Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Tolylfluanid

Product type: 7

ECHA/BPC/083/2015

Adopted

9 December 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance tolylfluanid for product type 7

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 7 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 30th October 2008, the evaluating Competent Authority Finnish Safety and Chemicals Agency submitted an assessment report and the conclusions of its evaluation to the ECHA on 17th March 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member of Finland

The BPC opinion on the approval of the active substance tolylfluanid in product type 7 was adopted on 9 December 2015.

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 7 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 tolylfluanid in product type 7. 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 the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are required and available for the relevant matrices [soil, air, water]. Regarding analytical methods in animal and body fluids further validation is needed for analytical methods in blood and required at product authorisation (see section 2.5).

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

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
Labelling	
Pictograms	GHS07, GHS09
Signal Word	Warning
Hazard Statement Codes	H319 Causes serious eye irritation H335 May cause respiratory irritation H315 Causes skin irritation H317 May cause an allergic skin reaction H400:Very toxic to aquatic life
Specific Concentration limits, M-Factors	M =10 (Aquatic Acute 1)

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.

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
Labelling	
Pictograms	GHS07, GHS09
Signal Word	Danger
Hazard Statement Codes	H330 Fatal if inhaled H372 Causes damage to organs through prolonged or repeated exposure H319 Causes serious eye irritation H335 May cause respiratory irritation H315 Causes skin irritation H317 May cause an allergic skin reaktion H400:Very toxic to aquatic life
Specific Concentration limits, M-Factors	M = 10 (Aquatic Acute 1)

Tolylfluanid is already approved for product type 8 (Commission Directive 2009/151/EC) and product type 21 (Commission Implementing Regulation (EU) 2015/419) where it was agreed that the assessment covered both entries of tolylfuanid, as the distinction between the two classifications is relevant only in exceptional situations in which the dry form of the substance is available.

Regarding environment Aquatic Chronic 1 H410 with M=1 (Aquatic Chronic) classification is proposed according to Regulation (EC) No 286/2011. This is based on a NOEC of 0.00265 mg/l for *Daphnia magna.*

b) Intended use, target species and effectiveness

Tolylfluanid in PT7 is intended to be used mainly against moulds to protect paint film on wooden surfaces outdoors (corresponding to wood preservative use class 2 and 3). The end-use product, i.e. the paint, is used by professionals and non-professionals.

The data on tolylfluanid and the representative biocidal product have demonstrated sufficient efficacy against the target species, i.e. moulds. It can be concluded that 0.20-0.30% of tolylfluanid in end-use product (i.e. the paint) will likely be efficacious towards target organisms. However, additional tests under in-use conditions should be performed at product authorization stage.

Resistance has not been recorded due to the general nature of the mode of action of the active substance.

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

Human health

The evaluation of active substance indicated that tolylfluanid is a moderate skin sensitizer and an irritant of eye, skin and whole respiratory system. The acute inhalation toxicity depends on the content of the particles with an aerodynamic diameter below 50 µm. Tolylfluanid containing >0.1% of particles with an aerodynamic diameter below 50 µm is classified as fatal by inhalation and to cause damage to lungs through prolonged or

repeated exposure. Independent of the particle size, tolylfluanid effects during short term or subchronic exposure are targeted to thyroid, liver and kidneys but it is not proposed to be classified as mutagenic substance. It is free of carcinogenic effects as well as adverse effects on reproduction and development.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Production of end-use products	Primary exposure - Industrial use	Professionals	Acceptable with gloves, coated coveralls
Maintenance of machines	Primary exposure - Industrial use	Professionals	Acceptable after rinsing with gloves, coated coveralls
Manual Dipping	Primary exposure*	Professionals	Acceptable
Mechanical Dipping	Primary exposure*	Professionals	Acceptable with gloves, coated coveralls
Cleaning out dipping tank	Primary exposure*	Professionals	Acceptable
Spraying (incl. cleaning of the spray)	Primary exposure*	Professionals	Acceptable with gloves, impermeable coveralls, RPE (APF 10)
Brushing (incl. cleaning of the brush)	Primary exposure*	Professionals	Acceptable with gloves, coated coveralls
		Non-professionals	Acceptable for use outdoors
Handling of treated wet wood	Primary exposure*	Professionals	Acceptable
Sanding coated wood	Secondary exposure	Professionals	Acceptable
		Non-professionals	Acceptable
Cleaning work clothes at home	Secondary exposure	Professionals	Acceptable
Infant chewing wood off-cut	Secondary exposure	Infant	Acceptable
Dermal contact with wet paint	Secondary exposure	Toddler	Acceptable
Infant contacting wet paint and mouthing	Secondary exposure	Infant	Acceptable
Infant playing on coated wood structures and mouthing	Secondary exposure	Infant	Acceptable
Chronic inhalation exposure to evaporated residues	Secondary exposure	Child	Acceptable

* Primary exposure to the end-use product treated with tolylfuanid

Local Effects
Considering the CLP sub-categories (Skin Sens. 1A and 1B), tolylfluanid is not a highly potent sensitizer. Based on the 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 on 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. In addition, the concentrations of tolylfluanid in the end use products (max. 0.9%) are below the threshold for classification of the end use product according to Regulation (EC) No 1272/2008. Due to skin sensitizing property PPE (gloves, coveralls) are required in the industrial use of the biocidal product and eye-protectors in the tasks where splashes may occur. Furthermore, secondary exposure to tolylfluanid in treated articles may occur also to the tolylfluanid concentration below the threshold for classification of the product as sensitizing. Consequently, risks as a result of local toxicity are considered to be acceptable for professionals and non-professionals.

Systemic effects
Professional and non-professional systemic exposures were evaluated for the scenarios summarized in the table above. Safe uses were identified for professionals when wearing appropriate personal protective equipment. The use of gloves and coated coveralls is obligatory in all primary exposure scenarios except in manual dipping and cleaning of dipping tanks where systemic exposure is acceptable even without personal protective equipment (PPEs). Maintenance of production machines is acceptable only after rinsing the system prior to the maintenance work. Impermeable coveralls and respiratory protection equipment (RPE) in addition to the gloves are obligatory during spraying. Non-professional painting with a brush is safe outdoors. Non-professionals painting indoors is not a safe use due to conservative indoor painting model which assumes painting overhead. It is concluded that the secondary exposure to tolylfluanid in coatings does not pose a risk to non-professionals or professionals.

Based on groundwater risk assessment concentrations of N,N-dimethylsulfamide (N,N-DMS), a persistent second degradation product of tolylfluanid, are elevated and cause concern in relation to groundwater 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 groundwater containing N,N-DMS. 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 scenario including environmental compartments**	**Conclusion for tolylfluanid and N,N-DMS**
Industrial application, dipping	Emission to STP and to surface water/sediment via STP.	Acceptable to STP. Unacceptable to surface water/sediment (tolylfluanid).
Industrial application, storage after dipping	Emission to surface water/sediment and to soil from stored wood after dipping	Acceptable to surface water. Unacceptable to soil (N,N-DMS)..
Industrial application, automated spraying	Emission from small plant and large plant to STP and to surface water/sediment via STP	Acceptable to STP. Unacceptable to surface water/sediment from large plant (tolylfluanid).
Industrial application, storage after automated spraying	Emission from small plant and large plant to surface water/sediment and to soil from stored wood automated sprayed	Acceptable to surface water/sediment. Unacceptable to soil (N,N-DMS) .
Noise barrier, in service	Emission to STP, to surface water via STP and direct emission to soil	Acceptable
House, in service and in situ application	Emission to soil and groundwater. In service leaching after brushing and dipping/spraying, professional and non-professional in situ applications and combined in situ and in service. professional and non-professional application. Groundwater risk was calculated by using application rate from the house scenario and PEARL 3.3.3.	Unacceptable to groundwater (N,N-DMS). Unacceptable to soil in situ application by professionals and non-professionals (tolylfluanid) and by non-professionals (DMST).
Fence, in service and in situ application	Emission to soil. In service leaching after brushing and dipping/spraying, professional and non-professional in situ applications and combined in situ and in service.	Unacceptable in situ application by professional and non-professionals (tolylfluanid).
Bridge over pond, in service and in situ application	Emission to surface water. In service leaching after brushing and dipping/spraying, professional and non-professional in situ applications and combined in situ and in service.	Unacceptable in situ application by professionals and non-professionals (tolylfluanid).
City scenario, outdoor application; paint applied on window and door frames and doors	Emission to STP, via STP to surface water, soil and groundwater (pore water) from service life and application phase of professionals and non-professionals.	Acceptable
Direct emission to surface water in urban areas (storm water scenario)	Emission to surface water from service life and application phase of professionals and non-professionals after bypass of STP (mixed sewer system) and direct rainwater discharge (separate sewer system).	Acceptable after bypass. Unacceptable tolylfluanid from service life and non-professional application after direct discharge (tolylfluanid).

Unacceptable risk to surface water organisms from industrial dipping and automated spraying applications of paints containing tolylfluanid as a film preservative from large plant are not very likely due to the fact that industrial plants, in general, do not have direct connection to the STP and residues from industrial uses are to be recovered and treated as hazardous waste.

Unacceptable risk of N,N-DMS to soil organisms identified after 20 years of storage after dipping and automated spraying is not very likely either, because wood treated with paints containing tolylfluanid as a film preservative is not generally stored outside.

Besides, unacceptable risk of tolylfluanid to aquatic and soil organisms after in situ application at day 1is transient due to the rapid degradation of tolyfluanid in water and soil.

Groundwater risk caused by very mobile and persistent degradation product N,N-DMS cannot be excluded. The groundwater concentrations of N,N-DMS exceed the drinking water standard of 0.1 µg/l (Drinking water directive 98/83/EC4) as well as groundwater quality standard of 0.1 µg/l (Groundwater directive 118/2006/EC5) in the house scenario. In addition, calculated theoretical NDMA concentrations are also high and exceed the drinking water standard of 0.1 µg/l and the specific health based value (HBV) of 0.1 µg/l set for NDMA by the WHO. Although groundwater is seldom ozonated as such, ozone can be used for removing impurities from raw water, also in groundwater. In small municipalities, where surface water and groundwater are mixed, ozonation can take place after mixing. No appropriate risk mitigation methods are available in order to prevent possible groundwater pollution.

Based on the city scenario and the direct emission to surface water in urban areas scenario (storm water scenario) it can be concluded that a restricted use of paints containing tolylfluanid as a film preservative for outdoor application for window and door frames and doors is acceptable for service life and professional applications. The slight risk identified from direct rainwater discharge to surface water (separate sewer system) from service life can be considered as minor because worst case leaching rates are used for the evaluation. The risk identified from direct rainwater discharge to surface water (separate sewer system) during non-professional application can be mitigated protecting the painting area from spills.

Overall conclusion

Regarding human health safe use is identified for industrial and professional users when wearing appropriate personal protective equipment and for non-professionals applying paint with tolylfluanid as film preservative outdoors. For non-professional users when considering painting overhead indoors a risk was identified with the paint containing high concentrations of tolyfluanid. For the environment when the wood preservative scenarios for outdoor use (Use Class 3) are considered, a risk was identified for ground water from the metabolite N,N-DMS. However, a safe use for environment for outdoor paint is identified when a restricted use for window and door frames and doors are considered. This restricted use is safe for non-professional and professional users and the environment.

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	Tolyfluanid does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP	Tolylfluanid does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB	
	Toxic (T)	T	
Endocrine disrupting properties	Tolylfluanid is not considered to have endocrine disrupting properties. Tolylfluanid does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Tolylfluanid does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Tolylfuanid does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	As the proportion of impurities is below 20%, tolylfluanid does not fulfil criterion (f) of Article 10(1).		

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"[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).

[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

Tolylfluanid does not fulfil criteria for being a persistent organic pollutant (POP).

Tolylfluanid does not have potential for long-range transboundary atmospheric transport.

2.3. BPC opinion on the application for approval of the active substance tolylfluanid in product type 7

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 following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 96% w/w.
2. The authorisations of biocidal products are subject to the following condition(s):
    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
    b. In view of the possible risks identified for the uses assessed, the product assessment shall pay particular attention to:
        i. Industrial or professional users;
        ii. Non-professional users of treated paints containing tolylfluanid as a film preservative;
        iii. Surface water, soil and ground water, including the risk from degradation products.
3. The placing on the market of treated articles is subject to the following condition(s):
    a. The person responsible for the placing on the market of a treated article treated with or incorporating tolylfluanid 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.

2.4. Elements to be taken into account when authorising products

1. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
    a. If an unacceptable risk for professional users is identified, then safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment.
    b. An unacceptable risk is identified for non-professional in-door use of the treated mixtures containing tolyfluanid as a film or coating preservative. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, products should not be authorised for this use.
    c. If unacceptable risks are identified for the soil compartment following in situ application of the mixtures containing tolylfluanid as a film or coating

preservative, labels, and where provided, safety data sheets of biocidal products shall indicate that measures should be taken to protect the soil during the outdoor application of the treated mixtures to minimise emissions to the environment.

d. If unacceptable risks are identified for the surface water following in-situ application outdoors of the mixtures containing tolylfluanid as a film or coating preservative, labels and where provided safety data sheets of biocidal products shall indicate that treated mixtures shall not be used for outdoor constructions near or above water.

e. Tolylfluanid degrades to the persistent substance N,N-DMS which may form N-nitrosodimethylamine (NDMA) when water containing N,N-DMS is extracted for production of drinking water and ozonated. An unacceptable risk is identified for groundwater following outdoor application of the mixtures containing tolylfluanid as a film or coating preservative considering the risks from N,N-DMS and possible formation of NDMA after ozonation. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, products shall not be authorised for this use.

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.

For the method of analytical determination of tolylfluanid in body fluids and tissues further validation data should be submitted 6 months before the date of approval to the evaluating CA.

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