Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Ozone generated from oxygen

Product type: 11

ECHA/BPC/306/2021

Adopted

1 December 2021

Opinion of the Biocidal Products Committee

on the application for approval of the active substance Ozone generated from oxygen for product type 11

In accordance with Article 8(4) in combination with Article 93 of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 11 of the following active substance:

Common name:	**Ozone generated from oxygen**
Chemical name:	**Ozone**
EC No.:	**Not applicable for an *in situ* generated active substance**
CAS No.:	**Not applicable for an *in situ* generated active substance**

New active substance submitted under Article 8(4) in combination with Article 93 of the BPR

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of the BPC opinion

Following the submission of an application by EurO3zon on 5 June 2015 the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to the ECHA on 9 September 2020. Another application for the same active substance is evaluated by the Competent Authority of the Netherlands. The evaluation of this application has not yet been finalized and is not reflected in this opinion. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-41) and its Working Groups (WG III 2021). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the application for approval of the active substance ozone generated from oxygen in product type 11 was adopted on 1 December 2021.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that ozone generated from oxygen in product type 11 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of ozone generated from oxygen in product type 11.

Ozone is generated from ambient air, water or oxygen *in situ* using a device, but in all cases, oxygen is the relevant component. Information about the ozone generation process (e.g. amount of ozone, residual amount of precursor) is available and a specification for the precursor oxygen is established.

The generated active substance ozone is a colourless to pale blue gas with oxidising properties. Physico-chemical properties have been evaluated for the generated active substance Ozone and the precursor oxygen and are deemed acceptable. No product data has been submitted, as the only precursor which could be placed on the market with a biocidal claim might be liquid oxygen[1]. In the other cases, i.e. when ozone is generated from ambient air, water or oxygen not supplied with the intention to generate ozone (e.g. generic oxygen canisters), the generated active substance is the biocidal product[2].

Acceptable analytical methods are available for the active substance ozone generated in water or air.

Validated residue analytical methods are available for the active substance ozone in drinking and surface water and in air. Residue analytical methods for the active substance in soil, body fluids and tissues as well as in food and feeding stuff are not required for the intended use.

Validated residue analytical methods are available for the determination of bromate and bromoform in drinking water. According to Commission Directive 2003/40/EC[3] maximum limits of bromate and bromoform should be monitored after treatment of natural mineral waters by ozone-enriched air. Validated residue analytical methods are available for the determination of bromate and trihalomethane (sum of chloroform, bromoform, dibromochloromethane, bromodichloromethane) in drinking water. According to Commission Directive 2020/2184[4], the maximum limit of bromate and trihalomethane should be monitored in drinking water. Validated residue analytical methods are available for the determination of chlorate and chlorite in drinking water. According to the WHO Guidelines

[1] The placing on the market of oxygen with a biocidal claim would not fall under the transitional measures specified in Article 93 of the BPR

[2] CA-May15-Doc.5.1.a – Final "Management of in situ generated active substances in the context of the BPR - The case of ozone": https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/acdcf5ce-4113-4b85-abef-5ec2e1af5a5f/details

[3] Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters (OJ L 126, 22.5.2003, p. 34–39).

for drinking-water quality, 4th edition (2011) the maximum limit of chlorate and chlorite should be monitored in drinking water.

A harmonised classification is not available for ozone. A CLH dossier was submitted to ECHA on 24 July 2020.The proposed classification and labelling for ozone according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed classification according to the CLP Regulation[5]	
Hazard Class and Category Codes	Ox. Gas 1, H270 Acute Tox. 1, H330 STOT SE 1, H370 STOT SE3, H335 STOT RE1, H372 Muta. 2, H341 Carc. 2, H351 Aquatic acute 1; H400 Aquatic chronic 1; H410
Labelling	
Pictograms	GHS03, GHS06, GHS07, GHS08, GHS09
Signal Word	Danger
Hazard Statement Codes	H270: May cause or intensify fire: oxidizer H330: Fatal if inhaled H370: Causes damage to organs (nervous system) H335: May cause respiratory irritation H372: Causes damage to organs through prolonged or repeated exposure (cardiovascular, nervous, respiratory system) H341: Suspected of causing genetic defects H351: Suspected of causing cancer H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 100 for acute toxicity to aquatic life M = 1 for chronic toxicity to aquatic life
Justification for the proposal	
-	

b) Intended use, target species and effectiveness

In PT11, ozone generated from oxygen is used for preservation of aqueous cooling and processing liquids. Ozone is generated *in-situ* by an ozone generator using three key methods. For water treatment ozone is typically generated from ambient air or oxygen using the DBD method (dielectric barrier discharge). Other methods used are the generation from ambient air by UV light and the electrolytic generation from water. The *in-situ* generation of ozone takes place in a closed device. The intented and evaluated use is preservation of cooling water in recirculating cooling systems.

Ozone is a strong and unspecific oxidant inactivating microorganisms by oxidising crucial components of cells and cell membranes.

The active substance, which is identical to the representative biocidal product, demonstrated sufficient innate curative bactericidal activity in cooling water at an initial concentration of 0.4 mg/L.

---

[4] Directive (EU) 2020/2184 of the European Parliament and the Council of 16 December 2020 on the quality of water intended for human consumption

[5] The NL CA being the eCA of the second application for "ozone generated from oxygen" comes to a different conclusion in relation to skin and eye irritation/corrosion. Based on the same data, the NL CA proposes to classify ozone as Skin Irrit., H315 and Eye Irrit., H319.

As ozone is an unspecific, highly reactive active substance and no occurrence of resistance has been reported to date, the risk of resistance development is considered low.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Based on the physicochemical properties of ozone, it is expected that the main part of the substance reacts with the tissue at the site of contact. Following inhalation, ozone is effectively absorbed. Studies on oral and dermal absorption and on distribution were not submitted.

Classification with Acute Tox. 1 is proposed based on an estimated LC50 in the range of 1-10 ppm.

Ozone has no sensitising properties, but exacerbates allergic asthma in different species of animals and increases the risk for first childhood asthma admission in humans.

Single and repeated dose toxicity studies detected effects in heart (*e.g.* modification of heart rate and bradyarrhythmia), brain (e.g. loss of fibers and cell death in dopaminergic neurons as well as memory deficiencies) and respiratory effects (e.g. fibrosis, inflammation and necrosis). Based on these effects classification as STOT-SE 1 (nervous system) and STOT-SE 3 (respiratory irritation) is warranted.

There was no clear association between pre- and postnatal exposure to ozone and reproductive toxicity, including fertility, embryotoxic and foetotoxic effects.

Classification with Carc 2 and Muta 2 is proposed based on the available studies.

In principle and in accordance with the CLP Guidance, strong oxidising properties provide a reason for concern for skin irritation/corrosion. The available studies demonstrate some irritating effects, but the studies are not applicable to determine skin as well as eye irritation and corrosion and can only be used as supportive information. Hence, no classification for skin as well as eye irritation is warranted.

Ozone is not considered to be an endocrine disruptor with respect to human health.

For the systemic toxicity of ozone, there is no indication for the existence of NOAECs/NOAELs from the relevant epidemiological studies submitted for the critical effect mortality. In addition, ozone was identified as a suspected genotoxic carcinogen. In the absence of suitable information, the existence of a threshold for this effect cannot be assumed. As AEL values cannot be derived for suspected genotoxic carcinogens without established threshold, a minimal effect level (MEL) of 25 ppb is proposed for general population in analogy to the DMELs under REACH.

Regarding local effects, in controlled human volunteer studies a NOAEC of 60 ppb was derived based on changes in lung function, which can be used for risk assessment for short-term exposure for professionals.

Treatment of water with ozone leads to the formation of disinfection by-products (DBPs) depending on various parameters (e.g. availability of organic matter, halogens in water or pH value).

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure[6] and description of scenario**	**Exposed group**	**Conclusion**
Disinfection of cooling water of open recirculationg systems	Ozone *in situ* generated and treatment of water: Primary exposure of ozone plant operator or general plant operator without PPE in technical room or in room where application takes place. Due to a closed system inhalation and dermal exposure to ozone is not expected	Professionals	Acceptable (closed system)
Post-application	Secondary exposure of the general public via drift loss or evaporation from disinfected cooling water (cooling tower application) – inhalation **exposure to ozone**	General public / bystanders / residents	Acceptable
Post-application	Secondary exposure of the general public via drift loss or evaporation from disinfected cooling water (cooling tower application) – inhalation **exposure to disinfection by-products**	General public / bystanders / residents	No conclusion possible

Industrial/Professional user:

Ozone is generated from air or oxygen *in situ* using an ozone generator, and then used for preservation of water in cooling systems. Ozone generation and dosing into the water take place in a closed system. Unconsumed excess gas (residual ozone) from closed system passed through an ozone destruction unit (converting ozone to oxygen and venting to the outside atmosphere) The generation is done indoors in locked technical rooms, which are equipped with ventilation or negative pressure and with limited access only for trained professionals. Operators are not present at all time, but occasionally for inspection and maintenance. In normal working operation, there will be no release of ozone to air in the workplace. Failures or malfunctions are dealt with by means of elaborate safety measures (room monitoring with warning and alarm systems, and ozone generation interruption at alarm level, appropriate personal protective equipment like full-face gas filter mask).

Frequent false alarms are more dangerous compared to a higher threshold limit, because people will get used to it and will not react in an appropriate way if there is a “real” alarm. Therefore, the gas detection and warning device will typically be programmed at a higher level than derived reference value MEL, i.e. a peak limit of 600 µg/m^3 = 0.3 ppm, or more commonly 0.5 ppm.

Non-professional user/general public:

Non-professional use is not indended, therefore no risk assessment was performed.

[6] See document: Terminology primary and secondary exposure (available from https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/80f71044-fce2-43b3-a73c-e156effc9fcb/Terminology%20primary%20and%20secondary%20exposure.pdf)

Residential or bystander **exposure to ozone** residues based on spray/drift loss of cooling towers is expected to be very low as the calculated increase of ozone in ambient air resulting from spray/drift loss is below 1 µg/m^3 and therefore below the MEL. The short-term and long-term intake of these residues is not expected to present a human health conern when safety advices and instructions for professional use and workers are complied with.

Referring to **disinfection by-products** in spray/drift loss, without monitoring data for disinfection by-products in cooling tower blowdown water, no conclusion on the outcome of risk assessment concerning disinfection by-products can be presented. However, exposure to disinfection by-products based on spray/drift loss of cooling towers is expected to be very low, since possible amounts are distributed in the air. Thus, monitoring data for disinfection by-products in cooling tower blowdown water shall be submitted for national or Union authorisation.

Exposure of food, feed, drinking water and livestock anaimals is not expected from the intended PT11 uses. No specific measures are necessary.

Environment

Ozone is an atmospheric and highly reactive gas. Atmospheric ozone decomposes to oxygen and short-lived radicals. The approximately half-life in air is 12 hours. Since ozone does not have any hydrolysable groups within its structure it is not susceptible to hydrolysis. Phototransformation in water is also considered negligible.

Self-decomposition and decomposition in contact with organic matter are more relevant. Ozone rapidly decomposite in contact with metal oxides and soil organic matter with an estimated half-life in soil of < 1 h. Moreover, ozone is not expected to bioaccumulate and is not subject to biodegradation. Ozone is acutely and chronically toxic to fish with lowest effect values being 9.3 µg/L (96h-LC50 for O. mykiss) and 2.3 µg/L (3 month-NOEC for O. mykiss), respectively.

Ozone is not considered to be an endocrine disruptor with respect to non-target-organisms.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
PT11 – Preservation of cooling water of open recirculating systems	*In situ* generated ozone is dosed automatically into the recirculating cooling water which can either be freshwater or marine water. The environment may be exposed to ozone via discharge of blowdown water either directly or indirectly (via STP) to surface water and via spray drift and evaporation of cooling water in the cooling tower. As ozone is expected to completely decompose in the STP, no indirect emissions to the terrestrial compartment are expected via application of sewage sludge on agricultural soil (soil and groundwater). Likewise, due to the physico-chemical properties of ozone, direct exposure of the terrestrial compartment was considered unlikely and was therefore not assessed quantitatively. The air compartment may be exposed to ozone either through evaporation via the cooling tower or by release of ozone to outside air during the generation of ozone. Both processes were addressed in the evaluation and the environmental emissions classified as negligible.	Acceptable if indirectly released to the environment via STP). **Unacceptable** risks for the surface water have been identified for direct discharge of treated cooling water into the surface water which can be mitigated by RMM (e.g. increasing the dwell time of the blowdown water in the sewer or installing a settling pond).

The assessed use of the biocidal product does neither lead to significant direct emissions of ozone to the terrestrial compartment nor to significant indirect emissions. Consequentely, the risks for the terrestrial compartment are considered negligible.

Accordingly, the assessed use to the biocidal prouct does not lead to significant emissions to the STP and the environmental risk due to the release of treated cooling water to surface water via STP (indirect emission) is also considred negligible.

In contrast, unacceptable risks for the direct discharge of treated cooling water into the surface water were identified. Due to the rapid decomposition of ozone in the cooling water, these unacceptable risks for surface water could be mitigated for example through increasing the dwell time of the blowdown water in the sewer (depending on the size of the cooling tower) or by installing a settling pond.

With regard to the formation of disinfection by-products, no conclusive risk assessment could be presented due to the lack of an agreed guidance for a quantitative environmental risk assessment of disinfection by-products. This assessment will therefore be postponed to either the product authorisation or until the renewal of the active substance depending on when and/or an agreement has been reached on guiding principles for an assessment of DBP in the context of the environmental risk assessment.

Overall conclusion

The use of ozone generated from oxygen for preservation of cooling water in recirculating cooling systems does not result in unacceptable risks for human health. For the environment, a safe use could be demonstrated if treated cooling water is released indirectly (via STP) to the environment, whereas for the direct release to surface water, risk

mitigation measures are needed (e.g. increasing the dwell time of the blowdown water in the sewer or by installing a settling pond) to mitigate the risks identified for surface water.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property	Conclusions		
CMR properties	Carcinogenicity (C)	Cat 2	Ozone does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	Cat 2	
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP	Ozone does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	Ozone does not fulfil criterion (d) of Article 5(1) or criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. Ozone does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Ozone does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Not relevant. Ozone does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Ozone generated from oxygen does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Ozone generated from oxygen does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012 and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[7], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[8] and "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment[9]" agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

Ozone is inorganic and it is not persistent. LRTAP (Long-range Transboundary Air Pollution) is not applicable to ozone from biocidal applications: Only small amounts of ozone are emitted in association with the use as biocide. Furthermore, ozone has a half-life of approximately 12 hours in the planetary boundary layer.

2.3. BPC opinion on the application for approval of the active substance ozone generated from oxygen in product type 11

In view of the conclusions of the evaluation, it is proposed that ozone generated from oxygen shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: For ozone generated from the precursor oxygen the specification is set in accordance to DIN EN 12876:2015 with a minimum purity of 90%. Oxygen shall be supplied from sources, which complying with this norm. For product authorisation, compliance with this norm shall be demonstrated by submission of certificates of analysis. For water and air, no specification was set.

2. The authorisations of biocidal products are subject to the following condition(s):

    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. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

[7] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

[8] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

[9] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

i. professional users;

ii. surface water following direct discharge of treated cooling water.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as ozone is proposed to be classified as Acute Tox. 1 (H330), STOT SE 1 (H370), STOT SE3 (H335), STOT RE1 (H372), Muta. 2 (H341), Carc. 2 (H351), Aquatic acute (H400).

2.4. Elements to be taken into account when authorising products

1. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

    a. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

    b. An unacceptable risk for surface water is identified following direct discharge of treated cooling water. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures (like increasing the dwell time of the blowdown water in the sewer or by installing a settling pond) or by other means, these uses should not be authorised.

    c. For cooling tower applications, monitoring data for disinfection by-products in cooling tower blowdown water shall be submitted for national or Union authorisation.

2. For other applications, data on typical levels of ozone and disinfection by-products in the relevant matrices specific for the intended uses and related conditions shall be provided at product authorisation level.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of ozone generated from oxygen.

o0o