

DIRECTIVES

COMMISSION DIRECTIVE 2011/66/EU

of 1 July 2011

amending Directive 98/8/EC of the European Parliament and of the Council to include 4,5-Dichloro-2-octyl-2H-isothiazol-3-one as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ⁽¹⁾, and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

- (1) 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 ⁽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. That list includes 4,5-Dichloro-2-octyl-2H-isothiazol-3-one.
- (2) Pursuant to Regulation (EC) No 1451/2007, 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 8, wood preservatives, as defined in Annex V to that Directive.
- (3) Norway was designated as Rapporteur and submitted the competent authority report, together with a recommendation, to the Commission on 8 September 2008 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, within the Standing Committee on Biocidal Products on 16 December 2010, in an assessment report.
- (5) It appears from the evaluations that biocidal products used as wood preservatives 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. It is therefore appropriate to include 4,5-Dichloro-2-octyl-2H-isothiazol-3-one in Annex I to that Directive.

- (6) Not all potential uses have been evaluated at Union level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.
- (7) In view of the risks identified for human health, it is appropriate to require that safe operational procedures are established for products authorised for industrial or professional use, and that those products are used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means.
- (8) In view of the risks identified for the aquatic and terrestrial compartments, it is appropriate to require that freshly treated timber is stored after treatment under shelter or on impermeable hard standing, or both, and that any losses from the application of products used as wood preservatives and containing 4,5-Dichloro-2-octyl-2H-isothiazol-3-one are collected for reuse or disposal.
- (9) Unacceptable risks for the environment were identified in various scenarios for in-service use of treated wood not covered and not in contact with the ground, which is either continually exposed to the weather or protected from the weather but subject to frequent wetting (use class 3 as defined by OECD ⁽³⁾) and wood in contact with fresh water (use class 4b as defined by OECD ⁽⁴⁾). It is therefore appropriate to require that products are not authorised for the treatment of wood intended for those uses, unless data is submitted demonstrating that the product will meet the requirements of both Article 5 of and Annex VI to Directive 98/8/EC, if necessary by the application of appropriate risk mitigation measures.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

⁽³⁾ OECD series on emission scenario documents, Number 2, Emission Scenario Document for Wood Preservatives, Part 2, p. 64.

⁽⁴⁾ Ibid.

- (10) It is important that the provisions of this Directive be applied simultaneously in all Member States in order to ensure equal treatment of biocidal products on the market containing the active substance 4,5-Dichloro-2-octyl-2H-isothiazol-3-one and also to facilitate the proper operation of the biocidal products market in general.
- (11) A reasonable period should be allowed to elapse before an active substance is included in Annex I to Directive 98/8/EC in order to permit Member States and interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.
- (12) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.
- (13) Directive 98/8/EC should therefore be amended accordingly.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall adopt and publish, by 30 June 2012 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 July 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 1 July 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following entry is added:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
44	4,5-Dichloro-2-octyl-2H-isothiazol-3-one	4,5-Dichloro-2-octyl-isothiazol-3(2H)-one EC No: 264-843-8 CAS No: 64359-81-5	950 g/kg	1 July 2013	30 June 2015	30 June 2023	8	<p>When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.</p> <p>Products shall not be authorised for treatment of wood that will be continually exposed to the weather, protected from the weather but subject to frequent wetting or in contact with fresh water, unless data have been submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(1) for products authorised for industrial or professional use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means;</p> <p>(2) labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing under roof, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.'</p>

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: <http://ec.europa.eu/comm/environment/biocides/index.htm>