals
cleaning work clothes at home	**Secondary exposure**: cleaning work clothes at home	non-professionals
child touching a boat surface	**Secondary exposure**: touching a wet boat (dermal route)	children

A quantitative risk assessment was conducted for systemic effects following exposures via inhalation and dermal routes. The professional scenarios represent long-term exposures. The non-professional scenarios represent acute/short-term exposure. For children touching a boat surface, the dermal route was considered relevant.

Systemic effects: with regard to the risk assessment for systemic effects, workers (professionals) should carry out tasks using appropriate personel protective equipment (PPE) by which exposure can be reduced to acceptable levels.

Combined exposure: there is no combined exposure foreseen with systemic doses from two tasks or exposure scenarios. Cleaning of a brush is already added in the scenarios of brush and roller application. No unacceptable risks were identified for non-professionals. For secondary exposure no unacceptable risks were identified for non-professionals or for a child touching a wet boat (dermal route considered only).

A specific concern was identified with respect to the use of the tolylfluanid in treated articles as tolyfluanid is classified as a sensitizer. No unacceptable risks as a result of local toxicity were identified for professionals and non-professionals.

Based on environmental monitoring and modelling relatively high concentrations of N,N-dimethylsulfamide, a persistent second degradation product of tolylfluanid, 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 genotoxic, mutagenic and carcinogenic (Carc. Cat. 2).

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenarios including environmental compartments**	
	Commercial ships	**Pleasure craft**
New building – application	Direct releases to marine surface water following spray application by professionals	Direct releases to soil and/or STP following spray, brush and roller application by professionals. Indirect releases to marine surface water via STP by professionals.
Maintenance and repair – application and removal of paint	Direct release to marine surface water following spray application and high pressure washing by professionals	Direct releases to soil (ground water) and/or STP following spray, brush and roller application by professionals and non-professionals. Direct releases to marine surface water by removal of paint by professionals and non-professionals. Indirect releases to marine surface water via STP by professionals and non-professionals.
In-service life stage	OECD-EU Commercial harbour OECD-EU Shipping lane	OECD-EU Marina
Aggregated exposure	Application and in-service releases were summed up. Removal and in-service releases were summed up.	Removal and in-service releases were summed up
For all scenarios evaluated the exposure is estimated within the harbour or marina as well as adjacent to the harbour and marina (defined as the wider environment). In addition, both for commercial and pleasure craft scenarios, worst case and typical case situations were evaluated.		

Aquatic compartment

No sediment risk assessment was carried out for tolylfluanid, because tolylfluanid degrades rapidly in water and was not detected in sediment in a water-sediment study. It was concluded that the surface water risk assessment covers also the sediment

Sediment risk assessment was, however, carried out for DMST and N,N-DMS as both degradation products of tolylfluanid were detected in sediment in >10% in the water-sediment study. These degradation products did not cause unacceptable risk to water or sediment organisms in any of the scenarios.

Commercial ships

For aggregated exposure of commercial ships, an unacceptable risk was identified in the commercial harbour in all scenarios except in typical case situations where removal releases were summed up with service-life releases. Risk mitigation methods are needed for the commercial harbour. In surrounding areas of the commercial harbour (wider environment), however, no unacceptable risks were identified.

For worst case new building application as well as application and removal of paint in maintenance and repair scenarios of commercial ships, unacceptable risks were identified in harbours. Risk mitigation methods are needed for these harbours. No unacceptable risk was identified for typical case situations in harbours and in surrounding areas (wider environment) of a harbour. Unacceptable risks of tolylfluanid were not identified from in-service use of commercial ships.

Pleasure crafts

For aggregated exposure of pleasure craft, unacceptable risk of tolylfluanid was identified in marinas, but not in surrounding areas (wider environment). Risk mitigation methods are needed for marinas.

Unacceptable risk of tolylfluanid was also identified in marinas from servive-life scenarios. Risk mitigation methods are needed.

No unacceptable risk was identified in any maintenance and repair scenarios, but unacceptable risks although hypothetical were identified for release via an STP in professional worst case application and removal of paint of pleasure craft. Risk mitigation methods are needed.

Groundwater

According to the groundwater risk assessment of N,N-DMS the groundwater limit value of 0.1 µg/l was exceeded in one of the scenarios (pleasure craft use). Risk mitigation is needed.

Terrestrial compartment

Tolylfluanid and DMST cause unacceptable risk to soil organisms from pleasure craft use from all applied scenarios. Risk mitigation is needed.

STP

No unacceptable risk of tolylfluanid or degradation products for the STP was identified.

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)	Tolylfluanid: Not P or vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	Tolylfluanid: Not B or vB
	Toxic (T)	Tolylfluanid: T
Endocrine disrupting properties	Tolylfluanid is not considered to have endocrine disrupting properties.	

Consequently, the following is concluded:

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

Tolylfluanid 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" agreed at the 54th meeting of the representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products[2]. 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 and d).

2.2.2. POP criteria

Tolylfluanid has been identified as T, but not considered to be P or B.

Tolylfluanid is not expected to have long-range transport potential because the estimated half-life in air of 21.5 hours is below the criterion of 2 days given for persistent organic pollutants (POP) as defined in the Annex D of the Stockholm Convention 2001.

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

In view of the conclusions of the evaluation, it is proposed that tolylfluanid shall be approved and be included in the Union list of approved active substances, subject to the

[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)

following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 960 g/kg

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

3. In the event that products containing tolylfluanid are subsequently authorised for use in non-professional antifouling products, persons making products containing tolylfluanid available on the market for non-professional users shall ensure that the products are supplied with appropriate gloves.

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

5. Authorisations are subject to the following conditions:

    a. For industrial or professional users, 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. Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry.

    c. 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 losses and minimize emissions to the environment, and that any losses or waste containing tolylfluanid shall be collected for reuse or disposal.

    d. 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 of the European Parliament and of the Council[3] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[4] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

    e. Where a treated article has been treated with or intentionally incorporates one or more biocidal products containing tolylfluanid, and where necessary due to the possibility of skin contact as well as the release of tolylfluanid under normal conditions of use of the article, the person responsible for placing the article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

The active substance gives rise to concern for both human health and environment, i.e. it is a skin sensitiser, and toxic to aquatic life of acute category 1 mentioned in Article 28(2) of the BPR. Therefore inclusion in Annex I of Regulation (EU) No 528/2012 is not acceptable.

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

2.4. Elements to be taken into account when authorising products

1. Tolylfluanid has been 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. Tolylfluanid 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 concentarions in surface water can be relatively high. For tolylfluanid 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 marina's adjacent to estuarine mouth with your boat treated with tolylfluanid containing antifouling products".

2. Whilst the efficacy data provided is sufficient to recommend approval of the active 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.

3. Products for brushing or rolling of antifouling paint may be used by non-professionals. The possibility of skin sensitisation to non-professionals from products containing tolylfluanid should be addressed by a risk assessment at product authorisation since the active substances is classified as a potential sensitiser.

4. Safe uses to the environment have been identified for scenarios representative of shipping lanes and the wider environment (i.e. areas adjacent to commercial harbours and marinas). A risk has been identified within marinas and commercial harbours. 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, permitting the proposal for the approval of tolylfluanid. However, further data shall be required as detailed below.

2.5.1. Residues monitoring method

<u>Seawater</u>

The LOQ of the presented method does not fulfil the requirements based on the PNEC. The method validation data must cover the LOQ required for tolylfluanid and DMST. Data must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (eCA).

Body fluids and tissues

The presented method in blood is not validated according to present guidelines. The validation data shall contain test results of the precision and accuracy of the method. Methods for the other relevant body tissues with sufficient validation should be submitted, or a justification for non-submission. Data must be provided as soon as possible but no later than 6 months before the date of approval to the eCA.

Fish and shellfish

No method for fish and shellfish is available. It has been substituted by methods in other matrices of animal origin. A fully validated method, including the linear range and the specificity, for fish and shellfish matrices shall be submitted for tolylfluanid. These data must be provided as soon as possible but no later than 6 months before the date of approval to the eCA.

2.5.2. Sorption data

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.

2.5.3. Human health scenarios

Cleaning of spray equipment scenario is included in the assessment report for information only, following discussions at the Biocides Technical Meeting. Further agreement and descriptive information from the antifouling industry on this scenario, submitted in May 2014 to the eCA, was not included as it had not yet been discussed at the ad hoc Working group on Human Exposure. Should this ad hoc Working Group consider it an appropriate scenario for all antifouling products with spray applications, the scenario might be included in the risk assessment at product authorisation stage.

Due to a possible risk for children touching wet paint on boats, also oral exposure after hand-to-mouth contact shall be evaluated at product authorisation stage depending on discussions at the ad hoc Working group on Human Exposure.

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