

COMMISSION DIRECTIVE 2009/87/EC**of 29 July 2009****amending Directive 98/8/EC of the European Parliament and of the Council to include indoxacarb 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 Article 11(4) thereof,

Whereas:

- (1) The United Kingdom (UK) has received on 12 December 2005 an application from DuPont de Nemours S.A., in accordance with Article 11(1) of Directive 98/8/EC, for the inclusion of the active substance indoxacarb in its Annex I or IA for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to Directive 98/8/EC. Indoxacarb was not on the market on the date referred to in Article 34(1) of Directive 98/8/EC as an active substance of a biocidal product.
- (2) After carrying out an evaluation, the UK submitted a competent authority report, together with a recommendation, to the Commission on 5 March 2007.
- (3) The competent authority report was reviewed by the Member States and the Commission within the Standing Committee on Biocidal Products on 28 May 2008, and the findings of the review were incorporated in an assessment report.
- (4) It appears from the examinations made that biocidal products used as insecticides, acaricides or to control other arthropods and containing indoxacarb may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include indoxacarb in Annex I.
- (5) Not all potential uses have been evaluated at the Community level. It is therefore appropriate that Member States assess those 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.

(6) In the light of the findings of the assessment report, it is also appropriate to require that risk mitigation measures are applied at product authorisation level to products containing indoxacarb and used as insecticides, acaricides or to control other arthropods.

(7) Such measures should be aimed at limiting the risks to non-target species and the aquatic environment. To this end, certain conditions such as ensuring that products are not placed in areas accessible to infants, children and companion animals and do not enter into contact with water should be imposed.

(8) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.

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

(10) The Standing Committee on Biocidal Products was consulted on 30 May 2008 and delivered a positive opinion on the draft Commission Directive amending Annex I of Directive 98/8/EC to include indoxacarb as an active substance. On 11 June 2008 the Commission submitted the said draft for scrutiny by the European Parliament and the Council. The European Parliament did not oppose the draft measures within the set deadline. The Council opposed the adoption by the Commission indicating that the proposed measures exceeded the implementing powers provided for in Directive 98/8/EC. As a consequence, the Commission did not adopt the draft measures and submitted an amended draft of the concerned Directive to the Standing Committee on Biocidal Products. The Standing Committee was consulted on the said draft on 20 February 2009.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

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.

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

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 6 months after its entry into force.

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.

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, 29 July 2009.

For the Commission

Stavros DIMAS

Member of the Commission

ANNEX

The following entry 'No 19' 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 (*)
'19	Indoxacarb (enantiomeric reaction mass S:R 75:25)	Reaction mass of methyl (S)- and methyl(R)-7-chloro-2,3,4a,5-tetrahydro-2-[methoxycarbonyl-(4-trifluoromethoxyphenyl) carbamoyl]indeno[1,2-e][1,3,4]oxadiazine-4a-carboxylate (This entry covers the 75:25 reaction mass of the S and R enantiomers) EC No: n/a CAS No: S-enantiomer: 173584-44-6 and R-enantiomer: 185608-75-7)	796 g/kg	1 January 2010	n/a	31 December 2019	18	<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, 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.</p> <p>When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.</p> <p>Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans, of non-target species and of the aquatic environment. In particular, labels and/or safety-data sheets of products authorised shall indicate that:</p>

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 (*)
								<ol style="list-style-type: none"> 1. Products shall not be placed in areas accessible to infants, children and companion animals. 2. Products shall be positioned away from external drains. 3. Unused products shall be disposed of properly and not washed down the drain. <p>For amateur uses, only ready-to-use products shall be authorised.'</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>