COMMISSION DIRECTIVE 2008/80/EC

of 28 July 2008

amending Directive 98/8/EC of the European Parliament and of the Council to include cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO) as an active substance in Annex I thereto

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 Annexes I, IA or IB to Directive 98/8/EC. That list includes cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO).

(2) Pursuant to Regulation (EC) No 1451/2007, K-HDO 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 Directive 98/8/EC.

(3) Austria was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 22 March 2006 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 22 February 2008, in an assessment report.

(5) Although the risk assessment was limited to very specific application systems, it appears from the examinations made that biocidal products used as wood preservatives and containing K-HDO may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include K-HDO in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing K-HDO can be granted, modified or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) Not all potential uses have been evaluated at the Community level. It is therefore appropriate that Member States pay particular attention to the risks to the compartments and populations that have not been representatively addressed in the Community level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks to acceptable levels.

(7) In particular, in view of the possible risks for the environment and workers, authorisations for products to be used in other systems than industrial, fully automated and closed ones should not be granted unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in accordance with Article 5 of Directive 98/8/EC and Annex VI thereto.

(8) In the light of the findings of the assessment report, it is appropriate to require that products containing K-HDO be used with appropriate protective equipment. In view of the risks identified for infants, it is also appropriate to require that K-HDO not be used for the treatment of wood that may come in direct contact with infants.

(9) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance K-HDO and also to facilitate the proper operation of the biocidal products market in general.

[1] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2008/31/EC (OJ L 81, 20.3.2008, p. 57).
[2] OJ L 325, 11.12.2007, p. 3.

(10) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the 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.

(11) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 8 containing K-HDO to ensure that they comply with Directive 98/8/EC.

(12) Directive 98/8/EC should therefore be amended accordingly.

(13) 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 2009 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2010.

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, 28 July 2008.

For the Commission

Stavros DIMAS

Member of the Commission

ANNEX

The following entry 'No 10' is inserted in Annex I to Directive 98/8/EC

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 (*)
'10	K-HDO	Cyclohexylhydroxydiazene 1-oxide, potassium salt EC No: n/a CAS No: 66603-10-9 (This entry also covers the hydrated forms of K-HDO)	977 g/kg	1 July 2010	30 June 2012	30 June 2020	8	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, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) in view of the possible risks for the environment and workers, products shall not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in accordance with Article 5 and Annex VI; (2) in view of the assumptions made during the risk assessment, products must be used with appropriate personal protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means; (3) in view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.'

(*) 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