COMMISSION IMPLEMENTING REGULATION (EU) 2021/348

of 25 February 2021

approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10

(Text with EEA relevance)

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 lists includes carbendazim.

(2) Carbendazim has been evaluated for use in biocidal products of product-type 7, film preservatives, and product-type 10, masonry preservatives, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond respectively to product-types 7 and 10 as described in Annex V to Regulation (EU) No 528/2012.

(3) The evaluating competent authority of Germany submitted the assessment reports together with its conclusions to the Commission on 2 August 2013.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency ([4]) (the 'Agency') were adopted on 10 December 2019 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) It can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC.

(6) According to the opinions of the Agency, biocidal products of product-types 7 and 10 containing carbendazim may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(7) It is therefore appropriate to approve carbendazim for use in biocidal products of product-types 7 and 10, subject to compliance with certain specifications and conditions.

(8) The opinions of the Agency conclude that carbendazim meets the criteria for classification as mutagen category 1B and reproductive toxicant category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([5]).

([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).

([4]) Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Carbendazim, Product type: 7, ECHA/BPC/234/2019, adopted on 10 December 2019; Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Carbendazim, Product type: 10, ECHA/BPC/235/2019, adopted on 10 December 2019.

([5]) 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).

(9) Since carbendazim should be approved under the terms of Directive 98/8/EC, taking into account those properties, the period of approval should be considerably shorter than 10 years in accordance with the latest practice established under that Directive. In addition, since carbendazim has benefitted from the transitional period provided for in Article 89 of Regulation (EU) No 528/2012 since 14 May 2000 and has been under peer review since 2 August 2013, and with the view to examine at Union level as soon as possible in the context of a potential renewal of approval whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied for carbendazim, the period of approval should be three years.

(10) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities of the Member States should evaluate whether the conditions of Article 5(2) of that Regulation can be satisfied in their territories in order to decide whether a biocidal product containing carbendazim can be authorised.

(11) The opinions of the Agency also conclude that carbendazim meets the criteria for being a persistent and toxic substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([6]).

(12) For the purposes of Article 23 of Regulation (EU) No 528/2012, carbendazim meets the condition laid down in points (a) and (d) of Article 10(1) of that Regulation and should therefore be considered a candidate for substitution. The competent authorities of the Member States should therefore perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing carbendazim.

(13) The opinions of the Agency also conclude that the outdoor use of paints and plasters treated with or incorporating carbendazim poses unacceptable risks for surface water and sediment during their service life. No adequate risk mitigation measure could be identified to avoid releases of carbendazim in sewers during service-life of such treated articles when used outdoors. Consequently, in addition to the recommendations in the opinions of the Agency, the Commission considers appropriate that biocidal products containing carbendazim should not be authorised for use in paints and plasters which are intended to be used outdoors. Furthermore, paints and plasters treated with or incorporating carbendazim should not be allowed to be placed on the market for outdoor use. Lastly, paints and plasters treated with or incorporating carbendazim should be labelled to indicate that they are not to be used outdoors.

(14) Since, as concluded by the Agency, carbendazim meets the criteria for classification as mutagen category 1B, reproductive toxicant category 1B, and as skin sensitiser category 1 in accordance with Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating carbendazim should be appropriately labelled when placed on the market.

(15) This Regulation does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC ([7]) and 98/24/EC ([8]), and Directive 2004/37/EC of the European Parliament and of the Council ([9]).

(16) 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.

([6]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

([7]) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

([8]) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

([9]) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

(17) 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

Carbendazim is approved as an active substance for use in biocidal products of product-types 7 and 10, 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*.

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

Done at Brussels, 25 February 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
Carbendazim	IUPAC Name: Methyl-benzimidazol-2-ylcarbamate EC No: 234-232-0 CAS No: 10605-21-7	99,0 % w/w	1 February 2022	31 January 2025	7	Carbendazim is considered a candidate for substitution in accordance with points (a) and (d) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2. Products shall only be authorised for use in Member States where at least one of the conditions laid down in Article 5(2) of Regulation (EU) No 528/2012 is met. 3. Products shall not be authorised for use in paints which are intended to be used outdoors. The placing on the market of treated articles is subject to the following conditions: 1. Paints treated with or incorporating carbendazim shall not be placed on the market for outdoor use. 2. The person responsible for the placing on the market of a paint treated with or incorporating carbendazim shall ensure that the label of that paint indicates that it shall not be used outdoors. 3. The person responsible for the placing on the market of a treated article treated with or incorporating carbendazim shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					10	Carbendazim is considered a candidate for substitution in accordance with points (a) and (d) of Article 10(1) of Regulation (EU) No 528/2012.

						The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2. Products shall only be authorised for use in Member States where at least one of the conditions laid down in Article 5(2) of Regulation (EU) No 528/2012 is met. 3. Products shall not be authorised for use in plasters which are intended to be used outdoors.. The placing on the market of treated articles is subject to the following conditions: 1. Plasters treated with or incorporating carbendazim shall not be placed on the market for outdoor use. 2. The person responsible for the placing on the market of a plaster treated with or incorporating carbendazim shall ensure that the label of that plaster indicates that it shall not be used outdoors. 3. The person responsible for the placing on the market of a treated article treated with or incorporating carbendazim shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.