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HYPO-CHLOR[®]

Sterile Pharmaceutical Clean Room Formula

**5.25%, 0.52% AND 0.25%
STERILE SODIUM HYPOCHLORITE**



Veltek Associates, Inc.

15 Lee Boulevard • Malvern, PA 19355-1234

Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com VL-801-98 Rev. 12/18/03

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HYPO-CHLOR[®] **Sterile Clean Room Formula**

PRODUCT DESCRIPTION

HYPO-CHLOR is designed for pharmaceutical and biotechnology operations that demand a sterile sodium hypochlorite solution. HYPO-CHLOR is an effective one step, ready to use product that is available in premixed concentrations of 5.25%, 0.52% and 0.25%. Formulation of HYPO-CHLOR is accomplished with USP Purified Water. HYPO-CHLOR is tested in accordance with USP24 NF19 guidelines in development of the Certificate of Analysis and Sterility Test Results. HYPO-CHLOR is produced sterile by aseptic filtration at 0.2 microns. The product is available in 16 oz. bottles with trigger sprayers, 13-OUNCE UNIT DOSE BOTTLES (mix with 2-gallon of water to make a 0.52% solution) and 1-gallon containers both sterile and non-sterile. Each container is double bag packaged and delivered each time with the lot specific Certificate of Analysis and Sterility Report. HYPO-CHLOR products are completely traceable and have been completely validated for sterility and shelf life.

Uses: HYPO-CHLOR Sterile Sodium Hypochlorite solutions are used for areas such as walls, ceilings, floors, surfaces and many other applications that require the use of a sterile sodium hypochlorite solution.

ORDERING INFORMATION

Order#	Description	Quan/cs.
SHC-01-5.25	HYPO-CHLOR 1 Gallon Non-Sterile@5.25%	4
SHC-02-5.25	HYPO-CHLOR 1 Gallon Sterile@5.25%	4
SHC-02-0.52	HYPO-CHLOR 1 Gallon Sterile@0.52%	4
SHC-02-0.25	HYPO-CHLOR 1 Gallon Sterile@0.25%	4
SHC-13Z-5.25	HYPO-CHLOR 13 oz. Unit dose Sterile@5.25%	12
SHC-16Z-5.25	HYPO-CHLOR 16 oz. Sterile@5.25%	12
SHC-16Z-0.52	HYPO-CHLOR 16 oz. Sterile@0.52%	12
SHC-16Z-0.25	HYPO-CHLOR 16 oz. Sterile@0.25%	12

Available Technical Data Supplements (Upon Request)

SC-001: Sterile Chemical Product Guide

VL-801: HYPO-CHLOR Technical Data Report

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The Use of HYPO-CHLOR® in Aseptic Manufacturing Operations

An Overview of Sodium Hypochlorite:

This section is not intended to be a label claim for the product HYPO-CHLOR®, but rather a discussion that is intended to assist one in the understanding the applicability of the information found on products deemed suitable for the clean room.

The use of a sodium hypochlorite in aseptic manufacturing operations stems back to the origination of the industry itself in the late 1940's. Sodium hypochlorite, or bleach, has been and still remains one of the most used decontamination products for clean room operations. It's effectiveness against microorganisms is well documented in what is termed 'Block's Book' (Block, Seymour Stanton (ed.), *Disinfection, Sterilization and Preservation*, Lea and Febiger, 4th Edition, Philadelphia, 1991). As this data is superior in its content, one should not need to reproduce the data contained in this report, as it would be duplication of proven science. This report should be used as a reference guide and sodium hypochlorite solutions should be further confirmed against one's internal environmental isolates in a time contact kill study prior to use.

During evaluation of antimicrobial effectiveness, one needs to remember the parameters of the AOAC protocol testing. The test requires a complete reduction of 10^6 organisms, in a 60-carrier test, at 20°C, in a soil load. The unknown factor is the time it takes to destroy all of the organisms. Registrations in the marketplace show the lowest time period to accomplish this for a sporicidal agent is 5 hours and 10 minutes for a disinfecting agent. This is not realistic, as the dry time on the surfaces in the clean room is 3-10 minutes. Due to laminar flow air movement, solutions dry faster and the label claim we see may not be applicable to the manner in which products are used. Thus, the pharmaceutical and biotechnology industry have used a lower organism enumeration rates of 1.0×10^4 and a dry time of 3-10 minutes to confirm a chemical's effectiveness against their environmental isolates.

A complete guide can be found in VAI Technical Documents:

98-DA-2001.PDF
VAL-DIS98.PDF
VAL-LABS99.PDF

Contact VAI technical Support at 1-888-478-3745 or by e-mail at help@sterile.com

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Using HYPO-CHLOR® Sterile

The purpose of this section of the report is to explain the “appropriate use” of the product in a clean room operation. The use of HYPO-CHLOR® in clean room operations reduces the concerns that may exist with Gluteraldehyde or Peracetic Acid/Hydrogen Peroxide mixtures. Unlike Gluteraldehyde or Peracetic Acid/Hydrogen Peroxide mixtures, sodium hypochlorite does not have the level of harmful vapors nor the accompanying health risks that are associated with these other solutions. End users are familiar with its smell and use precautions it is a well-used product in the home. The biggest concern with HYPO-CHLOR® relates to residues and deterioration of the surface. This problematic situation relates to remaining residues. **If handled appropriately, this concern can be eliminated from the scope.**

There are two problems with sodium hypochlorite. The first is what concentration should be used and the second deterioration of the surface. The first, concentration, points to industry standards that look at a 0.52% solution over a 5.25%. The concentration of 0.52% is suitable for clean room and leaves less of a residue than 5.25%.

The second situation is residues. Unlike other bleach products HYPO-CHLOR® is made with Sodium hypochlorite and Purified Water, USP. The product is then filtered at 0.2 microns. This eliminates impurities that may exist in the product. Such impurities relate to not only existent particulate and microbial contamination, but also to heavy metals. The product is clean when applied to the surface. When the product dries, the chlorine burns off to the environment and a portion of the sodium content remains as a residue. This residue is easily removed by either a hot WFI rinse or by a mechanical action rinse or wiping of the surface with a dry wipe and isopropyl alcohol (DECON-AHOL WFI). Too many times, we apply the chemical agent, allow it to air dry and do not address the residue on surface that it may be incompatible such as stainless steel or aluminum. If we took pieces of stainless and aluminum and soaked them in a solution of HYPO-CHLOR® at a concentration of 0.52% for 10-20 minutes, removed them and allowed them to dry, we would find no harmful effect to the surfaces.

The key is removal of the residue. This especially applies to the residue being “coated” with another chemical agent such as phenol. In this scenario, the sodium and existent moisture are trapped below the phenol residue. The sodium and water contact with the metal for a long time period provides the mechanism for the sodium to attach the impurities in the metal. This is one of the main causes for deterioration of the surface.



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To combat this problem, surfaces need to be occasionally cleaned and/or rinsed. This will remove the problematic sodium residue from the surface. It is suggested and proven that a monthly cleaning will resolve this problem. Many pharmaceutical and biotechnology organizations have found this system as effective in contending with the sodium residue.

Enclosed in this report is a test report proving the remove of the sodium residue from the surface by rinsing and/or by the use of VAI's DECON-Clean.

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HYPO-CHLOR[®]

Sterile Pharmaceutical Clean Room Formula

SPECIFICATIONS

<u>Specification</u>	<u>HYPO-CHLOR</u>
Filtration:	0.2 Micron Absolute
Appearance:	Straw Clear Liquid
Odor:	Bleach
Percentage of Sodium Hypochlorite:	Either a 5.25%, 0.52%, or 0.25%
Biodegradable:	Yes
Class of Wetting Agent:	Anionic
Detergency:	Excellent
Solubility(water):	Excellent
Wetting ability:	Excellent
Specific Gravity:	0.8-1.2 g/cc
Litmus Test Addition of HCl(Yellow):	Passes
Addition of HCl gives off Cl ₂ Gas:	Passes
Storage Stability:	Excellent
Freeze-thaw stability:	Excellent-if frozen, thaw & mix well
Weight/Gallon:	11.6 lbs/gal.
Testing/Parameters:	USP24 Monograph for Assay and USP 24 Sterility tested.
Documents with Each Lot:	Certificate of Analysis and the Certificate of Sterility

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HYPO-CHLOR®

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**5.25%, 0.52% AND 0.25%
STERILE SODIUM HYPOCHLORITE**

PRODUCT LABELING

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(CENTER PANEL)

HYPO-CHLOR®

Sterile Pharmaceutical Clean Room Formula

(At 5.25%, 0.52% and 0.25%)

ACTIVE INGREDIENTS:

	<u>@5.25%</u>	<u>@0.52%</u>	<u>@0.25%</u>
Sodium Hypochlorite	5.25% (25,390 ppm)	0.52% (2,539 ppm)	0.25% (1,269 ppm)
Purified Water, USP	94.75%	99.48%	99.75%

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Keep Out of Reach of Children

DANGER

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of Reach of Children. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Wear goggles, or face shield and rubber gloves when handling. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink large quantities of water. Call a Physician.

USE: Ready to use, apply and allow to air dry.

Contents: 1 gallon (128 ounces) or 16 ounces

HYPO-CHLOR®

Sterile Pharmaceutical Clean Room Formula

**REMOVAL OF EXISTENT RESIDUES
OF HYPO-CHLOR WITH DECON-Clean**

TECHNICAL REPORT

Veltek Associates, Inc.

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Surface Evaluation for Determining the Residual Levels of VAI Sterile Chemicals and Disinfectants

QA Test Report: Veltek Associates, Inc. Report#: 001701-RESID Date: 08/12/95 REV: 9/02/99

Discussion and Purpose of Testing:

Chemical residues on surfaces can be measured and appropriate operating procedures developed to reduce their existence. VAI has developed DECON-Clean[®] Residue remover to assure that the partial removal of existent chemical residues. All chemicals leave a residual on the surfaces that they come in contact. Residues take various forms such as Particulate Impurities and Chemical Ingredients. By removing these residue, a class 100 aseptic facility is less likely to transfer existent residues from their initial location to critical manufacturing sites.

Particulate and Impurity Residues:

Particulate and Impurity Residues are removed from the solution by filtration at 0.2 microns. All VAI Sterile chemicals and Disinfectants have this level of filtration. Particulate or Impurity Residues can cause contamination problems, and could provide a nutrient source for existent organisms in the aseptic manufacturing area.

Chemical Ingredient Residues:

Chemical Ingredient Residues pose a complicated problem associated with both buildup and cross-contamination. The removal of such residue should be considered as a standard practice to eliminate the possibility of the concerns.

DECON-Clean as a Residue Remover:

DECON-Clean has been developed to cope with the removal of residues within the class 100 aseptic manufacturing operation. The patented formula assures the breakdown of VAI's DECON-AHOL[®], STER-AHOL[®], DECON-PHENE[®], DECON-PHASE[®], DECON-CYCLE[®], PHENE-AHOL[®], DECON-Clean[®], DECON-QUAT 100[®], HYPO-CHLOR[®], STERI-PEROX[®], DECON-SPORE 100[®], DECON-SPORE 200[®], and DECON-SPORE 200[®] PLUS products. Elements in the formulation of the above listed VAI products are broken down by the DECON-Clean mixture. Once broken down, these residues or remnants of chemicals may be mopped, sponged, wiped or rinsed free from the surface.

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DECON-Clean's Effectiveness Test Procedure:

DECON-Clean was tested against the following chemicals for effectiveness of residue removal and was found extremely effective in the control of residual levels.

DECON-AHOL (70% and 91% RTU)	STER-AHOL (70% RTU)
DECON-PHENE (1:128 Use Dilution)	DECON-PHASE (1:256 Use Dilution)
DECON-CYCLE (1:256 Use Dilution)	PHENE-AHOL (70% ETOH-0.21% Phenol)
DECON-QUAT 100 (2:128 Use Dilution)	HYPO-CHLOR (5.25%, 0.52%, and 0.25%)
STERI-PEROX (3% and 6%)	DECON-SPORE 100 (0.86%)
DECON-SPORE 200 PLUS 5%	DECON-SPORE 200 (1:32 Use Dilution)

Test Procedure:

Controls:

1. A stainless steel surface (316L) was defined for the test.
2. Two (2) ounces of each chemical were prepared and the surface was completely exposed to the chemical in separate tests..
3. The chemical was permitted to completely dry.
4. Testing is to be conducted in a Class 100 laminar flow hood.
5. All safety precautions are to be taken referencing safety. This includes gowning, gloves and a NIOSH approved chemical mask.
6. DECON-AHOL Sterile USP 99% Isopropyl Alcohol was applied to the surface containing the residues.
7. The IPA was allowed to remain on the surface for 15 seconds and then collected into a sample bottle.
8. The samples were clearly marked as controls/chemical tested and delivered to the laboratory for Gas-Liquid Chromatography Testing.
9. Results to establish baselines residue were assessed and reported.

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Results:

<u>Chemical Tested</u>	<u>Results:</u>
DECON-AHOL 70% (RTU)	ppm of isopropyl alcohol = 0 ppm*
DECON-AHOL 91% (RTU)	ppm of isopropyl alcohol = 0 ppm*
STER-AHOL 70% (RTU)	ppm of ethanol = 0 ppm*
DECON-PHENE (1:128 Use Dilution)	ppm of Phenols and Chlorophenols = 759 ppm
DECON-PHASE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 727 ppm
DECON-CYCLE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 731 ppm
PHENE-AHOL ((70% ETOH/Phenol RTU	ppm of Phenols and Chlorophenols = 0.016 ppm*
DECON-QUAT 100 (2:128 Use Dilution)	ppm Peroxyacetic acid = 133 ppm
HYPO-CHLOR 5.25%	ppm of Sodium Chloride = 49,768 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 969 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 368 ppm
STERI-PEROX 3%	ppm Hydrogen Peroxide = 0.012 ppm*
STERI-PEROX 6%	ppm Hydrogen Peroxide = 0.067 ppm*
DECON-SPORE 200 PLUS 5%	ppm Peroxyacetic acid = 9 ppm
DECON-SPORE 100 (0.86%)	ppm Peroxyacetic acid = 7 ppm
DECON-SPORE 200 (1:32 Use Dilution)	ppm Peroxyacetic acid = 4 ppm

- *The level presented is a mathematical calculation as its value cannot be measured.*

Testing Residue Removal Ability of DECON-Clean as a SPRAY RINSE ONLY.

The above procedure for the control was repeated. After the chemical residue was established on the surface, the surface was cleaned with a DECON-Clean application at a use dilution of 1:128 as a RINSE ONLY. Once cleaning was performed testing proceeded from step #4 as listed above. Samples were collected and results are as follows:

Results:

<u>Chemical Tested</u>	<u>Results:</u>
DECON-AHOL 70% (RTU)	ppm of isopropyl alcohol = 0 ppm*
DECON-AHOL 91% (RTU)	ppm of isopropyl alcohol = 0 ppm*
STER-AHOL 70% (RTU)	ppm of ethanol = 0 ppm*
DECON-PHENE (1:128 Use Dilution)	ppm of Phenols and Chlorophenols = 61 ppm
DECON-PHASE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 48 ppm
DECON-CYCLE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 41 ppm
DECON-QUAT 100 (2:128 Use Dilution)	ppm Peroxyacetic acid = 11 ppm
HYPO-CHLOR 5.25%	ppm of Sodium Chloride = 134 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 24 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 16 ppm
STERI-PEROX 3%	ppm Hydrogen Peroxide = 0.000 ppm*
STERI-PEROX 6%	ppm Hydrogen Peroxide = 0.000 ppm*
DECON-SPORE 200 PLUS 5%	ppm Peroxyacetic acid = <2 ppm
DECON-SPORE 100 (0.86%)	ppm Peroxyacetic acid = <2 ppm
DECON-SPORE 200 (1:32 Use Dilution)	ppm Peroxyacetic acid = <2 ppm

- *The level presented is a mathematical calculation as its value cannot be measured.*

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Testing Residue Removal Ability of DECON-Clean USING MECHANICAL CLEANING

The above procedure for the control was repeated. After the chemical residue was established on the surface, the surface was cleaned with a DECON-Clean application at a use dilution of 1:128 and a VEL6-12X12 Dry Wiper using a circular mechanical cleaning action followed by a rinse. Once cleaning was performed testing proceeded from step #4 as listed above. Samples were collected and results are as follows:

Results:

Chemical Tested

Results:

DECON-AHOL 70% (RTU)	ppm of isopropyl alcohol = 0 ppm*
DECON-AHOL 91% (RTU)	ppm of isopropyl alcohol = 0 ppm*
STER-AHOL 70% (RTU)	ppm of ethanol = 0 ppm*
DECON-PHENE (1:128 Use Dilution)	ppm of Phenols and Chlorophenols = 0.00 ppm*
DECON-PHASE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 0.00 ppm*
DECON-CYCLE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 0.00 ppm*
DECON-QUAT 100 (2:128 Use Dilution)	ppm Peroxyacetic acid = 0.00 ppm*
HYPO-CHLOR 5.25%	ppm of Sodium Chloride = 2 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 0.00 ppm*
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 0.00 ppm *

Results (cont'')

Chemical Tested

Results:

STERI-PEROX 3%	ppm Hydrogen Peroxide = 0.000 ppm*
STERI-PEROX 6%	ppm Hydrogen Peroxide = 0.000 ppm*
DECON-SPORE 200 PLUS 5%	ppm Peroxyacetic acid = 0.00 ppm*
DECON-SPORE 100 (0.86%)	ppm Peroxyacetic acid = 0.00 ppm*
DECON-SPORE 200 (1:32 Use Dilution)	ppm Peroxyacetic acid = 0.00 ppm*

* The level presented is a mathematical calculation as its value cannot be measured.

Possible Residues from DECON-Clean

The above procedure was repeated and DECON-Clean was used as the chemical residue. Use dilution was 1:128. Additional testing also included a rinsing of the DECON-Clean with STERI-WATER USP Purified Water filter at 0.2 microns. Both results were rendered and are presented below:

Results DECON-Clean Residues:

Chemical Tested

DECON-Clean (1:128) Results: ppm of combined residues = 19 ppm

Results DECON-Clean Residues After Rinsing Chemical Tested

DECON-Clean (1:128) w/Rinse Results: ppm of combined residues = 0.00 ppm*

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Conclusion:

It is concluded from testing performed that the use of DECON-Clean as a chemical residue remover is extremely effective. Furthermore, the incorporation of a rinse of USP (filtered at 0.2 um.) is further recommended as the levels of all existent residues is further reduced.

The following Testing Study was conducted by:

Art Vellutato, Sr
Art Vellutato Jr. (Lead Project Mgr.)

HYPO-CHLOR[®]

Sterile Pharmaceutical Clean Room Formula
Sterile Sodium Hypochlorite at 0.25%, 0.52% and 5.25%

MATERIAL SAFETY DATA SHEET

COMPLIES WITH OSHA HAZARD COMMUNICATION STANDARD 29 CFR 1910.1200
(Complies with Commission Directive 91/155/EEC amended by 2001/58/EC)



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HYPO-CHLOR[®]

MATERIAL SAFETY DATA SHEET

**COMPLIES WITH OSHA HAZARD COMMUNICATION STANDARD 29 CFR 1910.1200
(Complies with Commission Directive 91/155/EEC amended by 2001/58/EC)**

I. Identification of Substance:

Product Name: HYPO-CHLOR[®] Sterile

MSDS #: SHC-98-01

Description: Sodium Hypochlorite and water formulated to 0.25%, 0.52%, and 5.25%

<u>MSDS Information</u>	<u>Manufacturer Information</u>	<u>Emergency Telephone Information</u>
Date Prepared: November 6, 2002	Veltek Associates, Inc.	Notify your Supervisor
Prepared by:	15 Lee Boulevard	Emergencies Chemtrec (800) 424-9300
Art Vellutato, Jr.	Malvern, PA 19355-1234	24-hour service
V.P. Technical Support Operations	TEL: (610) 644-8335	
Reviewed by:		Effective Date: November 6, 2002
Art Vellutato, Sr.		Date Supersedes: 12/01/97
Technical Director		

II. Composition/Data on Components:

Description: Clear, Light Yellow Liquid with Chlorine Odor

Synonyms: Bleach; hypochlorous acid, sodium salt; soda bleach; sodium oxychloride

CAS No.: 7681-52-9

<u>Ingredients</u>	<u>Concentration</u>	<u>Worker Exposure Limit</u>	<u>ppm</u>
Sodium Hypochlorite	5.25%	not established	52,500
None of the ingredients in this product are on the IARC, NTP, or OSHA carcinogen list.			
Sodium Hypochlorite	0.52%	not established	5,250
None of the ingredients in this product are on the IARC, NTP, or OSHA carcinogen list.			
Sodium Hypochlorite	0.25%	not established	2,500
None of the ingredients in this product are on the IARC, NTP, or OSHA carcinogen list.			

HIMIS RATING HEALTH 2 REACTIVITY 0 FLAMMABILITY 0 PERSONAL B

HAZARD RATINGS: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Extreme A = Safety Glasses B = Safety Glasses & Gloves

III. Hazards Identification:

Causes substantial but temporary eye injury. May irritate skin. May cause nausea and vomiting if ingested. Exposure to vapor or mist may irritate nose, throat and lung. The following medical conditions may be aggravated by exposure to high concentrations of vapor or mist; heart conditions or chronic respiratory problems such as asthma, chronic bronchitis or obstructive lung disease. Under normal consumer use conditions the likelihood of any adverse health effects are low. Occasional clinical reports suggest a low potential for sensitization upon exaggerated exposure to sodium hypochlorite if skin damage, (e.g.) irritation) occurs during exposure. Routine clinical tests conducted on intact skin with HYPO-CHLOR Liquid Bleach found no sensitization in the test subjects.

Inhalation: May cause irritation to the respiratory tract, (nose and throat); symptoms may include coughing and sore throat.

Ingestion: May cause nausea, vomiting.

Skin Contact: May irritate skin.

Eye Contact: Contact may cause severe irritation and damage, especially at higher concentration.

Chronic Exposure: A constant irritant to the eyes and throat. Low potential for sensitization after exaggerated exposure to damaged skin.

Aggravation of Pre-existing Conditions: Persons with impaired respiratory function, or heart disorders (or disease) may be more susceptible to the effects of the substance.

IV. First Aid Measures:

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

Ingestion: If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Skin Contact: Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

Note to Physician:

Consider oral administration of sodium thiosulfate solutions if sodium hypochlorite is ingested. Do not administer neutralizing substances since the resultant exothermic reaction could further damage tissue. Endotracheal intubation could be needed if glottic edema compromises the airway. For individuals with significant inhalation exposure, monitor arterial blood gases and chest x-ray.

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V. Firefighting Measures:

Not Flammable or explosive. In fire, cool containers to prevent rupture and release of sodium chlorate.

Fire: Not considered to be a fire hazard. Substance releases oxygen when heated, which may increase the severity of an existing fire. Containers may rupture from pressure build-up.

Explosion: This solution is not considered to be an explosion hazard. Anhydrous sodium hypochlorite is very explosive.

Fire Extinguishing Media: Use any means suitable for extinguishing surrounding fire. Use water spray to cool fire-exposed containers, to dilute liquid, and control vapor.

Special Information: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

VI. Accidental Release Measures:

Spill Procedures: Absorb and containerize. Wash residual down to sanitary sewer. Contact the sanitary treatment facility in advance to assure ability to process wash-down material.

Wash Disposal: Dispose of in accordance with all applicable federal, state and local regulations

VII. Handling and Storage:

STORAGE & HANDLING PRECAUTIONS: KEEP OUT OF REACH OF CHILDREN. Do not contaminate water, food, or feed. Do not reuse empty containers. Keep containers clean and closed.

VIII. Exposure Control and Personal Protection:

Hygienic Practices: Wear Safety Glasses. With repeated or prolonged use, wear gloves.

Engineering Controls: Use general ventilation to minimize exposure to vapor or mist.

Work Practices: Avoid eye and skin contact and inhalation of vapor or mist.

KEEP OUT OF REACH OF CHILDREN.

Airborne Exposure Limits:

Sodium Hypochlorite:

AIHA (WEEL) - STEL - 2 mg/m³

-OSHA Permissible Exposure Limit (PEL):

0.5 ppm (TWA), 1 ppm (STEL) as Chlorine

-ACGIH Threshold Limit Value (TLV):

1 ppm (TWA), 3 ppm (STEL) as Chlorine

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Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):

If the exposure limit is exceeded, a full facepiece respirator with an acid gas cartridge may be worn up to 50 times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. **WARNING:** Air purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

Eye Protection:

Use chemical safety goggles and/or a full face shield where splashing is possible. Maintain eye wash fountain and quick-drench facilities in work area.

RESPIRATORY PROTECTION: General ventilation is normally adequate. Protect breathing system with an appropriate respirator if spraying causes exposure to mists.

GLOVES: Required for exposure to the concentrate when diluting or for long exposures to end-use dilutions. Persons sensitive to cleaning chemicals should always wear gloves.

EYE PROTECTION: Use Safety Glasses when diluting concentrates or when splashing or spraying of diluted product into the eyes is likely.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Not normally necessary for routine handling.

WORK/HYGIENE PRACTICES: Wash hands after using. Do not get into eyes, on skin, or clothing. May be harmful if swallowed. Protect food and drink from contamination by product.

VENTILATION: Local Exhaust: Normally Sufficient Mechanical (General): Not Normally Needed

NOTE: *The information herein is presented in good faith and believed to be accurate as of the effective date shown above. However, no warranty, expressed or implied is given. It is the responsibility of the user to comply with all Federal, State and Local laws and regulations.*

IX. Physical and Chemical Properties:

Appearance: Colorless to yellowish liquid.

Odor: Chlorine-like odor.

Solubility: 100% in water.

Density: 1.07 - 1.14

pH: 9 - 10 (neutral solution-no excess sodium hydroxide)

% Volatiles by volume @ 21C (70F): ca. 95

Boiling Point: 40C (104F) Decomposes slightly

Melting Point: -6C (21F)

Veltek Associates, Inc.

15 Lee Boulevard ● Malvern, PA 19355-1234

Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com VL-801-98 Rev. 12/18/03

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XIV. Transport Information:

U.S. DOT Hazard Class: Not restricted

U.S. DOT Proper Shipper Name: Hypochlorite solution which is not more than 7% available chlorine.
Not Restricted per 49CFR172.101(c)(12)(iv).

XV. Regulations:

PLEASE CONSULT YOUR STATE AND LOCAL AUTHORITY FOR INGREDIENTS LISTED AS PERTAINING TO REPORTING REQUIREMENTS FOR HAZARDOUS SUBSTANCE LIST.

No special regulation other than transportation and disposal (see section VII and section IX). Conform to Federal, State and Local Regulations for disposal. Follow usage instructions on container.

XVI. Other Information:

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