

Executive Summary: AQUAFOX™'s AX-275, AX-525 and AX-1650 EPA-Certified Disinfecting Solutions

Introduction:

AQUAFOX™, a 17-year old technology firm, specializes in Electrochemical Activation (ECA) generators, offering eco-friendly, residue-free alternatives to conventional chemical cleaning. Aiming to transform medical facility sanitation, AQUAFOX™ provides efficient, cost-saving techniques to reduce human error while championing healthier, sustainable practices.

This summary aims to provide an overview of the complex technical and regulatory material necessary for you to make informed decisions about the value of using our on-site generated and EPA-certified Hypochlorous (HOCl) disinfectants.

Products: AX-275, AX-525 and AX-1650

These labels designate three Hypochlorous (HOCl) solutions, with the numbers indicating respective concentrations, 275-ppm, 525-ppm and 1650-ppm (parts per million) for hard surface disinfection. Higher concentrations mean faster kill of more challenging pathogens.

The FDA (U.S. Food and Drug Administration) has designated HOCl as the form of free available chlorine that has the highest bactericidal activity against a broad range of microorganisms, which is exactly what we are going to explore. The FDA also considers HOCl to be the most reactive form of chlorine (that's the source of anti-microbial acidity) and 80% more effective than bleach. Plus, as we will see, it's more eco-friendly.

Regulatory Considerations for AQUAFOX™ HOCl Products

HOCl, produced through the electrolysis of a saline solution, was discovered nearly two centuries ago. Although its advantages were recognized early on, producing it in specific concentrations proved challenging until recent advancements like those introduced by AQUAFOX™. A primary concern was its short shelf life, an issue AQUAFOX™ has adeptly addressed through onsite devices. This modern approach, however, brings forth intricate regulatory dilemmas that can appear contradictory.

1. The EPA (Environmental Protection Agency) supervises the regulation of *pre-packaged disinfectants* for surface application. Within this realm, there's a juxtaposition of older and newer regulations, leading to some discrepancies. Historically, regulations centered on the direct impact of HOCl on pathogens, whereas more recent ones require the inclusion of "soil" in assessments.
2. There's also the distinct FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) regulatory framework for *onsite-produced solutions*. Here, vendors like AQUAFOX™ must substantiate both the efficacy and safety of their offerings.
3. Beyond these regulatory facets lies the practical aspect of ensuring consistent, efficient disinfection in medical-setting routines. This involves usage guidelines, target pathogen determination, and adherence to safety protocols.

EPA Registration

All three AQUAFOX™ HOCl products have achieved EPA registration through required rigorous testing at registered GLP (Good Lab Practice) facilities, assuring their safety and effectiveness as disinfectants as well as claims made for the products.

Additionally, AX-1650 is the highest concentration HOCl product registered with the EPA and AX-525 has been included in EPA's List N as a solution expected to kill the coronavirus SARS-CoV-2 and other emerging pathogens.

The procedures and results of this and other extensive testing are documented in detail in the 2 attachments titled: *AQUAFOX™ EPA-Certified Disinfectants – Technical Summary* and *AQUAFOX™ On-Site Generated Solutions - Technical Summary* whose contents are briefly summarized below.

FIFRA Requirements Specific to On-Site Generation

FIFRA mandates specific provisions for on-site generating devices, encompassing labeling standards consistent with EPA claims and production guidelines. FIFRA also emphasizes the accuracy and authenticity of labeling components including the product's name, ingredient list, effectiveness claims, and usage instructions, among other items as certified by the manufacturer with respect to product performance, safety, and efficacy. Further elaboration is in the above-mentioned Technical Summary.

Efficacy Data

Laboratory evaluations have conclusively demonstrated the efficacy of these three specific concentrations of HOCl in neutralizing a vast array of pathogens (200+, including different strains) within exposure times ranging from 30 seconds to the EPA's standard requirement of 10 minutes. Across these studies, outcomes either met the stringent pass-fail criteria set by the EPA or showcased remarkable kill rates ranging from 99.99% to 99.9999%. These findings not only affirm AQUAOX™ HOCl's potent antimicrobial properties but also its efficiency in varied time frames and application contexts, emphasizing its significant role in pathogen control. Further studies are planned using AX-1650 to more quickly eradicate *Candida auris* and *Clostridium difficile* spores. For a detailed analysis and a comprehensive list of tested pathogens, readers are directed to the accompanying technical documents.

Safety Data

"The trio of AQUAOX™ products are primarily composed of Hypochlorous (HOCl) as the active agent, accompanied by a trace amount of salt (NaCl) residue from the electrolysis process, all suspended in a water solution. These products successfully passed intensive toxicology evaluations and align with the United States Pharmacopeia (USP) safety standards for their designated uses. Crucial observations from these studies are:

- Absence of skin or eye irritation.
- Lack of allergic manifestations.
- Proven safe for consumption or inhalation, even at peak concentrations.
- No negative effects on wound healing observed over a month-long study.

For augmented validation, the AQUAOX™ 1650 was examined by the EPA with laboratory results supplied at a 2200-ppm concentration. Products are ranked by the EPA into four toxicity tiers: Category I represents the highest toxicity and Category IV the lowest. Our 2200-ppm HOCl solution secured a Category IV classification. It's pivotal to acknowledge that the EPA lacks a 'non-toxic' classification, even when products exhibit no adverse outcomes in lab tests on humans and animals.

Our suite of products has consistently demonstrated their safety credentials in multiple laboratory examinations.

Using our designated spraying equipment, several conclusions were drawn:

- The particle size is adequately large, negating respiratory concerns.
- Particles descend rapidly due to their size.
- The sprayer's electrostatic charge ensures particles attach promptly to surfaces, minimizing airborne duration.
- A study where lung tissue was subjected to an ultrasonic aerosol of a 550-ppm solution for an entire day found no harmful repercussions. Notably, the impact of HOCl exposure was indistinguishable from mere air exposure.

Assessments on residual Chlorine's impact are comfortably within the safety thresholds set by the Occupational Safety and Health Administration (OSHA).

Also, comprehensive testing on a range of materials was conducted using AX-275 and AX-525. Notably, AX-525 exhibited minimal corrosiveness on the Boeing Aluminum Test (AX-275 showed none), while both products adhered to standards across various materials including rubber, paint, fabrics, vinyl, leather, and more.

Usage Recommendations

These products are intended for use on hard surfaces in medical or veterinary facilities, applying with a trigger sprayer, AQUAOX™ electrostatic spray applicator, or AQUAOX™ microfiber cloths which assure no streaking, corrosion, material damages, or fumes. More extensive directions are supplied on the enclosed product label and in the systematic descriptions provided by AQUAOX™ that are designed to assure effectiveness while limiting operator errors.

Benefits to Hospitals and Medical Facilities

- AQUAOX™ AX-275, AX-525, and AX-1650 offer a tailored selection of products based on context and the level of antimicrobial disinfection targeted.
- Onsite generation is both cost-effective and convenient while allowing just-in-time generation of the necessary products.
- These HOCl products offer optimum balance between thoroughly effective disinfection and user/patient safety.

- AQUAOX™’s integrated cleaning protocols offer maximum effectiveness coupled with minimal opportunities for user error.
- More effective disinfection results in reduction in iatrogenic infections, absenteeism, problems with allergies or irritations, and overall improved cleanliness of facilities.
- The marked effectiveness of these products against fungi, viruses, bacteria and spores both on pre-cleaned surfaces and those that cannot be wiped as well as confirmable reduction in airborne pathogens when electrostatically sprayed or aerosolized.
- Continuous use of these HOCl products have been documented to reduce general biofilm accumulation on surfaces.

Testimonials

In the service of assuring you of the legitimacy of the claims we are making, we have included testimonials from current users describing their satisfaction with respect to use, safety, effectiveness, and other perceptions. We hope their descriptions of their experiences will convey the level of confidence we would like you to feel toward our products and services.

Conclusion

AQUAOX™, a 17-year-old technology firm, specializes in Electrochemical Activation (ECA) generators, providing eco-friendly disinfecting solutions. Their products, AX-275, AX-525, and AX-1650, provide varying concentrations of Hypochlorous (HOCl) solutions for disinfecting surfaces against challenging pathogens like Fungi (*Candida aurus*, Bacteria (MRSA), *Mycobacterium* (BCG), Enveloped Viruses (corona), and Spores (C.Diff).

The FDA deems HOCl 80% more bactericidally effective than bleach. Despite historical challenges with HOCl's production and shelf life, AQUAOX™ has introduced advancements that resolve these concerns, particularly on-demand, on-site generation. Their products meet regulatory standards set by the EPA, notably AX-1650 as the highest registered HOCl concentration and AX-525 achieving List N recognition for its potential against SARS-CoV-2 and other emerging pathogens.

Rigorous tested in GLP facilities, their products show 99.99% to 99.9999% effectiveness against pathogens. Moreover, the products are user-friendly, non-irritating, and non-toxic, even at peak concentrations. Furthermore, continuous usage demonstrably decreases biofilm accumulation on surfaces, among other benefits, ultimately enhancing the overall cleanliness and health of medical facilities.

Finally, having met the requisite governmental regulatory requirements which, at 10-minute kill time, are necessary but suboptimal for ultimate hospital disinfecting effectiveness, AQUAOX™ is presently pursuing laboratory confirmation of the disinfection Holy Grail, namely a kill time ≤ 5 minutes for the most challenging pathogens, like encased *C. diff* Spores.