II

(Non-legislative acts)

REGULATIONS

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 algaecides 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.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Biocidal Products Committee Opinions on the application for approval of the active substance ozone generated from oxygen; Product types: 2, 4, 5 and 11; ECHA/BPC/303/2021, ECHA/BPC/304/2021, ECHA/BPC/305/2021 and ECHA/BPC/306/2021; adopted on 1 December 2021.

([3]) Biocidal Products Committee Opinions on the application for approval of the active substance ozone generated from oxygen; Product types: 2, 4, 5 and 11; ECHA/BPC/350/2022, ECHA/BPC/351/2022, ECHA/BPC/352/2022 and ECHA/BPC/353/2022; adopted on 26 September 2022.

(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

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Ozone generated from oxygen	IUPAC name: Ozone EC No: not applicable CAS No: not applicable	For ozone generated from the precursor oxygen supplied in containers, the following specifications apply: The purity of oxygen shall be at least 90 % by volume fraction and the hydrocarbons content reported as methane equivalents (methane index) shall not exceed a volume fraction of 50 ppm. Depending on the production route of oxygen, oxygen may contain quantities of the following impurities: water, nitrogen, argon, carbon dioxide and other rare gases.	1 July 2024	30 June 2034	2	The authorisation of biocidal products is subject to the following conditions: (a) 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; (b) the product assessment shall pay particular attention to: (i) professional users; (ii) non-professional users; (iii) the secondary exposure of the general public.
					4	The authorisation of biocidal products is subject to the following conditions: (a) 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; (b) the product assessment shall pay particular attention to: (i) professional users; (ii) the secondary exposure of the general public; (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulations of the European Parliament and of the Council (EC) No 396/2005 [2] or (EC) No 470/2009 [3], and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

					5	The authorisation of biocidal products is subject to the following conditions: (a) 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; (b) the product assessment shall pay particular attention to: (i) professional users; (ii) the secondary exposure of the general public; (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 396/2005 or Regulation (EC) No 470/2009, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					11	The authorisation of biocidal products is subject to the following conditions: (a) 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; (b) the product assessment shall pay particular attention to: (i) professional users; (ii) surface water following direct discharge of treated cooling water.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed 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 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).

(3) 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).