



2024/241

17.1.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/241

of 15 January 2024

**not approving *Willaertia magna c2c maky* as an active substance for use in biocidal products of product-type 11 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 <sup>(1)</sup>, and in particular Article 9(1), point (b), thereof,

Whereas:

- (1) On 16 December 2018, the Commission decided not to approve *Willaertia magna c2c maky* as an active substance for use in biocidal products of product-type 11 <sup>(2)</sup>.
- (2) On 9 August 2019, the European Chemicals Agency ('the Agency') received a new application, in accordance with Article 7(1) of Regulation (EU) No 528/2012, for the approval of *Willaertia magna c2c maky* as an active substance for use in biocidal products of product-type 11, preservatives for liquid cooling and processing systems, as described in Annex V to that Regulation. That application was evaluated by the competent authority of Malta ('the evaluating competent authority').
- (3) On 16 June 2022, 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.
- (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 approval of active substances. On 5 June 2023, in accordance with Article 8(4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency <sup>(3)</sup>, having regard to the conclusions of the evaluating competent authority.
- (5) In its opinion of 5 June 2023, the Agency concludes that biocidal products of product-type 11 containing *Willaertia magna c2c maky* may not be expected to satisfy the criteria laid down in Article 19(1), point (b)(i), (iii) and (iv), of Regulation (EU) No 528/2012. Despite the submission of a new application for approval and certain additional data compared to the data included in the first evaluation on which the Agency submitted its opinion in 2018 <sup>(4)</sup>, unacceptable risks were identified for human health during the secondary exposure of by-standers and of the general public, in particular related to the possible 'trojan-horse effect' of *Willaertia magna c2c maky* having ingested *Legionella pneumophila*. Furthermore, unacceptable risks were identified for the environment for the same reasons, as well as due to concerns on the full impact of a continuous release into the environment of *Willaertia magna c2c maky*, especially on microbial populations present in the environment. Finally, the Agency found that sufficient efficacy of *Willaertia magna c2c maky* to control *Legionella pneumophila* was still not demonstrated.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> Commission Implementing Decision (EU) 2018/1985 of 13 December 2018 not approving *Willaertia magna c2c maky* as an active substance for use in biocidal products of product-type 11 (OJ L 317, 14.12.2018, p. 27).

<sup>(3)</sup> Biocidal Products Committee Opinion on the application for approval of the active substance *Willaertia magna c2c maky*; Product-type: 11; ECHA/BPC/376/2023, adopted on 5 June 2023.

<sup>(4)</sup> Biocidal Products Committee Opinion on the application for approval of the active substance: *Willaertia magna c2c maky*, product-type 11, ECHA/BPC/206/2018, adopted on 26 April 2018.

- (6) Taking into account the opinion of the Agency of 5 June 2023, the conditions for approval of *Willaertia magna c2c maky* laid down in Article 4(1) of Regulation (EU) No 528/2012 are not met. Therefore, *Willaertia magna c2c maky* should not be approved for use in biocidal products of product-type 11.
- (7) 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*

*Willaertia magna c2c maky* is not approved as an active substance for use in biocidal products of product-type 11.

*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, 15 January 2024.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN