

COMMISSION IMPLEMENTING REGULATION (EU) No 437/2014**of 29 April 2014****approving 4,5-Dichloro-2-octyl-2H-isothiazol-3-one as an existing 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 Regulation (EC) No 1451/2007 ⁽²⁾ establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council ⁽³⁾. That list includes 4,5-Dichloro-2-octyl-2H-isothiazol-3-one.
- (2) 4,5-Dichloro-2-octyl-2H-isothiazol-3-one has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 21, antifouling products, as defined in Annex V to that Directive, which corresponds to product-type 21 as defined in Annex V to Regulation (EU) No 528/2012.
- (3) Norway was designated as Rapporteur and submitted the competent authority report, together with a recommendation, to the Commission on 21 December 2010 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.
- (4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated in an assessment report reviewed within the Standing Committee on Biocidal Products on 13 March 2014.
- (5) According to that assessment report, biocidal products used for product-type 21 and containing 4,5-Dichloro-2-octyl-2H-isothiazol-3-one 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 4,5-Dichloro-2-octyl-2H-isothiazol-3-one for use in biocidal products for product-type 21 subject to compliance with such specifications and conditions.
- (7) Since the evaluation did not address nanomaterials, the approval 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

4,5-Dichloro-2-octyl-2H-isothiazol-3-one 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⁾ Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).⁽³⁾ 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, 29 April 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⁾
4,5-Dichloro-2-octyl-2H-isothiazol-3-one	IUPAC Name: 4,5-Dichloro-2-octylisothiazol-3(2H)-one EC No: 264-843-8 CAS No: 64359-81-5	950 g/kg	1 January 2016	31 December 2025	21	<p>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.</p> <p>Persons making products containing 4,5-Dichloro-2-octyl-2H-isothiazol-3-one available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves.</p> <p>Authorisations are subject to the following conditions:</p> <p>(1) 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.</p> <p>(2) Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry.</p> <p>(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 minimize emissions to the environment, and that any losses or waste containing 4,5-Dichloro-2-octyl-2H-isothiazol-3-one shall be collected for reuse or disposal.</p> <p>(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.</p>

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⁾
						Where an article has been treated with or intentionally incorporates one or more biocidal products containing 4,5-Dichloro-2-octyl-2H-isothiazol-3-one and where necessary due to the possibility of skin contact as well as the release of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one 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.

⁽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/comm/environment/biocides/index.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).