Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Ozone generated from oxygen

Product type: PT 11

ECHA/BPC/353/2022

Adopted

26 September 2022

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 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 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 BPC opinions

Following the submission of an application by The European Ozone Trade Association Limited on 22 August 2016, the evaluating Competent Authority The Netherlands submitted an assessment report and the conclusions of its evaluation to ECHAon 28 October 2021. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-xx) and its Working Groups (WG II 2022). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Another application for the same active substance submitted by EurO3zon on 5 June 2015 was evaluated by the evaluating Competent Authority Germany. The BPC adopted the opinion (ECHA/BPC/306/2021) on this application at BPC-41 which is published on the ECHA web-site at: https://echa.europa.eu/documents/10162/c6e4fc14-79ed-66f8-3875-6b2f34f862ea.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the approval of the active substance Ozone generated from oxygen in product type [PT] was adopted on 26 September 2022**.**

The BPC opinion was adopted by consensus.

The opinion is 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 the active substance 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. The active substance Ozone generated from oxygen is generated *in situ*. The assessed concentrations correspond to pure (100%) ozone unless stated otherwise. The physico-chemical properties of the active substance have been evaluated and are deemed acceptable for the appropriate use of the active substance. The product is defined as an in situ generated substance generated from the nonmarketable precursors ambient air and water or liquid oxygen (not supplied with the intention to generate ozone). For product authorization, physical, chemical and technical properties for the *in situ* systems under consideration (ozone generated from oxygen) only need to be reported as far as they are relevant for the SPC.

Validated analytical methods are available for the relevant matrices air and water. Analytical methods for the determination of ozone in soil, body fluids and tissues, food and feed stuffs are not considered necessary based upon the very short half-life of ozone.

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[1]	
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

[1] The NL CA being the eCA of this 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.

	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

The intended use disinfection of cooling and processing water was evaluated. The small scale simulated use efficacy test that was provided for the active substance approval for ozone generated from oxygen proved innate efficacy (bactericidal) and substantiate the use of ozone as a biocide in PT 11 for professional use.

Ozone is a strong oxidant. It is this property which makes it very effective in destroying microorganisms. The inactivation takes place mainly as a result of damaging vital cellular components.

The technical active substance generated in situ and the biocidal product are identical. There are no reported cases of resistance to ozone from any generation method.

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

Human health

Considering PT11 use, the principal route of exposure to ozone is via inhalation. Ozone is a gas making the potential exposure via the inhalation route the significant route of exposure. The oral or dermal routes are unlikely to be important in the context of the representative biocidal products and their recommended use. In fact, the critical human health effects, for which toxicological reference values exists, are via inhalation; no reference values of ozone are derived for oral and dermal exposure. As such dermal exposure is not considered relevant to the risk assessment.

For the exposure assessment, in a controlled human volunteer study a NOAEC of 40 ppb was derived based on changes in lung function (FVC, FEV1.0) and symptoms score at LOAEC of 80 ppb. As supporting studies on airway inflammation reported upregulation of lung cytokines and immune cells from the level 80 ppb, a NOAEC 60 ppb from changes in lung function can be used for risk assessment for short-term exposure.

For 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) is proposed in analogy to the DMELs under REACH.

PT11

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Mixing/loading and application	Primary exposure: connecting / disconnecting ozone generator units for application into open / closed recirculating water cooling systems	Professionals	Acceptable (closed system)
Maintenance & inspection	Primary exposure (post-application): equipment maintenance and inspection, monitoring of open recirculating water system	Professionals	Acceptable (with RMM)
Cleaning	Secondary exposure: cleaning of open or closed recirculating water system	Professionals	Acceptable (with RMM)
Residue released from cooling towers	Secondary exposure: inhalation of residues released from cooling towers	General public	acceptable

Conclusion of risk characterisation for professional user

Ozone is a gas where the first direct adverse effects of ozone in humans is related to local inhalation effects and accordingly a NOAEC short term professional is derived. In addition, a MEL value is derived. For this reason, only an exposure and risk characterisation for local inhalation effects is performed.

Exposure to professional workers is negligible under the anticipated conditions of use. Using the appropriate engineering controls and PPE/RPE where relevant, plant workers are not expected to be exposed to unacceptable levels of ozone during its use. In addition, ozone detectors are present throughout the plant to continuously monitor ozone to ensure levels do not exceed 0.1 ppm conform national regulations compliant with relevant member state workplace/occupation exposure limits. Therefore, exposure to professional users is considered acceptable.

Conclusion of risk characterisation for indirect exposure

Open cooling towers are fitted with drift eliminator to minimise secondary (indirect) exposure *via* drift to the environment. Ambient gas detectors are located around the tower and at the top (i.e. point of exit) to monitor levels of ozone released to ensure they do not exceed equivalent levels of ambient ozone in the environment. Together with the rapid degradation of ozone to oxygen and dilution with outdoor air, concentration of ozone residues resulting from release of cooling towers is low or equivalent to ambient levels. On this basis, the risk of acute (i.e. bystander) and medium-term (i.e. resident) exposure to residues realised from cooling towers is considered acceptable.

Indirect exposure via food

The product (in the form of ozonated water) is intended to preserve recirculating liquids for cooling machinery and other systems in an industrial setting. The recirculating cooling system / process is separate to the manufacturing process of food and feed (i.e. cooling liquid is not incorporated into food during manufacture). Therefore, no contamination of ozone in food is expected and dietary exposure to ozone is not relevant for the intended uses.

Livestock exposure to ozone can be excluded when the product is used according to the recommended uses. Since animals are not expected to be present during preservation of recirculating liquid-cooling systems / processes, no risk with respect to animal safety is expected. Therefore, indirect exposure *via* food from livestock is not relevant for the intended uses.

DBPs

It is known that using ozone for disinfection can lead to the formation of potential health hazardous disinfection by-products (DBPs) e.g. bromate. However, it is recognised that the draft guidance on DBPs is only available for swimming pools scenarios in PT 2. Due to the complex nature of predicting the compounds formed as DBPs, where the available data are applicable to drinking and swimming pool water and not the scenarios presented in the current assessment, it is considered that the application of inappropriate guidance to substances and scenarios that have not been adequately investigated or reviewed in the formal guidance would result in unreliable conclusions. Therefore, no further consideration of disinfectant by-products is required as a risk assessment cannot be performed. The assessment of DBPs can be performed at product authorisation on provision of suitable guidance.

Endocrine disruption

A full assessment on the endocrine disrupting properties relevant to human health was performed in accordance with the Commission Delegated Regulation (EU) 2017/2100 and the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) no 528/2012 and (EC) No 1107/2009. Ozone is not considered to be an endocrine disruptor with respect to human health when applying the specific scientific criteria for endocrine disruption.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
PT11		
once through cooling systems	Emission to surface water	unacceptable
	Emission to air and subsequent emission to soils	acceptable
large open recirculating cooling systems	Emission to surface water	acceptable provided sufficient dilution in surface water is achieved
	Emission to air and subsequent emission to soils	acceptable
small open recirculating cooling systems	Emission to surface water	acceptable
	Emission to the sewer and subsequent emission to surface water	acceptable
	Emission to air and subsequent emission to soils	acceptable
closed cooling systems	Emission to the sewer and subsequent emission to surface water	acceptable

No risk has been identified for any of the applications within PT11 with release to the sewer as ozone degrades rapidly. Nevertheless, depending on the blowdown water volume, direct emission to surface water when applied as a cooling water preservative may result in unacceptable risks for the aquatic environment when no additional measure to reduce the

ozone concentration are applied. Additional data and/or risk mitigation measures may be required to authorise products as a cooling water preservative in systems with direct emission to surface water. Ozone may however result in disinfection by-products that might pose potential risks for the environment. The information currently available is however insufficient to draw final conclusions regarding the risks of disinfection by-products. These need to be addressed during product authorisation.

An assessment on the endocrine disrupting properties relevant to the environment was performed in accordance with the Commission Delegated Regulation (EU) 2017/2100 and the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) no 528/2012 and (EC) No 1107/2009. Ozone is not considered to be an endocrine disruptor with respect to the environment when applying the specific scientific criteria for endocrine disruption.

Overall conclusion

A safe use for human health and the environment is identified for all intended uses except for the direct discharge of treated cooling water from large once through cooling systems into the surface water with ozone generated from oxygen within PT11.

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 or by installing a settling pond.

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 generated from oxygen 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 generated from oxygen 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 generated from oxygen does not fulfil criterion (e)

Property		Conclusions	
CMR properties	Carcinogenicity (C)	Cat 2	Ozone generated from oxygen 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 generated from oxygen does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1) of Article 5(1) and does not fulfil criterion (e) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	T	
	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.		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Ozone generated from oxygen does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Ozone generated from oxygen 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"[2], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment[4]" 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 generated from oxygen does not fulfil the criterion for being a B substance. It is neither P nor does it show a potential for long-range transport. Hence, ozone generated from oxygen does not meet the criteria for being a persistent organic pollutant.

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: minimum purity of the active substance evaluated: 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 complying with this norm. For product authorisation, compliance with this norm shall be demonstated 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:

        i. Professional users.

        ii. General public.

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).

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[2] 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)

[3] 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)

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

2.4. Elements to be taken into account when authorising products

1. Authorities should assess whether authorisation of a biocidal product for use by the general public is possible considering the compliance with Article 19(4) of Regulation (EU) 528/2012.

2. 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. Residues of ozone and related disinfection by-products in the relevant matrix from the intended uses shall comply with EU or national regulations. Monitoring data on typical levels of ozone and disinfection by-products in the relevant matrix (e.g. blowdown water) specific for the intended uses and related conditions shall be provided at product authorisation level.

    c. Based on the currently available endpoints, unacceptable risks for the aquatic environment may be expected when ozon-treated cooling fluids are directly discharged to surface water. If the risk cannot be reduced to an acceptable level by additional data, appropriate risk mitigation measures, or by other means, these uses should not be authorised.

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.

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