Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Ozone generated from oxygen

Product type: 2

ECHA/BPC/303/2021

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 2

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 2 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 the 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 2 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 the ozone generated from oxygen in product type 2 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 2.

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. Physio-chemical properties have been evaluated for the generated active substance ozone and the precursor oxygen and 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 bromates 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.

In some European Member States there are specific requirements for swimming water (e.g. DIN 19643 (2012): Treatment of water of swimming pools and baths or RIVM (2014): Norms en methoden voor kwaliteitsparameters in het te wijzigen Besluit hygiëne en veiligheid badinrichtingen en zwemgelegenheden - RIVM rapport nr. 2014-0121s).

According to these requirements limits of ozone, trihalomethanes, bromates and chlorate and chlorite should be monitored in swimming water. Validated residue analytical methods are available for the determination of ozone, of chlorate and chlorite, of bromates and of trihalomethanes (sum of chloroform, bromoform, dibromochloromethane, bromodichloromethane) in swimming 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 SE 3, H335 STOT RE 1, H372 Muta. 2, H341 Carc. 2, H351 Aquatic acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictogram codes	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

Ozone generated from oxygen in PT 2 is used for disinfection of various aqueous matrices. 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

[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.

(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 intended and evaluated use is disinfection of pool water in public and private swimming pools, performed by professional and non-professional users respectively.

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

The active substance, which is identical to the representative biocidal product, demonstrated sufficient innate bactericidal activity within two minutes under simulated use conditions at a concentration of 0.3 mg/L. As ozone is an unspecific, highly reactive active substance and no occurence 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 physico-chemical 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 the 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.

Disinfection of water with ozone leads to the formation of disinfection by-products (DBPs) depending on various parameters (e.g. availablility 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**
Generation, application, post-application	*In situ* generation of ozone and treatment of water (swimming pool). 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)
Generation, application, post-application	Primary exposure of non-professional user to ozone for water disinfection in private swimming pool / spa: operation of ozone generator device	Non-professionals	Acceptable with RMMs
Post-application	Secondary exposure of swimmer / bathing guests (public pool/spas, private pools) **to ozone**: oral ingestion of pool water and dermal exposure during swimming (assuming an ozone concentration in pool water < 0.05 mg/L)	General public	Acceptable
Post-application	Secondary exposure of swimmer / bathing guests (public pool/spas, private pools) **to ozone**: inhalation exposure while staying in or next to the pool	General public	Acceptable (if ozone concentration in pool air is kept below the MEL)
Post-application	Secondary exposure of swimmer/bathing guests (public pool/spas, private pools) **to disinfection-by-products**: dermal and inhalation exposure and oral ingestion of pool water during swimming.	General public	Acceptable (if concentration limits of DBPs are complied with)

Professional user:

Ozone generation as well as dosing into water take place in closed systems. Unconsumed excess gas (residual ozone) from closed system passes through an ozone destruction unit (converting ozone to oxygen and venting to the outside atmosphere). The generation is

[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).

done indoor in locked technical rooms 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 not be any release of ozone into the air of the workplace. Failures or malfunctions are dealt with by means of elaborated safety measures (room monitoring with warning and alarm systems, 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/m3 = 0.3 ppm, or more commonly 0.5 ppm.

Non-professional user / general public:

Exposure to ozone:

The non-professional user has no increased exposure to ozone (relative to ozone already present in air), since the following risk mitigation measures (RMM) are in place:

1) The ozone generation and treatment takes place in a closed vacuum operated system with off-gas ozone destruction.

2) Maintenance of ozone equipment is only carried out by trained professionals

3) The non-professional user spends very limited time in the proximity of the ozonation system, the ozonation system is located in a locked machine room

4) Gas warning and detection device is operated in combination with the ozonation unit to ensure that no exposure above the reference value (MEL) will occur from the ozone generator and the ozone destructor

5) The installed gas detection and warning devices shall have a fail-safe relay output interlocked with the ozone generator in order to switch off ozone production in case of an alarm. 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.

6) The non-professional user should be informed that increased ozone levels, e.g. in case of malfunctions of the ozone unit, might be harmful

In the event of device malfunctioning leading to ambient ozone levels above the peak exposure limit, a warning signal will alert the non-professional user.

The primary exposure of a non-professional user to biocidal ozone by inhalation is much lower than exposure to ambient air ozone when outside.

Relevant secondary exposure of the general public for ozone is not expected. Since the ozone generator includes a residual ozone destruction unit, it is assumed that ozone

concentrations in pool water will not exceed a value of 0.05 mg/L[7]. This amount will further be rapidly degraded due to the short half-life of ozone, and therefore no relevant secondary oral and dermal exposure is expected. Secondary inhalation exposure is acceptable if ozone levels in the pool air are kept below the MEL.

The secondary exposure of the general public to biocidal ozone is in the same range as exposure to ambient air ozone when outside. Considering that exposure to ambient air ozone occurs daily when outside, no relevant additional exposure from the biocidal ozone in pools is expected for the general public.

Exposure to DPBs:

During ozonation of pool water, the formation of DBPs has been assessed according to the "*Draft Guidance for human risk assessment of disinfection by-products (DBPs)"*. It should be noted that for disinfection purposes ozonation of pool water is frequently combined with additional chlorination, from which even more and/or different DBPs are expected as reaction products. For several of these DBPs also WHO guideline values have been derived. These DBPs are not included in the presented residue assessment.

The concentrations of **bromate** provided by literature show that exceedance of the given concentration limit might occur. This is confirmed by the applicant in case pools are operated without granular activated carbon filters or not according to the German standard 19643. Therefore, as bromate is a carcinogen, risk mitigation measurements might be necessary to ensure that the given concentration limits are met or measured data have to be submitted for national or Union authorisation to show under which conditions (for example using a granular activated carbon filter, pH value adjustment, water change, control of the bromide concentration) ozonation can be performed meeting the given concentration limit. According to the Guidance on the BPR: Volume V, Disinfection By-Products (2017) the Dutch limit of 100 µg/L should be taken into consideration for the assessment.

For **chlorate**, the maximum concentration limit of 30 mg/L according to the "*Draft Guidance for human risk assessment of disinfection by-products (DBPs) under European biocide law (Regulation (EU) 528/2012)*" was used for exposure calculations. Comparing the calculated exposure with the derived TDI of 0.003 mg/kg bw results in an unacceptable risk. It is assumed that there are other, more important sources for the chlorate formation in swimming pools like chlorination. Ozonation is not the main route for the formation of chlorate. Considering the derived TDI of 0.003 mg/kg bw/d and the ingestion amounts and body weights, a maximum of up to 0.096 mg/L chlorate (infant, worst-case) is acceptable. Thus, for national or Union authorisation, it has to be ensured that up to 0.096 mg/L chlorate is formed by ozonation in swimming water. In addition, it should be discussed within the further development of the above mentioned DBP guidance if it is necessary to set a new limit for swimming water.

For the **other DBPs** trihalomethanes (THMs), monobromoacetic acid and dibromoacetic acid (HAA) provided monitoring data from 6 German pools operated with ozone according to DIN 19643 (3 ozone-chlorine pools and 3 ozone-bromine pools) show that respective levels were lower than the concentration limits according to the "*Draft Guidance for human risk assessment of disinfection by-products (DBPs)" (sum of THMs ≤ 50µg/L,* Monobromoacetic Acid ≤ 800 µg/L, Dibromoacetic Acid (HAA) ≤ 1000 µg/L). For pool air, no data is available for exposure assessment. To prevent concerning THM values in the air, first, the organic

[7] The value of 0.05 mg/L is set as limit value for ozone in swimming water in the German DIN 19643. The same value is set for drinking water in the German Drinking Water Ordinance as well as the EU Directive 2003/40/EC for natural mineral waters and spring waters.

precursors of the water are to be controlled, secondly, the THMs being formed are to be adsorbed, and thirdly, ventilation of the room air is to be sufficient.

Exposure of food, feed, drinking water and livestock animals is not expected from the intended PT2 uses.

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-composition and decomposition in contact with organic matter are more relevant.

Ozone rapidly decomposes 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-LC_{50} 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**
PT2 – Disinfection of swimming pool /spa	The use of *in situ* generated ozone for the disinfection of (public) swimming pools is automated, continuous and occurs in a closed system indoor. For trained professional, professional and non-professional use, an ozone dosage of up to 2 mg/L is applied, resulting in a maximum ozone concentration in pool water of 0.05 mg/L[7]. The main supposedly emission path will be via air, because the active substance evaporates from pool water to indoor air. With the use of a destruct unit (always part of the generation process) emission to outside air is negligible. As ozone decomposes in the swimming pool system releases are not expected via STP to the aquatic compartment (surface water and sediment) as well as due to sewage sludge application on agricultural soil to the terrestrial compartment (soil and groundwater)	Acceptable

No unacceptable risk for air was identified in connection with the evaluated intended use. The assessed use of the biocidal product does neither lead to direct emissions of ozone to the STP nor to indirect emissions to the aquatic (surface water and sediment) or terrestrial (soil and groundwater) compartment.

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 the renewal of the active substance depending on when 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 disinfection of swimming pool water does not result in unacceptable risks for the professional user and the environment. A safe use for the non-professional user has only been identified if appropriate measures as described above are in place. Furthermore, to have an acceptable risk for secondary exposure of the general public, it is essential that the ozone concentration in pool air is kept below the MEL and that the concentration limits of ozone and DBPs are complied with in pool 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	No	

	controlling target organisms via their endocrine system(s)		
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"[8], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[9] and "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment[10]" 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 2

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:

[8] 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)

[9] 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)

[10] 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).

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 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. non-professional users;

        iii. 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).

2.4. Elements to be taken into account when authorising products

1. Depending on the outcome of the discussions at the meeting 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, authorities should assess whether authorisation of a biocidal product for use by the non-professional user 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. Ozone levels in pool air must be kept below the MEL.

    c. Data on typical levels of ozone and disinfection by-products in the relevant matrix air or water specific for the intended uses and related conditions shall be provided at product authorisation level.

    d. For swimming pool disinfection by non-professional users, the following measures must be adhered to:

- the ozone generation and treatment shall take place in a closed vacuum operated system with off-gas ozone destruction;

- the ozonation system shall be located in a locked machine room and a gas warning and detection device shall be operated in combination with the ozonation unit to ensure that no exposure above the reference value (MEL) will occur from the ozone generator and the ozone destructor;

- the installed gas detection and warning devices shall have a fail-safe relay output interlocked with the ozone generator in order to switch off ozone production in case of an alarm;

- Installation, inspections and maintenance of ozone equipment should only be carried out by (trained) professionals.

e. Residues of ozone and related disinfection by-products in the relevant matrix air or water from the intended uses shall comply with EU or national regulations and the concentration limits for disinfection by-products (for chlorate in swimming water: 0.096 mg/L).

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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