DECONTAMINATION SYSTEM OPERATOR MANUAL

Model(s): ADS

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1.0 INTRODUCTION

1.1 Purpose

The AeroClave ADS utilizes an EPA-approved hospital disinfectant to give end users the ability to decontaminate their vehicles and equipment after every transport. The modular design and small size of the ADS allows this unit to be tucked away in a cabinet or on the wall inside the treatment area. It's always ready to be run at a moment's notice while on the road or back at your facility.

The nozzle assembly is installed inside the patient compartment to deliver an even blanket of disinfectant to every surface. The mounting bracket pivots to allow for easy positioning on the ceiling, wall or on top of the main module. The standard locations for the nozzle are either over the back doors or on the bulkhead between the patient compartment and the driver's cab.

The ADS provides the most convenient, hands-off solution to decontaminate your vehicle's interior quickly, safely, and effectively. The AeroClave process provides consistent, reliable delivery of the perfect amount of disinfectant, decontaminating to OSHA and NFPA specifications every time in a matter of minutes.

1.2 Terms and Definitions

Warning Countdown: Period of time prior to the start of a decontamination cycle when the treatment area should be vacated.

Personnel Scan: Period of time prior to the start of a decontamination cycle when the motion detector, located in the treatment area, performs a final security check to ensure that all personnel have vacated the treatment area.

Injection Phase: In this phase, the solution is aerosolized and applied evenly to the treatment area. A typical injection phase can last anywhere from 5-30 minutes, depending on the size of the treatment area.

Dwell Phase: Once an injection phase has been completed, the treatment area is allowed to sit in a dwell period. The dwell period gives the aerosolized solution an opportunity to evenly distribute throughout the treatment area, ensuring complete coverage on all surfaces.

Aeration Phase: The aeration phase is when the solution is removed and the treatment area is returned to its normal habitable state.

1.3 AeroClave Process Overview

The AeroClave Process is ideal as the final step in the decontamination of emergency vehicles, facilities and equipment. The AeroClave fogging technology creates a fine, atomized particle that reaches into nooks, crevices and corners that disinfecting sprays and wipes just can't reach. The dry mist permeates the entire area disinfecting surfaces while reaching under counters and furniture. The process provides consistent, reliable delivery of the right amount of disinfectant, decontaminating to specification every time. Fogging is recommended as a supplemental measure either before or after regular cleaning and disinfecting procedures.

1.4 Aerosolized Application Process

1.4.1 **Set-up Phase:** You must prepare the area for treatment so that the aerosolized mist can cover all surfaces you wish to treat.

1. Survey the area being decontaminated. Be sure to note the following:
   a. That all personnel/animals have been vacated from the treatment area.
   b. That all doors (other than exit/entry) and windows have been properly shut.
   c. That any and all items not wished to be decontaminated have been removed from the treatment area.
   d. That all surfaces wishing to be decontaminated are exposed (e.g., open drawers and cabinet doors).
2. Adequately isolate the area by shutting down and/or close off all HVAC, ventilation, or exhaust fans.
3. Once the treatment area has been deemed safe, exit the area, being sure to properly shut exit/entry door.

WARNING: The fine aerosol generated by the process may activate some styles of smoke detectors. Optical- based smoke sensor systems are typically the most susceptible to these false alarms. The facility or asset being treated must be evaluated on a case-by-case basis, and appropriate measures must be taken prior to treatment.

1.4.2 **Injection Phase:** In this phase, the decontamination solution is aerosolized and applied evenly to the treatment area. A typical injection phase will last anywhere from 5-30 minutes, depending on the interior volume of the vehicle.

1.4.3 **Dwell Phase:** Once the injection phase has completed, the treatment area is allowed to sit in a dwell period for a minimum of 10 minutes. The dwell period gives the aerosolized solution an opportunity to evenly distribute throughout the treatment area, ensuring full coverage on all surfaces.

1.4.4 **Aeration Phase:** The aeration phase is when the solution is removed from the treatment area. This can be done in various ways: re-energizing the facility HVAC system, providing

external ventilation, promoting air circulation with fans, etc. The solution will also naturally break down itself over a period of time if none of these aeration options are available.

1.5 Vital Oxide Disinfectant

1.5.1 The AeroClave aerosolized application process uses Vital-Oxide, an EPA-approved hospital disinfectant solution to decontaminate rooms, vehicles and equipment.

1.5.2 It is EPA registered in all 50 states and Puerto Rico.

1.5.3 The disinfectant works using Highly Selective Oxidation. These oxidizing properties allow it to destroy a wide range of pathogens.

1.5.4 Vital Oxide kills microbes by chemically altering certain amino acids that contain sulfur. The amino acids are building blocks in the proteins that help to form cell walls. When these proteins are destroyed, the cell wall ruptures and the organism dies. In the chemical reaction, Vital Oxide takes on an electron from the amino acid and reverts back to a chlorite ion. The amino acid gives up an electron, and giving up an electron is what chemists call oxidation.

1.5.5 The proprietary technology of the disinfectant causes the disinfectant molecules to become molecular free radicals. This creates a magnetic-like attraction that allows the disinfectant to seek out electron donors and selectively target harmful pathogens.

1.6 Efficacy

1.6.1 Via independent laboratory testing, this hospital grade disinfectant has proven complete inactivation of MRSA, Norovirus, HIV, H1N1, Hepatitis B, Hepatitis C, Legionella, Pseudomonas Aeruginosa and much more.

1.6.2 99.999% elimination of bacteria, including E.coli, salmonella and listeria.

1.6.3 Also effective against mold and mold spores, including Aspergillus niger, Alternaria alternata, Penicillium and Stachybotrys.

1.7 Benefits

1.7.1 The biggest advantages of the disinfectant are its short cycle time, incredible effectiveness, universal applications, and most importantly, its safety profile.

1.7.2 Vital-Oxide is shelf stable, with over one year of shelf life, and ready to use (RTU), so no mixing is required.

1.7.3 Vital-Oxide produces no harmful by-products for the environment, contains no VOC's and is 100% biodegradable.

1.7.4 Wide range of uses, including hospitals, nursing homes, cruise ships, ambulances, police vehicles, fire stations and equipment, kennels, athletic facilities, including gyms and locker rooms, and laboratories.

1.7.5 Vital-Oxide has long-term effectiveness, extremely low toxicity, is non corrosive to treated surfaces, and is non-irritating to the skin.

1.7.6 Products are assigned to a toxicity category by the EPA. These categories range from category 1 (Highly toxic and Severely irritating) to category 4 (Practically non-toxic and not an irritant). Vital-Oxide received an EPA category 4 rating for all exposure routes with the exception of mild eye irritation.

1.7.7 National Safety Foundation (NSF) rated No Rinse Required on food contact surfaces at full strength.

1.7.8 Odors are completely eliminated on a molecular level, not covered up by fragrance or nose numbing chemicals.

2.0 SAFETY GUIDELINES

READ AND UNDERSTAND THIS OPERATOR'S MANUAL PRIOR TO USE OF THE SYSTEM. STRICTLY FOLLOW ALL SAFETY INSTRUCTIONS IN THIS OPERATOR'S MANUAL PRIOR TO, DURING, AND AFTER USE OF THE SYSTEM. SYSTEM OPERATORS MUST COMPLY WITH ALL SAFETY PRECAUTIONS MENTIONED IN THIS SECTION.

Use only AeroClave-approved solutions when operating this equipment. Failure to do so will result in voiding of warranty and may result in INJURY or DEATH. Follow all label instructions on approved solutions.

2.1 Operational Safety Guidelines

2.1.1 Only trained and qualified personnel should operate the AeroClave Decontamination System.

2.1.2 Only a qualified AeroClave service technician may repair or maintain this equipment.

2.1.3 Review and follow all labels and warnings marked on AeroClave products.

2.1.4 Do not put fingers, tools, or other foreign objects into spray area. Improper use may result in severe pain, injury or death.

2.1.5 Risk of injury including shock, death, or burn may occur if improperly handled.

2.1.6 Only use AeroClave-approved solutions for decontamination. Use of other solutions poses risk of injury, machine failure, and/or unintended results, and is prohibited.

2.1.7 Read and understand AeroClave-approved solutions MSDS’s and retain documents in an employee accessible location.

2.1.8 In case of exposure of skin to AeroClave solution, wash thoroughly with soap and water.

2.2 Operator Qualification

2.2.1 The operator must be trained and qualified to this manual or equivalent preceding manual. Hands on training in the operation of the AeroClave Decontamination System is required.

2.2.2 The operator must review and understand the AeroClave product manual and complete the necessary training given by qualified AeroClave personnel.

3.0 PRODUCT DESCRIPTION

3.1 Technical Specifications

3.1.1 **Main Unit**: The main unit of the ADS (Figure 1) is designed to be permanently mounted inside the patient compartment. The modular design and small size of the AeroClave ADS allows this unit to be tucked away in a cabinet or on the wall. All connections are made through the back of the unit.

FIGURE 1

Specifications:

- Case dimensions: (H)11.5 in x (W)12.5 in x (D)6.5 in
- Exterior: Stainless steel construction
- Weight: 15 lbs.
- Power supply: 12 VDC, 4 amps
- Mounting brackets: Both wall-mount and shelf-mount
- Remote control range: Maximum 100 ft.
- Reservoir: 2000 ml with valve
- Air requirement: Minimum 1 cfm @ 30 psi
- Operating temp: 35°F to 80°F at between 45% to 75% relative humidity

3.1.2 **Main Nozzle Assembly**: The main nozzle assembly (Figure 2) is installed inside the patient compartment to deliver an even blanket of disinfectant to every surface. The mounting bracket pivots to allow for easy positioning on the ceiling, wall or on top of the main module.

Each ADS unit includes one main nozzle assembly, which contains the main nozzle and a number of safety components. This assembly must be installed in the main treatment area, which in the case of an ambulance is the patient compartment. This allows the built-in motion detector to scan the treatment area for unauthorized personnel before the system will run a cycle. In addition, the strobe will be visible as a warning that the system is running a cycle.

FIGURE 2

Nozzle Assembly Specifications:

- Case dimensions: (H)2.0 in x (W)5.5 in x (D)4.7 in
- Nozzle: Brass or acrylic
- Safety components:
    - motion detector
    - strobe light
    - air flow sensor

3.1.3 **Optional Remote Nozzle**: In some larger applications a second or third remote nozzle may be needed for complete coverage of the treatment area. The Remote Nozzle (Figure 3) only includes a spray nozzle, without any of the safety components.

FIGURE 3

Remote Nozzle Assembly Specifications:

- Dimensions: (L) 1.5in x (W) 1.5in x (D) 2.25in
- Material: Stainless steel and plastic

4.0 SET-UP/OPERATION

4.1 Pre-decontamination Set-up

4.1.1 Prior to any decontamination using the Ambulance Decontamination System, pre-clean the treatment area of any and all gross contaminants (blood, vomit, etc.).

4.1.2 Survey the area being decontaminated. Be sure to note the following:

a) That all personnel/animals have been vacated from the treatment area.

b) That all doors (other than exit/entry) and windows have been properly shut.

c) That any and all items not wished to be decontaminated have been removed from the treatment area.

d) That all surfaces wishing to be decontaminated are exposed (e.g., open drawers and cabinet doors).

4.1.3 Once the treatment area has been deemed safe, you may start the process.

4.2 Decontamination Cycle Operation

4.2.1 **Power On/Off:** Use the green button, located on the upper right face of the main unit, to power on the ADS. The ADS will remain on until the Shut Off timer, referred to below, detects the specified time period of inactivity.

4.2.2 **Main Screen:** When initially powered up, the touchscreen will display the AeroClave logo (Figure 4). To access the Main Menu (Figure 5), press the logo.

FIGURE 4

4.2.3 **Main Menu: (**Figure 5)

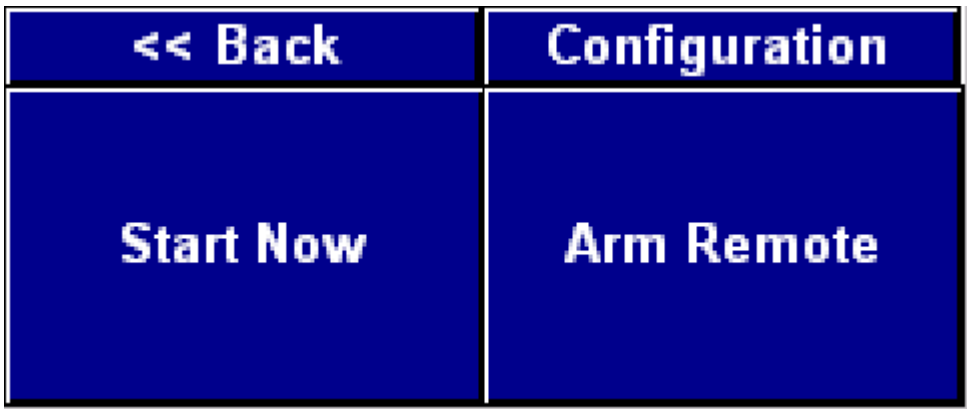

FIGURE 5

4.2.4 **Configuration Settings:** Access the Configuration screen (Figure 6) by pressing the button labeled Configuration. The only two user configurable variables are presented on the screen.

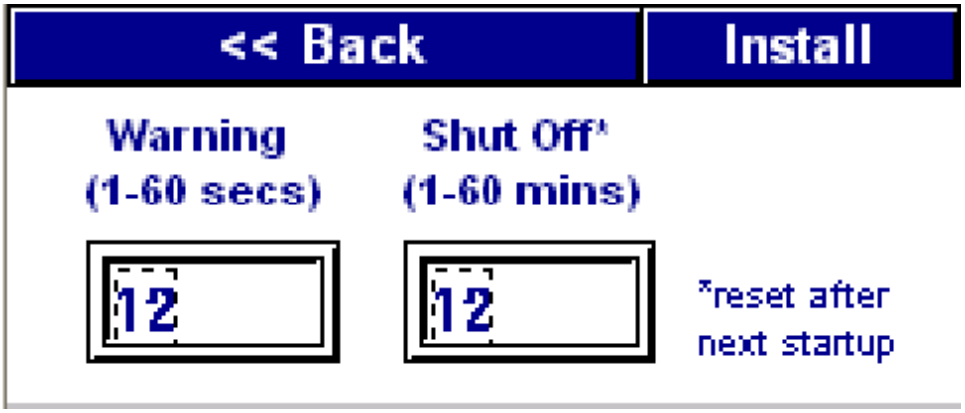

FIGURE 6

Variable 1 — Warning Timer: The AeroClave process will begin after the time specified in the Warning text box. This gives you time to start the countdown and exit the treatment area. The warning timer may be set from 1 to 60seconds.

Variable 2 — Shut Off Timer: The ADS utilizes power from the vehicle's electrical system. To minimize the possibility of draining the vehicle's batteries, a Shut Off Timer is started when the unit is powered on. The unit will turn itself off after the specified timeframe if the unit is inactive. The default time is 15 minutes, but you may set the time between 1 and 60 minutes.

NOTE: After adjusting these variables, a reboot of the system is required prior to the next operation cycle.

4.2.5 **Starting AeroClave Process:** There are two methods to run an AeroClave cycle. Both are accessed from the Main menu (Figure 7).

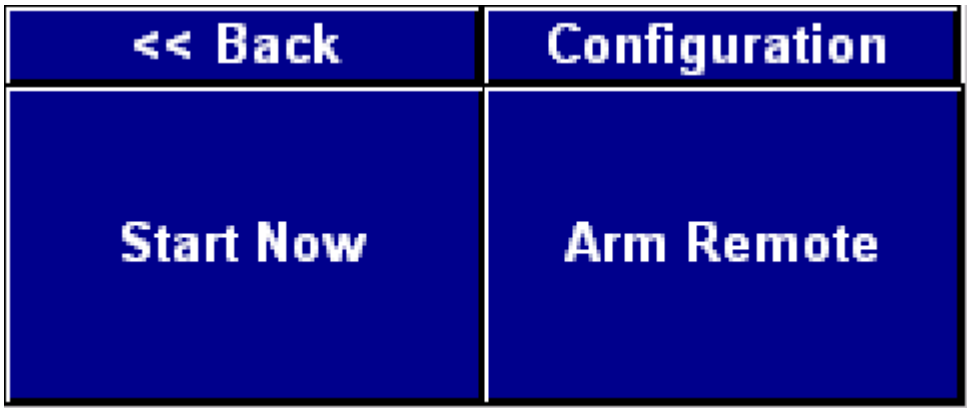

FIGURE 7

Method 1 — Start Now: Simply press the Start Now button (Figure 8). The Warning Countdown will immediately begin. This countdown is to allow time for you to exit the treatment area. You must exit the treatment area in the time allotted by the Warning Timer referred to above. After the Warning Countdown has finished, there will be a dwell period while the system will use the motion detector to scan for unauthorized personnel. Only after the system determines that the treatment area is clear will the aerosolization begin.

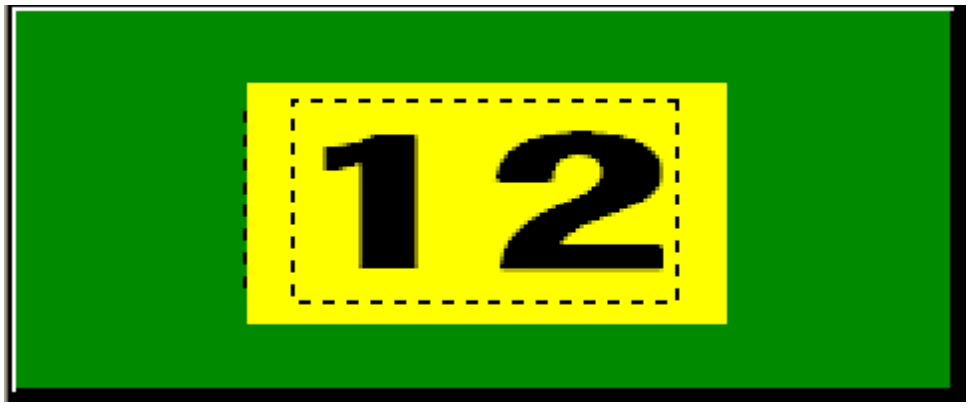

FIGURE 8

Method 2 — Arm Remote: Press the Arm Remote button to tell the system that you will begin the cycle with the remote control (Figure 9). The touch screen will flash the message "Use remote to start system" (Figure 10) until you do so.

FIGURE 9

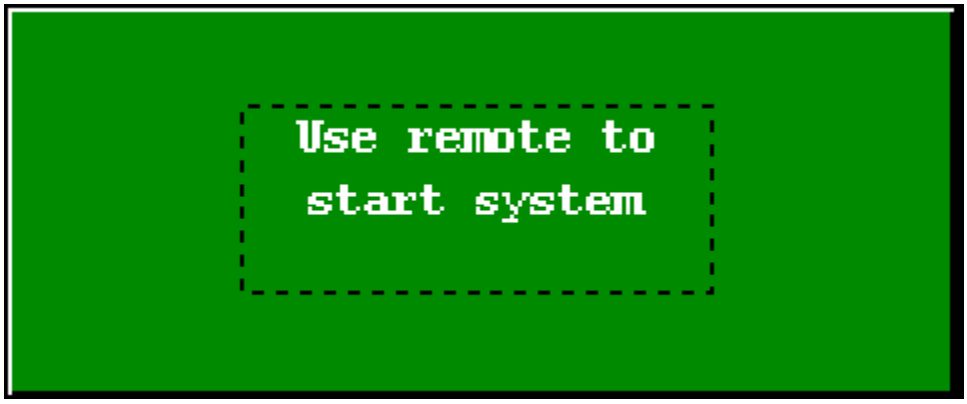

FIGURE 10

This method of starting a cycle allows you to completely exit the treatment area before starting the countdown. The remote control has a maximum range of 100 feet depending on the surrounding level of wireless interference.

4.3 Emergency Stop Operation

4.3.1 **Stopping the AeroClave Process:** The AeroClave process is designed to be self-monitoring and will run unattended until completion. In addition, the ADS will power itself off after being inactive for the timeframe specified in its configuration.

4.3.2 If you have the need to stop the AeroClave cycle before its completion, you must do an Emergency Stop. There are two methods to affect an Emergency Stop:

Method 1: While the cycle is in any mode of the process the touchscreen on the main unit may be pressed at anytime to abort the cycle.

Method 2: The Remote Control may be used as an Emergency Stop button at anytime to abort the cycle. This is true no matter if you started the cycle with the remote or not. This is the recommended method to use if the system has gone into the injection phase of the cycle.

5.0 PREVENTATIVE MAINTENANCE

The ADS must be flushed with distilled water on a monthly basis to ensure proper operation and a long life. The length of time necessary to fully flush the system is dependent on the number of nozzles installed inside the treatment area. After flushing the system, you should re-prime the system by switching the reservoir back to Vital Oxide and running for the prescribed time. Please refer to Table 1 for Flush and Re-Prime times. You must follow the following steps flush the system correctly.

5.1 General Guidelines

5.1.1 Flush ADS completely on a monthly basis.

5.1.2 Use **only** distilled or deionized water when flushing the ADS.

5.1.3 After the maintenance flush, re-prime the ADS with disinfectant

5.2 Maintenance Steps

5.2.1 Replace the fluid in the on-board reservoir with **distilled or deionized water only**.

5.2.2 Start the operation of the ADS unit like normal.

5.2.3 Use the remote control as an E-stop to stop the unit after it has run for the prescribed Flush Time (see Table 1).

5.2.4 Reset the system.

5.2.5 Switch the reservoir back to Vital-Oxide.

5.2.6 Start the operation of the ADS unit like normal.

5.2.7 Use the remote control as an E-stop to stop the unit after it has run for the prescribed Re-Prime Time (see Table 1).

5.2.8 Reset the system.

Table 1

# of Nozzles	Flush Time	Re-Prime Time
One	2 minutes	1 minute
Two or more	4 minutes	3 minutes

6.0 TROUBLESHOOTING

6.1 Error Messages

6.1.1 There are three situations that will cause the system to automatically shutdown. If you encounter one of these situations, the touchscreen will reflect the error. To acknowledge the error and reset the system simply press the touchscreen.

Situation 1 — Motion Detected Decon Aborted: The motion detector in the main Nozzle Assembly has detected an intrusion and has aborted the decontamination cycle. Press the touchscreen to reset the system.

Situation 2 — Air Pressure Drop Decon Aborted: The Air Pressure Sensor has detected that the air pressure for the system has fallen out of range and has shutdown the system. Please check that the air supply is sufficient for operation.

Situation 3 — Low Fluid Flow Decon Aborted: The system has detected that not enough fluid is flowing to complete the injection. This can be because the fluid reservoir is empty or that there is a leak in the system. Please check the reservoir level before every run.

7.0 APPENDIX

7.1 Appendix-A: Vital-Oxide MSDS

Material Safety Data Sheet: Vital Oxide

MSDS No: VO020215

Section 1: Product and Company Identification

Product Name Vital Oxide
Aqueous Oxidant
Manufacturer/Distributor Vital Solutions, LLC.
PO Box 9932
West Palm Beach, FL 33419
Phone Numbers
Product Information: (561) 848-1717
Medical Emergency: (800) 222-1222

Section 2: Composition/ Information on Ingredients

Ingredients CAS Number Wt %
Oxychlorine Compounds Mixture 0.200
n-Alkyl Dimethyl Benzyl Ammonium Chloride 68391-01-5 0.125
n-Alkyl Dimethyl Ethyl benzyl Ammonium Chloride 85409-23-0 0.125
Inert Ingredients Mixture 99.55
At these concentrations none of the ingredients are known to pose any hazards to human health.

Section 3: Hazards Identification

Emergency Overview
Colorless liquid with mild fresh odor. Avoid contact with eyes. Keep out of reach of children.
HMIS Rating: Health: 0 **Flammability:** 0 **Reactivity:** 0 **PPE:** None
Potential Health Effects
Eye Contact: Eye contact may cause mild eye irritation with discomfort.
Skin Contact: Does NOT cause skin irritation and the product is NOT skin sensitizer.
Inhalation: Does NOT cause any respiratory irritation. If consumer product accidentally contacts strong acids in restricted ventilation area, avoid breathing the vapors and allow adequate time for the vapors to disperse before re-entering the restricted area.
Ingestion: Non-Toxic
Carcinogenicity Information None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, and ACGIH as carcinogens.

Section 4: First Aid Measures

Inhalation
Does NOT cause any respiratory irritation. If consumer product accidentally contacts strong acids in restricted ventilation area, avoid breathing the vapors, and allow adequate time for the vapors to disperse before re-entering the restricted area.
Skin Contact
Does NOT cause skin irritation.
Eye Contact
In case of contact, flush eyes with plenty of water.
Ingestion
Non-toxic. Give a glass of water.

Section 5: Fire Fighting Measures

Flammable Properties: Flash Point: Not Available (Non Flammable)
Flammable Limits: Lower Flammable Limit: Not Established
Burn Rate: Unknown
Upper Flammable Limit: Not Established
Flammability Classification: Non-Flammable liquid **Autoignition Temperature:** Not Established
Hazardous Combustion Products: Thermal or other decomposition may yield chlorine dioxide or chlorine.
Extinguishing Media: N/A (Non-Flammable liquid) **Additional Considerations:** None
FIRE FIGHTING INSTRUCTIONS: Non-Flammable liquid
NFPA Rating: Health: 0 **Flammability:** 0 **Reactivity:** 0 **PPE:** NONE

Section 6: Accidental Release Measures

Spill Clean Up
No special cleanup measures are required for the consumer product. To avoid the possibility of "bleaching" the spill should be absorbed with paper towels, and the area rinsed with clean water.
Accidental Release Measures
Spills are slippery and should be cleaned up promptly.

Section 7: Handling and Storage

Handling: Keep away from heat and strong acids. Do not ingest. Keep container closed. Use only with adequate ventilation.
Storage: Keep container tightly closed and sealed until ready for use. Keep container in a well-ventilated place. Do not store above 120ºF or near fire of open flame. Store large quantities in buildings to comply with OSHA 1910.106. Do not transfer contents to bottles or other unlabeled containers. Do not reuse empty containers. Keep out of reach of children.
Incompatible materials: Strong acids
Special Packaging Materials: None

Section 8: Exposure Control/ Personal Protection

Engineering Controls: Use in adequately ventilated areas.
Personal Protective Equipment:
Eye/Face Protection: Not required for consumer product.
Skin Protection: Not required for consumer product.
Respirators: None required for normal use. If consumer product accidentally contacts strong acids in restricted ventilation area, avoid breathing the vapors, and allow adequate time for the vapors to disperse before re-entering the restricted area.
Exposure Limits:
Oxychlorine Compounds: n-Alkyl Dimethyl Ethyl benzyl Ammonium Chloride:
PEL (OSHA): Not available PEL (OSHA): Not available
TLV (ACGIH): Not available TLV (ACGIH): Not available
n-Alkyl Dimethyl Benzyl Ammonium Chloride:
PEL (OSHA): Not available
TLV (ACGIH): Not available

Section 9: Physical and Chemical Properties

Appearance: Colorless liquid **Odor:** Mild-Fresh
Physical State: Liquid **pH:** 8 - 9
Boiling Point (°F): 212 **Solubility in Water:** 100%
Freezing Point (°F): 32 **Vapor Pressure (mm Hg):** Not Available
Volatile Organic Compounds (VOC): None **Evaporation Rate:** Less than Ether
Specific Gravity: 1.003 @ 68°F (20°C) **Density (lb./gal):** 8.40 @ 68°F (20°C)

Section 10: Stability and Reactivity

Chemical Stability: The product is stable. **Incompatibility with other Materials:** Strong acids
Conditions to avoid: Contact with strong acids **Hazardous Polymerization:** Will not occur.
Hazardous Decomposition Products: Thermal or other decomposition may yield chlorine dioxide or chlorine.

Section 11: Toxicological Information

TOXICITY TESTING – ACUTE **Inhalation** – Studies with Wistar Albino rats exposed to a respirable aerosol made from a solution of Vital Oxide at a level of 2.08 mg/l for four hours resulted in no deaths and no abnormal necropsy observations. **Eye Contact** – Studies with New Zealand white rabbits showed this product is a very mild ocular irritant; mild conjunctival irritation was observed, but cleared within 24 hours. **Skin Contact** – Study of dermal toxicity in New Zealand white rabbits showed the product to be non- toxic: Dermal LD_{50}> 5,000 mg/kg of body weight; Study of dermal irritation in New Zealand white rabbits showed the product is not a dermal irritant. In Dermal Sensitization studies, Vital Oxide was determined not to be a sensitizer. **Swallowing** - Acute oral toxicity in albino rats: Nontoxic LD_{50}>5,000 mg/kg of body weight.
EPA TOXICITY RATING – IV This is the lowest category on the scale and is designed for substances that are the least hazardous.

Section 12: Ecological Information

Environmental Hazards: Not data available.
Environmental Fate: Not data available.

Section 13: Disposal Considerations

Waste Disposal: Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial and Local regulations.

Section 14: Transport Information

Shipping Information: Not regulated by DOT, IMO/IMDG and IATA/ICAO for ground, air or ocean shipments.

Section 15: Regulatory Information

U.S. Federal Regulations:
TSCA: All components appear in TSCA Inventory **OSHA:** Refer to Section 8 for exposure limits.
CERCLA SARA Hazard Category:
Section 311 and 312: This product has been reviewed according to the EPA "Hazard Categories" promulgated under Sections 311 and 312 of the Superfund Amendment and Reauthorization Act of 1986 (SARA Title III) and is considered, under applicable definitions, to meet the following categories: Information not available.
Section 313: This product contains following substances subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372: None
State regulations:
State Right to Know information is not provided. **California prop. 65 (no significant risk level):** None
International Regulations:
Canadian WHMIS: Not controlled
Canadian Environmental Protection Act (CEPA): Additional information available upon request.
EU Regulations: Additional information available upon request.

Section 16: Other Information

The information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of Vital Solutions, LLC. The Data on this sheet related only to the specific material designed herein. Vital Solutions, LLC assumes no legal responsibility for the use or reliance on this data.