# Commission Implementing Regulation (EU) 2015/419 of 12 March 2015 approving tolylfluanid as an active substance for use in biocidal products for product-type 21 (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) 2015/419

of 12 March 2015

approving tolylfluanid as an active substance for use in biocidal products for product-type 21

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[(2)] establishes a list of active substances to be evaluated with a view to their possible approval for use in biocidal products or inclusion into Annex I to Regulation (EU) No 528/2012. That list includes tolylfluanid.

(2) Tolylfluanid has been evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012 for use in biocidal products for product-type 21, antifouling products, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Finland was designated as evaluating competent authority and submitted an assessment report, together with its recommendations, to the Commission on 18 September 2012 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007[(3)].

(4) The opinion of the European Chemicals Agency was formulated on 17 June 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products used for product-type 21 and containing tolylfluanid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC of the European Parliament and of the Council[(4)] provided that certain specifications and conditions relating to its use are satisfied.

(6) Nevertheless, the acceptability of the risks related to the use of antifouling products, as well as the suitability of the proposed risk mitigation measures, need to be further confirmed. In order to facilitate, at the time of the renewal of the approvals of existing antifouling active substances, the review and comparison of the risks and benefits of

these substances as well as of the risk mitigation measures applied, the expiry date of approval of these substances should be the same.

(7) It is therefore appropriate to approve tolylfluanid for use in biocidal products for product-type 21 subject to compliance with certain specifications and conditions.

(8) Since the evaluations did not address nanomaterials, the approval should not cover such materials in accordance with Article 4(4) of Regulation (EU) No 528/2012.

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

Tolylfluanid shall be approved as an active substance for use in biocidal products for product-type 21, subject to the specifications and conditions set out in the Annex.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 March 2015.

*For the Commission*

*The President*

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/419. (See end of Document for details)*

ANNEX

| **Common Name** | **IUPAC NameIdentification Numbers** | **Minimum degree of purity of the active substance**[a] | **Date of approval** | **Expiry date of approval** | **Product type** | **Specific conditions**[b] |
|---|---|---|---|---|---|---|
| Tolylfluanid | IUPAC Name: N-(Dichlorofluoromethylthio)-N′,N′-dimethyl-N-p-tolylsulfamide EC No: 211-986-9 CAS No: 731-27-1 | 960 g/kg | 1 July 2016 | 31 December 2025 | 21 | 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. In the event that products containing tolylfluanid are subsequently authorised for use by non-professional users, persons making products containing tolylfluanid available |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | on the market for non-professional users shall ensure that the products are supplied with appropriate gloves.<br>For biocidal products, authorisations are subject to the following conditions:<br>(1) Products containing tolylfluanid shall not be authorised or used to control the growth and settlement of fouling organisms on freshwater going vessels.<br>(2) 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. |
| | | | | | | (3) | Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry. |
| | | | | | | (4) | Labels and, where provided, safety data sheets |