

The European Union recently issued Commission Implementing Regulation (EU) 2023/1078 of June 2nd 2023 approving ozone generated from oxygen as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

The following is an extract from the statement.

### COMMISSION IMPLEMENTING REGULATION (EU) 2023/1078 - of 2 June 2023

approving ozone generated from oxygen as an active substance for use in biocidal products of product-types 2, 4, 5 and 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 (1), and in particular Article 9(1), point (a), thereof,

Whereas:

(1) On 5 June 2015 and 22 August 2016, the European Chemicals Agency ('the Agency') received applications, in accordance with Article 7(1) of Regulation (EU) No 528/2012, for the approval of ozone generated from oxygen as an active substance for use in biocidal products of product-type 2, disinfectants and algacides not intended for direct application to humans or animals, product-type 4, food and feed area, product-type 5, drinking water, and product-type 11, preservatives for liquid-cooling and processing systems, as described in Annex V to Regulation (EU) No 528/2012. These applications were evaluated by the competent authority of Germany ('the evaluating competent authority of Germany') and the competent authority of the Netherlands ('the evaluating competent authority of the Netherlands').

(2) On 9 September 2020, the evaluating competent authority of Germany submitted the assessment report on the applications together with the conclusions of its evaluation to the Agency. The Agency discussed the assessment report and the conclusions in technical meetings.

(3) On 28 October 2021, the evaluating competent authority of the Netherlands submitted the assessment report on the applications together with the conclusions of its evaluation to the Agency.

The Agency discussed the assessment report and the conclusions 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. In accordance with Article 8(4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinions of the Agency on 1 December 2021 (2), having regard to the conclusions of the evaluating competent authority of Germany, and on 26 September 2022 (3), having regard to the conclusions of the evaluating competent authority of the Netherlands.

(5) In the opinions the Agency concludes that biocidal products of product-types 2, 4, 5 and 11 using ozone generated from oxygen may be expected to 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.

(6) Taking into account the opinions of the Agency, it is appropriate to approve ozone generated from oxygen as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 subject to compliance with certain conditions.

(7) 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.

(8) 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:** Ozone generated from oxygen is approved as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 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, 2 June 2023.

For the Commission. The President Ursula VON DER LEYEN

The notice can be found at [EUR-Lex - 32023R1078 - EN - EUR-Lex \(europa.eu\)](#)