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COMMISSION IMPLEMENTING REGULATION (EU) 2025/457

of 10 March 2025

renewing the approval of dinotefuran as an active substance for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 14(4), point (a), thereof,

Whereas:

(1) The active substance dinotefuran was approved as an active substance for use in biocidal products of product-type 18 by Commission Implementing Regulation (EU) 2015/416 ([2]) subject to the conditions set out in the Annex to that Regulation ('the approval').

(2) On 11 November 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of dinotefuran for use in biocidal products of product-type 18 ('the application'). The application was evaluated by the competent authority of Belgium ('the evaluating competent authority').

(3) On 1 September 2023, the evaluating competent authority submitted a recommendation on the renewal of the approval of dinotefuran to the European Chemicals Agency ('the Agency').

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for renewal of approval of active substances. The Biocidal Products Committee adopted the opinion of the Agency on 28 May 2024 ([3]), having regard to the conclusions of the evaluating competent authority.

(5) In its opinion, the Agency concluded that biocidal products of product-type 18 containing dinotefuran may be expected to still satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with. Therefore, the conditions set out in Article 12(1), read in conjunction with Article 4(1), of Regulation (EU) No 528/2012 are considered still satisfied.

(6) It is therefore appropriate to renew the approval of dinotefuran for use in biocidal products of product-type 18, subject to compliance with certain conditions.

(7) In its opinion, the Agency also concludes that dinotefuran meets the criteria for being a very persistent and toxic substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]). Dinotefuran therefore meets the condition laid down in Article 10(1), point (d), of Regulation (EU)

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Commission Implementing Regulation (EU) 2015/416 of 12 March 2015 approving dinotefuran as an active substance for use in biocidal products for product-type 18 (OJ L 68, 13.3.2015, p. 30, ELI: http://data.europa.eu/eli/reg_impl/2015/416/oj).
([3]) Biocidal Products Committee (BPC) Opinion on the application for renewal of the approval of the active substance: Dinotefuran, Product type: 18, ECHA/BPC/423/2024, adopted on 28 May 2024.
([4]) 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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

No 528/2012 and should, therefore, for the purposes of Article 23(1) of that Regulation, be considered a candidate for substitution. Therefore, the period of renewal should not exceed 7 years, pursuant to Article 10(4) of that Regulation.

(8) In accordance with Article 23(1) of Regulation (EU) No 528/2012 the competent authorities of the Member States are to perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution.

(9) In order to guarantee a safe use of treated articles treated with or incorporating biocidal products containing dinotefuran and to enable users of treated articles to make informed choices, the person responsible for the placing on the market of a treated article treated with or incorporating dinotefuran should ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012. A period of transition should be set for such requirement in order to allow sufficient time for economic operators to adapt. Furthermore, when authorising products, Member States competent authorities or, in the case of a Union authorisation, the Commission, should specify in the summary of the biocidal product characteristics of a biocidal product containing dinotefuran the relevant instructions for use and precautions to be included on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012.

(10) 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

The approval of dinotefuran as an active substance for use in biocidal products of product-type 18 is renewed, subject to the 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, 10 March 2025.

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])	Expiry date of approval	Product type	Specific conditions
Dinotefuran	IUPAC name: (RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine EC No: 605-399-0 CAS No: 165252-70-0	991 g/kg	30 November 2031	18	1. Dinotefuran is a candidate for substitution in accordance with Article 10(1), point (d), of Regulation (EU) No 528/2012. 2. The authorisation of biocidal products containing dinotefuran as an active substance is 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; (2) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels or maximum residue limits need to be set or the existing maximum residue levels or maximum residue limits need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ([2]) or Regulation (EC) No 396/2005 of the European Parliament and of the Council ([3]), and any appropriate risk mitigation measures shall be taken to ensure that such maximum residue levels or maximum residue limits are not exceeded. (3) Member States' competent authorities or, in the case of a Union authorisation, the Commission, shall specify in the summary of the biocidal product characteristics of a biocidal product containing dinotefuran the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
					3. The placing on the market of treated articles is subject to the following condition: as from 1 May 2025, the person responsible for the placing on the market of a treated article treated with or incorporating dinotefuran shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, 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 made available on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

([2]) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/oj).

([3]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/oj).