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.

(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.

[1] OJ L 167, 27.6.2012, p. 1.
[2] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

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

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions (2)
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 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 or on soil covered with an impermeable material to prevent losses and minimise emissions to the environment, and that any losses or waste containing tralopyril shall be collected for reuse or disposal.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions (2)
						(4) 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.

(1) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 8 of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

(2) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/environment/chemicals/biocides/index_en.htm

(3) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(4) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).