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COMMISSION IMPLEMENTING DECISION (EU) 2025/357

of 21 February 2025

not approving 5-chloro-2-methyl-2H-isothiazol-3-one (CIT) as an active substance for use in biocidal products of product-type 6 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 9(1), first subparagraph, point (b), thereof,

Whereas:

(1) On 22 August 2017, the European Chemicals Agency ('the Agency') received an application, in accordance with Article 7(1) of Regulation (EU) No 528/2012, for the approval of 5-chloro-2-methyl-2H-isothiazol-3-one ('CIT') as an active substance for use in biocidal products of product-type 6, preservatives for products during storage, as described in Annex V to that Regulation. The application was evaluated by the competent authority of France ('the evaluating competent authority').

(2) On 18 September 2019, the evaluating competent authority submitted the assessment report, together with the conclusions of its evaluation, to the Agency. The Agency discussed the assessment report and the conclusions of the evaluating competent authority in technical meetings ('Working Groups') within its Biocidal Products Committee. Based on the discussions in those Working Groups, the Biocidal Products Committee concluded during its meeting of 16 June 2020 that the information provided in the application was insufficient to conclude whether CIT has endocrine-disrupting properties that may cause adverse effects in non-target organisms, thus neither making it possible to determine whether CIT meets the criterion referred to in Article 10(1), point (e), of Regulation (EU) No 528/2012 with regard to endocrine-disrupting properties that may cause adverse effects in non-target organisms considering that these properties raise concern linked to the nature of their critical effects to the environment, nor to conclude on the acceptability of the risk concerning the environment related to the use of the representative biocidal product containing CIT.

(3) On 3 August 2020, following the conclusions of the Biocidal Products Committee, during the preparation phase of the Agency's opinion, the evaluating competent authority exceptionally requested the applicant, pursuant to Article 6(2), second subparagraph, and Article 8(2) of Regulation (EU) No 528/2012, to provide by 31 December 2022 sufficient data in order to permit a determination of whether CIT has endocrine-disrupting properties that may cause adverse effects in non-target organisms.

(4) On 22 December 2022, the applicant provided data in response to the request of the evaluating competent authority.

(5) On 27 September 2023, the evaluating competent authority submitted the revised assessment report to the Agency, after taking into consideration the data submitted by the applicant. According to that report, higher doses may had been chosen in one of the studies provided by the applicant in order to conclude whether CIT has endocrine-disrupting properties that may cause adverse effects in non-target organisms. Despite that, the evaluating competent authority proposed to conclude, taking into account other available data in the application, that CIT does not have endocrine-disrupting properties that may cause adverse effects in non-target organisms, and thus the condition laid down in Article 10(1), point (e), of Regulation (EU) No 528/2012 with regard to endocrine-disrupting properties that may cause adverse effects in non-target organisms is not met.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

(6) The Agency discussed in Working Groups within its Biocidal Products Committee the revised assessment report submitted by the evaluating competent authority. The Working Group of the Biocidal Products Committee concerning the environment concluded that, even by taking into account all available data in the application, it was impossible to conclude whether CIT has endocrine-disrupting properties that may cause adverse effects in non-target organisms, in particular due to the low concentrations used in the Fish Short Term Reproduction Assay study No. 229 of the Organization for Economic Co-operation and Development (OECD study No. 229) provided by the applicant on 22 December 2022, thus not agreeing with the conclusion of the revised assessment report submitted by the evaluating competent authority.

(7) In accordance with Article 8(4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency ([2]) on 27 May 2024, having regard to the conclusions of the evaluating competent authority.

(8) In that opinion, the Agency concluded that the data submitted in the application remained insufficient to conclude whether CIT has endocrine-disrupting properties that may cause adverse effects in non-target organisms, and thus it was not possible to conclude on the acceptability of the risks concerning the environment related to the use of the representative biocidal product containing CIT and on a safe use. Therefore, it has ultimately not been demonstrated by the applicant that the representative biocidal product containing CIT for use in biocidal products of product-type 6 may be expected not to have unacceptable effects itself, or as a result of its residues, on the environment, and thus that it may be expected to satisfy the criteria set out in Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012. In addition, the Agency concluded that it was not possible to determine whether CIT meets the condition for being considered a candidate for substitution provided for in Article 10(1), point (e), of Regulation (EU) No 528/2012 with regard to endocrine-disrupting properties that may cause adverse effects in non-target organisms.

(9) The evaluating competent authority adjusted its final assessment report of 24 June 2024 to reflect the Agency's opinion.

(10) Consequently, having regard to the opinion of the Agency, the Commission considers that, in accordance with Article 9(1), point (b), of Regulation (EU) No 528/2012, the applicant did not provide requisite information sufficient to determine whether CIT has endocrine-disrupting properties that may cause adverse effects in non-target organisms within the prescribed period.

(11) Moreover, since it has not been demonstrated that the criteria laid down in Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012 are met, the Commission considers that the conditions for approval of CIT laid down in Article 4(1) of that Regulation are not satisfied.

(12) It is therefore appropriate not to approve CIT for use in biocidal products of product-type 6.

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

HAS ADOPTED THIS DECISION:

Article 1

5-chloro-2-methyl-2H-isothiazol-3-one (CIT) is not approved as an active substance for use in biocidal products of product-type 6.

([2]) Biocidal Products Committee Opinion on the application for approval of the active substance: 5-chloro-2-methyl-2H-isothiazol-3-one (CIT); Product-type: 6; ECHA/BPC/421/2024, adopted on 27 May 2024.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 21 February 2025.

For the Commission
The President
Ursula VON DER LEYEN