# **COMMISSION IMPLEMENTING DECISION (EU) 2023/548**

# of 6 March 2023

not granting a Union authorisation for the biocidal product family 'UL Hydrogen Peroxide Family 1' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2023) 1372)

(Only the Dutch text is authentic)

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 44(5), first subparagraph, thereof

#### Whereas:

- (1) On 27 January 2017, Unilever Europe BV submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'UL Hydrogen Peroxide Family 1' of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-MS029571-20 in the Register for Biocidal Products.
- (2) 'UL Hydrogen Peroxide Family 1' contains hydrogen peroxide as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 2.
- (3) On 20 December 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 25 October 2021, the evaluating competent authority gave Unilever Europe BV the opportunity to provide written comments on the assessment report and the conclusions of the evaluation, in accordance with Article 44(1), second subparagraph, of Regulation (EU) No 528/2012. On 23 November 2021, Unilever Europe BV sent its comments to the evaluating competent authority. During the Agency's opinion-forming process on that assessment report, the report was updated by the evaluating competent authority, and on 13 May 2022, Unilever Europe BV was given the opportunity to provide comments on the updated assessment report and the draft opinion of the Agency before the final opinion was adopted by the Biocidal Products Committee of the Agency on 15 June 2022. No comments were provided by Unilever Europe BV on that occasion.
- (5) On 5 July 2022, the Agency submitted to the Commission its opinion (2) on 'UL Hydrogen Peroxide Family 1' in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (6) The opinion concludes that 'UL Hydrogen Peroxide Family 1' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, but that it does not meet the conditions laid down in Article 19(1), points (b)(iii), (b)(iv) and (d), of that Regulation.

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

<sup>(2)</sup> ECHA opinion on the Union authorisation of the biocidal product family 'UL Hydrogen Peroxide Family 1', ECHA/BPC/344/2022, adopted on 15 June 2022, https://echa.europa.eu/bpc-opinions-on-union-authorisation.

- (7) According to the opinion of the Agency, an unacceptable risk was identified for professional and non-professional users from secondary inhalation exposure, and measures to mitigate the identified risk are not available or applicable. Unacceptable environmental risks for the compartments sediment and soil were also identified, due to the presence in the products of the substance of concern PEG-2 hydrogenated tallow amine. The opinion of the Agency also indicated that data gaps were identified for certain endpoints, and it was not possible to conclude on the physical and chemical properties of the products and whether they could be deemed acceptable for the purposes of the appropriate use and transport of the product.
- (8) The Commission concurs with the opinion of the Agency and considers it therefore appropriate not to grant a Union authorisation for 'UL Hydrogen Peroxide Family 1'.
- (9) 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

A Union authorisation is not granted to Unilever Europe BV for the making available on the market and use of the biocidal product family 'UL Hydrogen Peroxide Family 1'.

### Article 2

This Decision is addressed to Unilever Europe BV, Weena 455, 3013AL Rotterdam, Netherlands.

Done at Luxembourg, 6 March 2023.

For the Commission The President Ursula VON DER LEYEN