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July 7, 2021

STABILIZED AQUEOUS OZONE (SAO®)
TOXICITY, BIODEGRADABILITY, ECOTOXICITY STATEMENT

Stabilized Aqueous Ozone (SAO®) is a non-toxic, biodegradable, and non-ecotoxic cleaner, sanitizer, and disinfectant generated by the lotus®PRO and iClean® mini devices. SAO is generated on demand and is composed of up to 1.7 mg/L of ozone generated from oxygen dissolved in cold water. When applied to surfaces the SAO oxidizes microbes breaking them down with the excess ozone in solution harmlessly reverting to oxygen and water.

On a percentage basis SAO is composed of > 99.99983% water and < 0.00017% ozone generated from oxygen. It is well established that ozone dissolved in water, known as aqueous ozone, is an effective biocide at as low as 0.3 ppm. Independent studies supplied by Tersano validate that SAO is an effective biocide passing the AOAC 960.09 standard for use as a food-contact sanitizer on hard, non-porous surfaces killing Escherichia coli (E.coli) and Staphylococcus aureus (Staph).

Toxicity:

As listed on the SDS, SAO generated by the lotusPRO and iClean devices is non-toxic having a 0-0-0 listing according to the NFPA diamond diagram for Health, Flammability, and Reactivity Hazards. SAO is also not harmful to humans and not harmful to skin. For SAO the "action is non-specific and selective to microbial cells; it does not damage human body cells because of their major antioxidative ability." [1] SAO is also less irritating to skin than conventional chemical cleaners [2].

When dissolved in water the toxicity profile of ozone greatly changes. The US EPA has stated that "Ozone has been extensively used for water purification, but ozone chemistry in water is not the same as ozone chemistry in air." [3] This if further demonstrated with the use in periodontics where "ozone gas has been found to have toxic effects if inhaled into the respiratory tract, ozonated water may be useful to control oral infections and various pathogens." [1]

There are no precautions required to be taken with SAO and there are no individual protection pictograms for SAO due to the low concentration of the active ingredient, ozone.

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Biodegradability:

Composed of >99.99% water and <0.01% dissolved ozone, SAO reverts to water and oxygen by the mechanism described by Gordon-Tomiyasu-Fukutomi [4].

Gordon, Tomiyasu and Fukutomi

$$O_3 + OH^- \xrightarrow{k_{10}} HO_2^- + O_2 \qquad k_{10} = 40\ M^{-1}s^{-1} \qquad (1.10)$$

$$HO_2^- + O_3 \xrightarrow{k_{11}} HO_2 + O_3^{\bullet-} \qquad k_{11} = 2.2\ 10^6\ M^{-1}s^{-1} \qquad (1.11)$$

$$HO_2 + OH^- \underset{k_{-12}}{\overset{k_{12}}{\rightleftharpoons}} H_2O + O_2^- \qquad k_{12} = 10^{-4.8} \qquad (1.12)$$

$$O_3 + O_2^- \xrightarrow{k_3} O_3^{\bullet-} + O_2 \qquad k_3 = 1.6\ 10^9\ M^{-1}s^{-1} \qquad (1.3)$$

$$H_2O + O_3^{\bullet-} \xrightarrow{k_{13}} OH + O_2 + OH^- \qquad k_{11} = 20\text{-}30\ M^{-1}s^{-1} \qquad (1.13)$$

$$HO^{\bullet} + O_3^{\bullet-} \xrightarrow{k_{14}} O_2^- + HO_2 \qquad k_{14} = 6\ 10^9\ M^{-1}s^{-1} \qquad (1.14)$$

$$HO^{\bullet} + O_3^{\bullet-} \xrightarrow{k_{15}} O_3 + OH^- \qquad k_{15} = 2.5\ 10^9\ M^{-1}s^{-1} \qquad (1.15)$$

$$HO^{\bullet} + O_3 \xrightarrow{k_{16}} HO_2 + O_2 \qquad k_{16} = 4.2\ 10^8\ M^{-1}s^{-1} \qquad (1.16)$$

Figure 1: The decomposition of ozone in aqueous solution [4]

SAO is Green Clean Institute Certified™ by the Green Clean Institute of Missouri to be "Biodegradable: The product is considered biodegradable, as it reverts to a natural or organic state without harm to the environment." [5]

The by-products of the ozone decomposition are not toxic. Ozonated water and its by-products are generally regarded as safe (GRAS) and considered safe for human consumption as defined by the US FDA "Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water" [6].

Ecotoxicity:

The lotusPRO generates ozone safely and infuses it into the aqueous environment stabilized by the SAO cartridge to create SAO. According to the European Chemical Agency's (ECHA) classification, labelling and packaging of substances and mixtures (CLP Regulation) using the M-factor for ozone, SAO is not classified as posing either an acute or chronic risk to the environment. From the M-factor, the CLP classification of an acute environmental hazard does not exist < 25 ppm with a chronic classification requiring a greater concentrative > 25 ppm.

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Table 4.1.3: Classification of a mixture for short-term (acute) hazards based on summation of the concentrations of classified ingredients

Sum of the concentrations (in %) of ingredients classified as:		Mixture is classified as:
Acute 1 × M[a]	≥ 25%	Acute 1
(M × 10 × Acute 1) + Acute 2	≥ 25%	Acute 2
(M × 100 × Acute 1) + (10 × Acute 2) + Acute 3	≥ 25%	Acute 3

Table 4.1.4: Classification of a mixture for long-term (chronic) hazards based on summation of the concentrations of classified ingredients

Sum of the concentrations (in %) of ingredients classified as:	Mixture is classified as:
Chronic 1 × M[a] ≥ 25%	Chronic 1
(M × 10 × Chronic 1) + Chronic 2 ≥ 25%	Chronic 2
(M × 100 × Chronic 1) + (10 × Chronic 2)+ Chronic 3 ≥ 25%	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4 ≥ 25%	Chronic 4

[a] *For explanation of the M factor, see 4.1.3.5.5.*

Source: UN GHS Purple Book

SAO Ozone Content: <0.00017%	
M-Factor acute: 100	M-Factor chronic: 1
Acute 1 – 0.017% Acute 2 – 0.170% Acute 3 – 1.700%	Chronic 1 – 0.0002% Chronic 2 – 0.0017% Chronic 3 – 0.0170% Chronic 4 – 0.0002%
Acute Hazard if Value ≥25%	Chronic Hazard if Value ≥25%

Due to the biodegradability of SAO, there is no risk for chronic exposure to ozone for aquatic life. SAO decomposes to water and oxygen in up to 24 hours through a half-life decay process meaning that optimally in 12 hours SAO contains only 35% of the initial ozone or 0.6 ppm which remains an effective biocidal product.

Studies on the phytotoxicity of aqueous ozone, toxicity to plants, have demonstrated that SAO is not classified as phytotoxic. The testing presented in academic journals demonstrates that "low residual ozone concentrations (31.2 µmol·L–1 (1.50 mg/L) or less at emitter discharge; 0.3 m from canopy) did not present any measurable risk to plant growth". [7] A comparative study on the potential effect of Tersano's stabilized aqueous ozone at 1 mg/L, and other disinfectants on the survivorship of diamondback moth larvae and adult D. semiclausum further demonstrated the safety of SAO [8]. "Bleach and hydrogen peroxide significantly affected the survival of diamondback moth larvae but aqueous ozone and the insecticide deltamethrin did not. Similarly, application of bleach, hydrogen peroxide, and deltamethrin significantly affected the survival of adult D. semiclausum while aqueous ozone did not." [8]

Summary:

On the balance of the data available concerning potential toxicity, biodegradability, and ecotoxicity, **SAO is affirmed to "not be hazardous according to GHS",** the Globally Harmonized System of Classification and Labelling of Chemicals. **SAO is safe to use and poses no risk to humans, plants, insects, or aquatic life.**

SIGNED FOR AND ON BEHALF OF:

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[2] H.J. Breidablik, et al., Effects of hand disinfection with alcohol hand rub, ozonized water, or soap and water: time for reconsideration?, Journal of Hospital Infection 105 (2020)

[3] Ozone Generators that are Sold as Air Cleaners, https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners, retrieved 07-01-2021

[4] Margareta Eriksson, "Ozone chemistry in aqueous solution –Ozone decomposition and stabilization", Licentiate Thesis, Department of Chemistry Royal Institute of Technology, Stockholm, Sweden, 2004

[5] "Tersano, Inc. Certification 2015", Green Clean Institute of Missouri, 2015

[6] TITLE 21--FOOD AND DRUGS, CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION (CONTINUED), PART 184 -- DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1563, retrieved 07-01-2021

[7] "Phytotoxicity of Aqueous Ozone on Five Container-grown Nursery Species", HORTSCIENCE 44(3):774–780, 2009

[8] S. Albert, et al., Assessing the potential of unmanned aerial vehicle spraying of aqueous ozone as an outdoor disinfectant for SARS-CoV-2, Environmental Research 196 (2021) 110944, https://doi.org/10.1016/j.envres.2021.110944