

Hypochlorous acid is a weak, highly unstable acid which can only exist in a solution.<sup>1</sup> Aquaiox Inc. produces hypochlorous acid by electrolysis of a dilute salt solution passing through an electrolytic cell. At an acidic to neutral pH, the predominant chemical species is hypochlorous acid (HOCl).<sup>2</sup> Hypochlorous acid has demonstrated antimicrobial activity against numerous bacterial, viral and fungal pathogens, including antibiotic-resistant strains.<sup>3</sup>

Hypochlorous acid has a history of safe use as a disinfectant in numerous applications including household, hospital, food preparation, industrial and pharmaceutical applications. Hypochlorous acid is approved by the FDA for direct patient tissue contact as a wound care agent. It has also been used in root canal therapy.<sup>4</sup>

Aquaiox LLC markets a number of hypochlorous acid products at hypochlorous acid concentrations up to 0.0525% (525 ppm free available chlorine) for use as one-step cleaners and disinfectants for general cleaning and disinfecting hard, non-porous surfaces.<sup>5</sup> These products can be applied using a mop/bucket, a trigger spray bottle or a pressurized spray system.

This review was conducted to evaluate the risk of inhalation exposure to hypochlorous acid to those in hospital settings who apply these cleaning agents and to patients and other potentially exposed individuals.

Aquaiox LLC has evaluated AQUAOX Disinfectant 525, its most concentrated hypochlorous acid product, in a series of preclinical toxicology studies which were conducted in compliance with the ISO 10993 Standards. Testing included the evaluation of cytotoxicity, acute oral toxicity, repeat dose (28 day) dermal toxicity, dermal sensitization, acute inhalation toxicity as well as skin and eye irritation.

The results of these studies confirmed that AQUAOX Disinfectant 525, and by extrapolation all AQUAOX Disinfectant products marketed at hypochlorous acid concentrations less than 0.0525% are not cytotoxic, nor do they demonstrate signs of acute systemic toxicity or irritation following oral or inhalation exposure. AQUAOX Disinfectant 525 is not a dermal sensitizer nor is it a skin or eye irritant. It failed to exhibit any signs of local or systemic toxicity following 28 days of repeated dermal administration to intact and abraded skin.<sup>6</sup>

Aquaiox hypochlorous acid products are liquids which contain a maximum concentration of hypochlorous acid of 0.0525%. As a liquid, inhalation exposure to applicators, patients and other potentially exposed individuals to hypochlorous acid would require exposure to an atmosphere

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<sup>1</sup> National Center for Biotechnology Information—NCBI (2015) Hypochlorous Acid, PubChem 867 Compound Database; CID=24341, <https://pubchem.ncbi.nlm.nih.gov/compound/24341> 868 (accessed Aug. 9, 2015).

<sup>2</sup> Sansebastiano, G. et al. Page 262 in Food Safety: A Practical and Case Study Approach (Ed: R. J. Marshall) 2006, Springer Science & Business Media, Berlin.

<sup>3</sup> Wang TX, Kelly MD, Cooper JN, Beckwith RC, Margerum DW. Equilibrium, kinetic, and UV-spectral characteristics of aqueous bromine chloride, bromine, and chlorine species. *Inorg Chem.* 1994; 33:5872– 5878.

<sup>4</sup> European Union Risk Assessment Report, Sodium Hypochlorite, CAS No: 7681-52-9, EINECS No: 231-668-3, Final Report, November 2007.

<sup>5</sup> <http://www.aquaiox.com/sustainable-cleaning-disinfecting-sanitizing-products/>

<sup>6</sup> AQUAOX LLC., Technical Summary – Aquaiox On-Site Generated Disinfectants. [http://www.aquaiox.com/wp-content/uploads/2017/04/Technical-Summary\\_On-site\\_Disinfectants\\_vf.pdf](http://www.aquaiox.com/wp-content/uploads/2017/04/Technical-Summary_On-site_Disinfectants_vf.pdf)

which contains an aerosol of hypochlorous acid. Aquaox has determined that the recommended pressurized spraying system for product application generates an aerosol with a particle size diameter of approximately 30 to 50  $\mu\text{m}$ . In the average adult, particles larger than 10  $\mu\text{m}$  are deposited in the nasopharynx and cannot penetrate to tissue below the level of the larynx. Once deposited, particles are then subject to various particle clearance mechanisms.<sup>7</sup> Based on a particle size range of approximately 30 to 50  $\mu\text{m}$  Aquaox hypochlorous acid products potential inhalation exposure would be limited to the nose and oral pharynx. The bronchiolar and alveolar regions of the lung would not be exposed.

The preclinical testing described above has demonstrated that AQUAOX Disinfectant 525, and by extrapolation all AQUAOX Disinfectant products marketed at hypochlorous concentrations less than 525 ppm are not irritants following inhalation, dermal or ocular exposure. Based on these findings AQUAOX Disinfectant products are not considered to represent a risk to the health of applicators, patients or other potentially exposed individuals by the inhalation route of exposure.

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<sup>7</sup> Casarett & Doull's Toxicology The Basic Science of Poisons, Sixth Edition, McGraw-Hill, 2001, p523.