Y2X Life Sciences

Hypochlorous Acid (HOCl) Scientific Summary of Safety and Efficacy

Introduction

The ongoing global pandemic has highlighted the need for comprehensive disinfection strategies both in the home as well as public spaces such as schools, transit centers, hospitals, and offices. These approaches will require solutions that are highly effective as well as safe, non-toxic, and amenable to large-scale deployment in order to allow us to return to everyday activities. Chemical disinfectants offer a widely-recognized and effective way to stop the environmental spread of pathogens. Hypochlorous acid (HOCl) is a well-known chemical disinfectant that has been demonstrated to effectively inactivate and eradicate viruses, bacteria, endospores, prions, and fungi. HOCl has been recognized by the EPA as a registered disinfectant that can be used against emerging pathogens, including the coronaviruses, a family of viruses that includes SARS-CoV-2. Importantly, HOCl is safe for contact and inhalation and can be used in the presence of people (Nerandzic, Al Haq).

The New Role for Disinfection

This need for wide-spread disinfection has led to reevaluation of current approaches as the world shifts to large-scale disinfection on an industrial level. HOCl has emerged as the most effective and safest option to return to and maintain public safety and economic stability. HOCl has been demonstrated to be more effective than other chemical or alcohol-based disinfectants in controlling hard-to-kill, highly virulent viruses and bacteria. HOCl is 80-200 times more effective than bleach in surface disinfection, however, unlike other chemical disinfectants, HOCl is benign to humans, breaking down rapidly after use to salt and water. This preeminent safety profile means it can be used in the presence of people, does not require special PPE to apply, and requires no hazardous material clean-up or disposal (MSDS).

HOCl as a Powerful and Safe Disinfectant

<u>The Science of HOCl</u>

HOCl is a weak acid in the family of chlorine-containing disinfectants. It can be generated by the electrolysis of NaCl and water. HOCl is made in the human body; it is generated by white blood cells that are part of the immune system in response to infection and during inflammation, and is part of a powerful antimicrobial defense mechanism (Klebanoff).

HOCl's disinfectant properties have been recognized and leveraged for over 100 years, beginning with its use for disinfection of soldier's wounds during World War 1 (Cordova,

Beattie). The characterization and uses of HOCl have increased exponentially over the decades and it has been shown to be effective in reducing infectious organisms in, burns, wounds, surgical equipment, hospital rooms, operating suites, daycare centers, animal production facilities, farms, and greenhouses (Al Haq, Clark, Fertelli, Gray, Hakim, Holm, Sitlzer). To emphasize its safety, it is commonly used by dentists during a root canal to disinfect that hole in the gums after a tooth is extracted.

U.S. Regulatory Agencies Recognize the Safety and Efficacy of HOCl

HOCl is recognized to be both safe for human contact, as well as a powerful disinfectant. There is extensive literature on the exceptional safety of HOCl, which is both contact and inhalation safe (Thorn, Clark, Fertelli). This is in stark contrast to other chemical disinfectants such as peroxides, bleach, and peracetic acids, which require complex and costly precautions to prevent any possible exposure of the operator or people to misting, due to their toxic side-effects (CDC reports on peracetic acid and glutaraldehyde).

The U.S. FDA has approved a variety of therapeutic uses for HOCl in and on the human body, emphasizing its safety. These include disinfection of incisions during surgery to prevent infection and promote wound healing, spraying directly into the eye to treat the virus that causes pink eye, application on skin for cosmetic purposes, and to treat eczema.

The U.S. EPA has recognized the ability of HOCl to kill a variety of viral, fungal, and bacterial pathogens. Importantly, HOCl kills some of the most difficult pathogens affecting humanity, and the most costly pathogens to the healthcare system and economy. The disinfection power of HOCl is emphasized by its entry on a variety of specialized "Lists" that EPA publishes for some of the world's most difficult pathogens, including the coronavirus (List N).

Additionally, HOCl is not considered a toxic substance by OSHA and has no hazardous material disposal requirements (Material Safety Data Sheets).

HOCl for Viral Disinfection

The potent virucidal activity of hypochlorous acid has been demonstrated through numerous peer-reviewed publications and is highlighted in its ability to kill viruses that cannot be eradicated with alcohol-based sanitizers and disinfectants.

Coronaviruses – SARS, MERS and SARS-CoV-2

The exceptional anti-viral activity of HOCl has led to the EPA recognizing its efficacy against coronaviruses and the inclusion of HOCl products on "list-N", disinfectants approved for use against emerging viral pathogens including the novel coronavirus, SARS-Cov-2. The EPA registration of HOCl underlines its role as both a safe and extremely powerful disinfecting tool (EPA "N" list).

Avian Flu (H5N1)

The power of HOCl as an environmental viral disinfectant was highlighted in a 2015 study demonstrating that it could eradicate avian flu (H5N1), a highly pathogenic and difficult to control infection (Hakim).

Norovirus

HOCl has also been shown to kill viruses that cannot be killed with other sanitizers and disinfectants. Norovirus is highly virulent and can be easily spread through surface-mediated transfer, however, it cannot be killed using alcohol-based sanitizers. A recent study demonstrated that HOCl could effectively eradicate Norovirus both through spraying and fogging (Park).

Hepatitis B

The use of HOCl was shown to be efficient for the disinfection of medical equipment, specifically gastroscopes, that were contaminated with Hepatitis B surface antigen (HBsAg)(Gao).

HOCl for Bacterial Disinfection

In addition to its potent antiviral activity, hypochlorous acid is also recognized as one of the disinfectants with the highest bactericidal activity against a broad range of microorganisms. The efficacy of HOCl against a select group of some of the most virulent and antimicrobial resistant bacteria are discussed in detail below.

Clostridium Difficile

Hospitals are known to harbor high levels of difficult-to-kill bacteria, which can lead to hospital acquired infections (HAI). HOCl was shown to completely eradicate Clostridium difficile, one of the leading contributors to HAI, from profoundly contaminated hospital rooms (Sitzlar).

Anthrax

One of the most potent bioterrorism threats is Anthrax, which can also occur as a common but deadly environmental contaminant. This threat is augmented due to the inability of most antimicrobials to kill or remove anthrax from hands or surfaces. HOCl was shown to effectively remove Bacillus anthracis Surrogates more efficiently than soap or alcohol-based sanitizer (Nerandzic).

Legionella

Another highly pathogenic bacteria is Legionella which can cause both Legionnaires disease and Pontiac fever. HOCl misting was shown to reduce Legionella to non-detectable levels and was subsequently recommended for institutional use in local Italian Hospitals (Migliarina).

Methicillin-resistant Staphylococcus aureus (MRSA)

MRSA is an extremely dangerous antibiotic resistant HIA, which is the leading cause of morbidity and mortality in burn victims. The eradication of MRSA has been extremely

challenging, however, HOCl has been shown to be efficient at killing MRSA and reducing the incidence of infections. This can be done through both environmental disinfection as well as wound bathing, where HOCl solution is applied directly to the skin to prevent bacterial growth (Gray, Anagnostopoulos).

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