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)

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.

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(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.

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 437/2014. (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]
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	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. 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

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						are supplied with appropriate gloves. Authorisations are subject to the following conditions: (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. (2) Labels and, where provided, instructions for use

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							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