Commission Implementing Regulation (EU) No 1091/2014 of 16 October 2014 approving tralopyril as a new active substance for use in biocidal products for product-type 21 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1091/2014

of 16 October 2014

approving tralopyril as a new 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 Article 90(2) thereof,

Whereas:

(1) The United Kingdom has received on 17 July 2007 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[(2)], for the inclusion of the active substance tralopyril in its Annex I for use in product-type 21, antifouling products, as defined in Annex V to that Directive.

(2) Tralopyril was not on the market on 14 May 2000 as an active substance of a biocidal product.

(3) The United Kingdom submitted the assessment report, together with its recommendations, to the Commission on 1 September 2009 in accordance with Article 11(2) of Directive 98/8/EC.

(4) The opinion of the European Chemicals Agency was formulated on 8 April 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) It appears from that opinion that biocidal products used for product-type 21 and containing tralopyril may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain specifications and conditions relating to its use are satisfied.

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

(7) Since the evaluations did not address nanomaterials, the approvals should not cover such materials pursuant to Article 4(4) of Regulation (EU) No 528/2012.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1091/2014. (See end of Document for details)*

(8) 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 laid down.

(9) 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

Tralopyril 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, 16 October 2014.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1091/2014. (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]
Tralopyril	IUPAC Name: 4-bromo-2-(4-chlorophenyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile EC No: N/A CAS No: 122454-29-9	975 g/kg	1 April 2015	31 March 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 tralopyril are subsequently authorised for use in non-professional antifouling products, persons making products containing tralopyril

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						available on the market for non-professional users shall ensure that the products are supplied with appropriate gloves. Authorisations are subject to the following conditions: (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)	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 impermeable hard standing with bunding