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THE EUROPEAN UNION**

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COVER NOTE

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to:	General Secretariat of the Council of the European Union
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Subject:	Commission Directive ../../EU of XXX amending Directive 98/8/EC of the European Parliament and of the Council to included DDACarbonate as an active substance in Annex I thereto

Delegations will find attached Commission document D019084/02.

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EUROPEAN COMMISSION

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COMMISSION DIRECTIVE ../.../EU

of **XXX**

**amending Directive 98/8/EC of the European Parliament and of the Council to include
DDACarbonate as an active substance in Annex I thereto**

(Text with EEA relevance)

COMMISSION DIRECTIVE ../.../EU

of XXX

amending Directive 98/8/EC of the European Parliament and of the Council to include DDACarbonate 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 market¹, and in particular Article 11(4) thereof,

Whereas:

- (1) The United Kingdom received on 17 January 2007 an application from Lonza, in accordance with Article 11(1) of Directive 98/8/EC, for the inclusion of the active substance DDACarbonate in Annex I to that Directive for use in product-type 8, wood preservatives, as defined in Annex V to Directive 98/8/EC. DDACarbonate 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 United Kingdom submitted its report, together with a recommendation, to the Commission on 11 November 2010.
- (3) The report was reviewed by the Member States and the Commission within the Standing Committee on Biocidal Products on 2 March 2012, and the findings of the review were incorporated in an assessment report.
- (4) It appears from the evaluations that biocidal products used as wood preservatives and containing DDACarbonate may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include DDACarbonate for use in product type 8 in Annex I to that Directive.
- (5) Not all potential uses have been evaluated at Union level. For example, use by non-professional users was not assessed. It is therefore appropriate to require 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

¹ OJ L 123, 24.4.1998, p. 1.

appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.

- (6) In view of the risks identified for human health, for industrial users it is appropriate to require that safe operational procedures are established, and that products are used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means.
- (7) In view of the risks identified for the aquatic and terrestrial compartments, it is appropriate to require that industrial application is conducted within a contained area or on impermeable hard standing with bunding, 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 DDACarbonate are collected for reuse or disposal.
- (8) Unacceptable risks for the environment were identified for situations where wood treated by dipping with DDACarbonate was continually exposed to the weather or subject to frequent wetting (use class 3 as defined by OECD²), and where wood treated with DDACarbonate was used for outdoor constructions near or above water (the 'bridge' scenario in use class 3, as defined by OECD³) or was in contact with fresh water (use class 4b as defined by OECD⁴). 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.
- (9) The provisions of this Directive should be applied simultaneously in all Member States in order to ensure equal treatment on the Union market of biocidal products of product-type 8 containing the active substance DDACarbonate and also to facilitate the proper operation of the biocidal products market in general.
- (10) 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 to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.
- (11) Directive 98/8/EC should therefore be amended accordingly.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

² OECD series on emission scenario documents, Number 2, Emission Scenario Document for Wood Preservatives, part 2, p. 64.

³ Ibid.

⁴ Ibid.

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, by 31 January 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

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 (*)
"(**) [OPOC E: please insert substan ce number]	DDACar bonate	Reaction mass of N,N-Didecy]-N,N-dimethylammonium Carbonate and N,N-Didecy]-N,N-dimethylammonium Bicarbonate EC No: 451-900-9 CAS No: 894406-76-9	Dry weight: 740 g/kg	1 February 2013	Not applicable	31 January 2023	8	<p>The Union level risk assessment did not address all potential uses; certain uses, such as use by non-professionals, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where 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>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(1) For industrial users safe operational procedures shall be</p>

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								established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means;
								(2) labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, 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;
								(3) products shall not be authorised

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 (*)
								for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, or for treatment by dipping of wood that will be continually exposed to the weather or subject to frequent wetting, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures."

(*) 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>