EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving cyanamide as an existing active substance for use in biocidal products of product-types 3 and 18

(Text with EEA relevance)

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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 Delegated Regulation (EU) No 1062/2014[2] establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes cyanamide.

(2) Cyanamide has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council[3] for use in product-type 3, veterinary hygiene biocidal products, and product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive, which correspond to product-types 3 and 18 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 30 July 2013.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency ("the opinions") were formulated on 16 June 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to the opinions, biocidal products of product-types 3 and 18 containing cyanamide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(6) It is therefore appropriate to approve cyanamide for use in biocidal products of product-types 3 and 18, subject to compliance with certain specifications and conditions.

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1 OJ L 167, 27.6.2012, p. 1.

2 Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

3 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 (OJ L 123, 24.4.1998, p. 1).

(7) The opinions conclude that cyanamide meets the criteria for classification as carcinogenic category 2 and toxic for reproduction category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[4].

(8) Pending the adoption of scientific criteria for the determination of endocrine-disrupting properties, active substances that meet the criteria to be classified as carcinogenic category 2 and as toxic for reproduction category 2 are to be considered as having endocrine-disrupting properties. Cyanamide is therefore to be considered as having endocrine-disrupting properties, and as meeting the exclusion criterion set in Article 5(1)(d) of Regulation (EU) No 528/2012.

(9) Pursuant to Article 90(2) of Regulation (EU) No 528/2012, substances for which the Member States' evaluation has been completed by 1 September 2013 are to be approved in accordance with Directive 98/8/EC. The period of approval should be restricted to 5 years in accordance with the practice established under that Directive.

(10) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, cyanamide meets the conditions of Article 10(1)(a) of that Regulation and should therefore be considered a candidate for substitution.

(11) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities are required to evaluate whether the conditions of Article 5(2) of that Regulation can be satisfied to decide if a biocidal product containing cyanamide can be authorised or not.

(12) Since cyanamide is to be considered as having endocrine-disrupting properties, and meets the criteria for classification as skin sensitiser category 1 as defined in Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating cyanamide should be appropriately labelled when placed on the market.

(13) 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.

(14) 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

Cyanamide is approved as an active substance for use in biocidal products of product-types 3 and 18, 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*.

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER