VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

HYPO-CHLOR® 0.25%, 0.52%, & 5.25%

Sodium Hypochlorite and Water for Injection Solution
Sterile Pharmaceutical Cleanroom Formula

Product Description

HYPO-CHLOR® Products have been designed for all pharmaceutical, biotechnology, health care, and medical device cleaning rotations that demand a sterile sodium hypochlorite solution adequate for maintaining a clean and critical environment. EPA Registered **HYPO-CHLOR** Products are effective, one-step, ready to use products that is available in premixed concentrations of 0.25%, 0.52%, and 5.25% formulated with Water for Injection. When used as directed, **HYPO-CHLOR,** according to AOAC Efficacy Testing is effective as a sanitizer, disinfectant, and fungicide that is designed for most washable, non-porous, hard, inanimate environmental surfaces. The sodium residue left behind by **HYPO-CHLOR** can be easily removed with a DECON-AHOL® wipe down, therefore returning its surface to its original condition. Returning the surface to its original condition is an essential step in the reduction of corrosion and pitting.

Sanitizer – Disinfectant – Fungicide

HYPO-CHLOR Products are sodium hypochlorite concentrated at 0.25%, 0.52%, or 5.25% formulated with Water for Injection. **HYPO-CHLOR** Products are manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A/B, Former Class 100). Each lot of **HYPO-CHLOR** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **HYPO-CHLOR** is delivered each time with a lot specific Certificate of Analysis and Certificate of Sterility.

HYPO-CHLOR 0.25%, 0.52% and 5.25% concentrations are available sterile and non-sterile in 16 oz trigger sprays, 13 oz unit dose, or 1 gallon sized containers. **HYPO-CHLOR 0.25%,** for larger aseptic operations, is available in a 200L drum that is ready to use with attached tubing for dispensing. Each sterile container is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

Quality and Manufacturing

- Formulated with USP Water for Injection
- 5.25% assayed to current USP compendium
- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Raw components are air washed with 0.2 micron filtered air
- Aseptically filled into sterile components via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

HYPO-CHLOR – Sodium Hypochlorite and Water for Injection Solutions 0.25%, 0.52% and 5.25%	
Certificate of Analysis	**Specification**
Assay 0.25%:	0.25% - 0.31% w/w
Assay 0.52%:	0.43% - 0.63% w/w
Assay 5.25%:	4.57% - 6.56% w/w
Litmus paper turns blue:	Pass
Addition of HCL gives off CL2 gas:	Pass
Yellow flame test:	Pass
Expiration Period:	18 months

Features and Benefits

- EPA registered sanitizer, disinfectant, and fungicide
    - **HYPO-CHLOR** 0.25% EPA Registration Number: 68959-7
    - **HYPO-CHLOR** 0.52% EPA Registration Number: 68959-6
    - **HYPO-CHLOR** 5.25% EPA Registration Number: 68959-5
- Each sterile container is double bagged packaged
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis and Certificate of Sterility
- Specifically formulated for as a sterile cleanroom pharmaceutical formula
- Available in three ready-to-use solutions: 0.25%, 0.52%, and 5.25%
- Designed for all washable environmental surfaces
- Available in unit dose and pre-mixed solution trigger sprayers and gallons
- Available in both sterile and non-sterile
- 200L drums available for larger aseptic manufacturing operations
- Comes in a convenient 16 oz trigger spray that has the option of spray or stream
- 16 oz containers comes with sterile spray attachment
- **HYPO-CHLOR** 5.25% 13 oz Unit Dose can be mixed with 2 gallons of water to make a 0.25% solution or 1 gallon of water for a 0.52% solution
- Remaining sodium residue can be removed with our DECON-CLEAN® or DECON-AHOL®
- Available in a saturated wipe: see **HYPO-CHLOR®** Wipe

Uses

HYPO-CHLOR® Products are for use in cleanrooms and controlled areas to disinfect hard, non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas, and in laboratories. **HYPO-CHLOR** Products can be used on machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most non-porous hard surface materials.

ABCD Cleanroom Introduction System®

The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed individual containers are each additionally contained in two easy tear bags.

Ordering Information

HYPO-CHLOR – Sodium Hypochlorite and Water for Injection Solutions 0.25%, 0.52%, and 5.25%		
Part Number	**Description**	**Qty/cs.**
SHC-01-0.25	HYPO-CHLOR 0.25%, 1 Gallon, Non-Sterile	4
SHC-02-0.25	HYPO-CHLOR 0.25%, 1 Gallon, Sterile	4
SHC-16Z-0.25	HYPO-CHLOR 0.25%, 16 oz, Unattached Trigger, Sterile	12
SHC-10-200L-0.25	HYPO-CHLOR 0.25%, 200L Drum, Sterile	1
SHC-01-0.52	HYPO-CHLOR 0.52%, 1 Gallon, Non-Sterile	4
SHC-02-0.52	HYPO-CHLOR 0.52%, 1 Gallon, Sterile	4
SHC-16Z-0.52	HYPO-CHLOR 0.52%, 16 oz , Unattached Trigger, Sterile	12
SHC-01-5.25	HYPO-CHLOR 5.25%, 1 Gallon, Non-Sterile	4
SHC-02-5.25	HYPO-CHLOR 5.25%, 1 Gallon, Sterile	4
SHC-13Z-5.25	HYPO-CHLOR 5.25%, 13 oz, Unit Dose, Sterile (mix with 2 gallons of water to make a 0.25% solution and 1 gallon of water to make a 0.52% solution)	12
SHC-16Z-5.25	HYPO-CHLOR 5.25%, 16 oz, Unattached Trigger, Sterile	12

SHC-02-0.25

SHC-01-0.52

SHC-16Z-5.25

USING HYPO-CHLOR STERILE

HYPO-CHLOR® 0.25%, 0.52%, & 5.25%

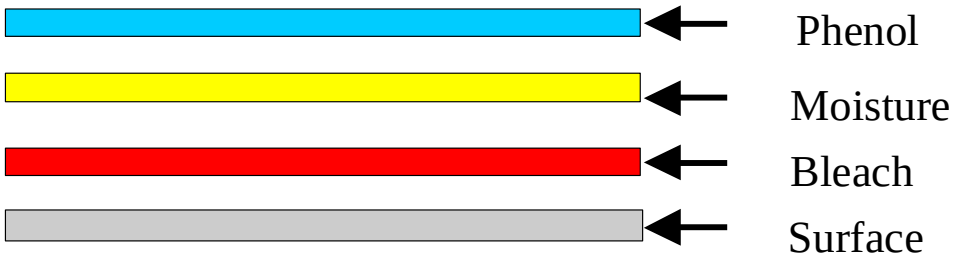
Sodium Hypochlorite and Water for Injection Solution

The purpose of this section of the technical data is to explain the "appropriate use" of the product in a clean room operation. The biggest concern with **HYPO-CHLOR** Products 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 is the 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 cleanrooms and leaves less of a residue than 5.25%.

The second situation is residues. Unlike other bleach products **HYPO-CHLOR** Products are made with sodium hypochlorite and Water for Injection (WFI). 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 left on the surface or that it may be incompatible with surfaces 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 existing moisture are trapped below the phenol residue. The sodium and water being in contact with the metal for a long time period provides the mechanism for the sodium to attack the impurities in the metal. This is one of the main causes for deterioration of the surface.



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®.

SURFACE EVALUATION FOR DETERMINING THE RESIDUAL LEVELS VAI STERILE CHEMICALS AND DISINFECTANTS

Discussion and Purpose of Testing:

The aim of this study was to evaluate the cleaning efficiency of the new environmentally friendly and biodegradable DECON-CLEAN® formula. In accordance with recent EPA regulations (Significant New Use Rule, 25 Sep 2014) the DECON-CLEAN formula was updated and the alkylphenol based detergent was replaced with environmentally friendly ethoxylated alcohol surfactant.

Chemical residues can be quantified and appropriate operating procedures can be developed to reduce their existence on surfaces. VAI developed DECON-CLEAN residue remover to assure the removal of existing chemical residues. By removing these residues, a class 100 aseptic facility is less likely to transfer existing residues from their initial location to critical manufacturing sites.

Particulate Impurities:

Particulate impurities can cause contamination problems and may provide a nutrient source for existing organisms in the aseptic manufacturing area. Particulate impurities can be removed from solution by filtration. All VAI sterile chemicals and disinfectants receive a level of filtration.

Chemical Ingredient Residues:

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

DECON-CLEAN® as a Residue Remover:

DECON-CLEAN® has been developed to cope with the removal of residues within the ISO 5 (Grade A/Class 100) aseptic manufacturing operation. The patented formula assures the breakdown of VAI's DECON-AHOL®, STER-AHOL®, DECON-PHENE®, DECON-CYCLE®, DECON-QUAT 100®, **HYPO-CHLOR®**, STERI-PEROX®, DECON-QUAT 200, Cage2Wash®, Process2Clean® and DECON-SPORE 200® Plus products. Once broken down, these residues or remnants of chemicals may be mopped, sponged, wiped or rinsed free from the surface.

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)
DECON-PHENE® (1:128 Use Dilution)
DECON-CYCLE® (1:256 Use Dilution)
HYPO-CHLOR® (5.25%, 0.52%, and 0.25%)
STER-AHOL® (70% RTU)
DECON-SPORE 200® Plus (5%)
DECON-QUAT® 100 (2:128 Use Dilution)
STERI-PEROX® (3% and 6%)

Test Procedure:

1. Residue and residue removal were determined gravimetrically.
2. Stainless steel coupons (316L) were used as the test surface.
3. Testing was conducted in a Class 100 laminar flow hood.
4. All appropriate safety precautions were taken.
5. 5 ml of each chemical was prepared and applied to separate stainless steel coupons.
6. The chemicals were permitted to air dry.
7. The chemical residue was determined gravimetrically.
8. Cleaning was performed with DECON-CLEAN® by two separate methods; spray rinse only and mechanical cleaning.
9. Residue after cleaning was determined gravimetrically.

Chemical Residue after Drying.

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 = 2 ppm
DECON-CYCLE® (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 3 ppm
DECON-QUAT® 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 3 ppm
HYPO-CHLOR® 5.25%	ppm of Sodium Chloride = 252 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 30 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 18 ppm
STERI-PEROX® 3%	ppm Hydrogen Peroxide = 1 ppm
STERI-PEROX 6%	ppm Hydrogen Peroxide = 1 ppm
DECON-SPORE 200® Plus (5%)	ppm Peroxyacetic acid = 3 ppm

** No residue detectable gravimetrically.*

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

After the chemical residue was established on the surface, the surface was cleaned with a RINSE ONLY of DECON-CLEAN® at a use dilution of 1:128.

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 ppm
DECON-CYCLE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 0 ppm
DECON-QUAT 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 0 ppm
HYPO-CHLOR 5.25%	ppm of Sodium Chloride = 1 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 0 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 0 ppm
STERI-PEROX 3%	ppm Hydrogen Peroxide = 0 ppm**
STERI-PEROX 6%	ppm Hydrogen Peroxide = 0 ppm**
DECON-SPORE 200 Plus (5%)	ppm Peroxyacetic acid = 0 ppm

*** Visual residue spots, not detectable gravimetrically*

Testing Residue Removal Ability of DECON-CLEAN® using MECHANICAL CLEANING

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 using a VEL6-12X12 Dry Wiper with a circular mechanical cleaning action.

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 ppm
DECON-CYCLE® (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 0 ppm
DECON-QUAT® 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 0 ppm
HYPO-CHLOR® 5.25%	ppm of Sodium Chloride = 0 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 0 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 0 ppm
STERI-PEROX® 3%	ppm Hydrogen Peroxide = 0 ppm**
STERI-PEROX 6%	ppm Hydrogen Peroxide = 0 ppm**
DECON-SPORE 200® Plus (5%)	ppm Peroxyacetic acid = 0 ppm

*** No visual residue spots*

Conclusion:

It is concluded from the testing performed that the use of DECON-CLEAN® is extremely effective as a chemical residue remover. Furthermore, the incorporation of mechanical cleaning further reduces the levels of residues as well as any visual, but gravimetrically undetectable, residue spots.

Our DECON-CLEAN® Products:

VAI Product Label Colors

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DECON-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 60%	WHITE	WHITE		
DECON-AHOL WFI FORMULA 91%	WHITE	WHITE		
DECON-AHOL FORMULA 99%	WHITE	WHITE		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DECON-HAND STERILE	WHITE SEMI-TRANSPARENT	PRINTED BOTTLE		
DECON-HAND NON-STERILE	CLEAR	PRINTED BOTTLE		
DECON-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	WHITE		
STERI-OIL	WHITE	WHITE		
STERI-BUFFER	CLEAR	WHITE		
DECON-PHENE	WHITE	WHITE		
DECON-CYCLE	WHITE	WHITE		
DECON-CLEAN	WHITE	WHITE		
DECON-QUAT 100	WHITE	WHITE		
DECON-QUAT 200C	WHITE	WHITE		
DECON-QUAT 200V	WHITE	WHITE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DECON-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	WHITE		
DECON-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	WHITE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DECON-GLASS	WHITE	WHITE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		

PRODUCT LABELING

HYPO-CHLOR® 0.25%, 0.52%, & 5.25%

Sodium Hypochlorite and Water for Injection Solution

(Any specific product label is available upon request.)

HYPO-CHLOR 0.25%, 0.52%, and 5.25% Family of Products

EPA and Health Canada

IMPORTANT NOTICE

This product is registered in both the U.S. and Canada. It has BOTH U.S. and Canadian labeling. WHEN USING THIS product in the U.S. follow the U.S. information, where indicated. WHEN USING THIS product in Canada, follow the Canadian information, where indicated.

HYPO-CHLOR® 0.25% Label

HYPO-CHLOR® 0.52% Label

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant

Aseptically Filtered at 0.2µ

Sodium Hypochlorite at 0.25% Wt./Wt. in USP Water for Injection

Sodium Hypochlorite at 0.52% Wt./Wt. in USP Water for Injection

Ingredients 0.25%:
Sodium Hypochlorite CAS#7681-52-9.....0.25%
USP Water for Injection.....99.75%
Total 100.0%

Ingredients 0.52%:
Sodium Hypochlorite CAS#7681-52-9.....0.52%
USP Water for Injection.....99.48%
Total 100.0%

KEEP OUT OF THE REACH OF CHILDREN
WARNING

See panel for first aid, directions for use, and additional precautions.

Net Contents: (In the US XXoz or gallons) (In Canada XX mL or litres)

HYPO-CHLOR 0.25%
SDS#: VEL-127
Case Label#: SHC-0.25-00 • Rev 5/15
EPA Reg No. 68959-7
EPA Est. No. 68959-PA-001
Canadian DIN: 02360225

HYPO-CHLOR 0.52%
SDS#: VEL-126
Case Label#: SHC-0.52-00 • Rev 5/15
EPA Reg No. 68959-6
EPA Est. No. 68959-PA-001
Canadian DIN: 02350217

Manufactured by:
Veltek Associates, Inc.
15 Lee Blvd. Malvern, PA 19355-1234 USA
Tel: 001-610-644-8335
Fax: 001-610-644-8336
www.sterile.com

In Canada: Distributed By:
Canada Clean Rooms (CCR)
200 Terence Matthews
Kanata, ONT K2M 2C6
Inquiries: (888) 595-8070
www.ccrkanata.com

Made in USA

HYPO-CHLOR® 0.25% and 0.52%

HYPO-CHLOR 0.25% and **HYPO-CHLOR** 0.52% are effective sanitizers, disinfectants, and fungicides, on environmental, inanimate, hard non-porous surfaces that are non-food contact. AOAC efficacy tests have shown that both are effective against *Pseudomonas aeruginosa (ATCC# 15442), Staphylococcus aureus (ATCC# 6538), and Salmonella enterica (ATCC# 10708)* in 10 minutes as bactericides and disinfectants, *Staphylococcus aureus (ATCC# 6538) and Klebsiella pneumoniae (ATCC# 4352)* in 5 minutes as sanitizers, and *Trichophyton mentagrophytes (ATCC# 9533)* in 10 minutes as fungicides.

FIRST AID

If in Eyes:

If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing:

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Swallowed:

Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told be a poison control center or a doctor. Do not give anything to unconscious person.

If Inhaled:

Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

EMERGENCIES: For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada in English, French and Spanish (and 23 other languages) call CARECHEM24 toll free at 866-928-0789.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMAL

WARNING. Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through

skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS
Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

PHYISCAL AND CHEMICAL HAZARDS:
Contact with acid releases toxic chlorine gas. Do not mix this product with other chemicals.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage: Store in original container in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

Disposal: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

Container Disposal: This product is not dilutable. Non-refillable container. Do not reuse or refill this container to hold materials other than this product or diluted product.

For containers equal to or less than 5 gallons: Offer container for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration.

For containers greater than 5 gallons: Offer container for recycling if available, or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration.

DIRECTIONS FOR USE

Read the label before using.

In the United States: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

In Canada: This product is to be used only in accordance with the directions on the label. It is an offence to use this product in a way that is inconsistent with the directions on the label.

This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to

sterilization or high-level disinfection.

LOCATIONS OF USE:
Disinfects and sanitizes clean rooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most non-porous hard surface materials.

HYPO-CHLOR® 0.25% and **HYPO-CHLOR** 0.52% are ready to use. Do not dilute. Hold container upright 15-20 cm (6-8 inches) from surface when applying.

DISINFECTION:
Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with **HYPO-CHLOR** 0.25% or **HYPO-CHLOR** 0.52% and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth wiper.

SANITIZATION:
Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with **HYPO-CHLOR** 0.25% or **HYPO-CHLOR** 0.52% and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes wipe dry with sterilized cloth wiper.

FUNGICIDAL:
Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with **HYPO-CHLOR** 0.25% or **HYPO-CHLOR** 0.52% and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth wiper.

Rinsing may be done with sterile water, if needed.

Spraying a **HYPO-CHLOR** 5.25%, 0.52%, or 0.25% Trigger

EPA and Health Canada

IMPORTANT NOTICE

This product is registered in both the U.S. and Canada. It has BOTH U.S. and Canadian labeling. WHEN USING THIS product in the U.S. follow the U.S. information, where indicated. WHEN USING THIS product in Canada, follow the Canadian information, where indicated.

HYPO-CHLOR® 5.25%® md Label

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant

Aseptically Filtered at 0.2µ

Sodium Hypochlorite at 5.25% Wt./Wt. in USP Water for Injection

Ingredients 5.25%:
Sodium Hypochlorite CAS#7681-52-9.....5.25%
USP Water for Injection.....94.75%
Total 100.0%

KEEP OUT OF THE REACH OF CHILDREN
WARNING

See panel for first aid, directions for use, and additional precautions.

Net Contents: (In the US XXoz or gallons) (In Canada XX mL or litres)

SDS#: HC-98-01
Case Label#: SHC-5.25-00 • Rev 5/15
EPA Reg No. 68959-5
EPA Est. No. 68959-PA-001
Canadian DIN: 02349159

Manufactured by:
Veltek Associates, Inc.
15 Lee Blvd. Malvern, PA 19355-1234 USA
Tel: 001-610-644-8335
Fax: 001-610-644-8336
www.sterile.com

In Canada: Distributed By:
Canada Clean Rooms (CCR)
200 Terence Matthews
Kanata, ONT K2M 2C6
Inquiries: (888) 595-8070
www.ccrkanata.com

Made in USA

HYPO-CHLOR® 5.25%

HYPO-CHLOR 5.25% is an effective sanitizer, disinfectant, fungicide, and bactericide on environmental, inanimate, hard non-porous surfaces that are non-food contact. AOAC efficacy tests have shown that it is effective against *Pseudomonas aeruginosa (ATCC# 15442), Staphylococcus aureus (ATCC# 6538), and Salmonella enterica (ATCC# 10708)* in 10 minutes as a bactericide and disinfectant, *Staphylococcus aureus (ATCC# 6538) and Klebsiella pneumoniae (ATCC# 4352)* in 5 minutes as a sanitizer, and *Trichophyton mentagrophytes (ATCC# 9533)* in 10 minutes as a fungicide.

FIRST AID

If in Eyes:

If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing:

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Swallowed:

Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told be a poison control center or a doctor. Do not give anything to unconscious person.

If Inhaled:

Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

EMERGENCIES: For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada in English, French and Spanish (and 23 other languages) call CARECHEM24 toll free at 866-928-0789

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMAL

WARNING. Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

PHYISCAL AND CHEMICAL HAZARDS:

Contact with acid releases toxic chlorine gas. Do not mix this product with other chemicals.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage: Store in original container in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

Disposal: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. Follow Federal/Provincial/ State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

Container Disposal: Non-refillable container. Do not reuse or refill this container to hold materials other than this product or diluted product.

For containers equal to or less than 5 gallons: Fill container ¼ full with water and recap. Shake 10 seconds and dispose of rinsate in sanitary sewer. Offer container for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration.

For containers greater than 5 gallons: Fill container ¼ full with water. Tip container on its side and roll back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container on its other end and tip it back and forth several times. Dispose of rinsate in sanitary sewer. Offer container for recycling if available, or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration.

DIRECTIONS FOR USE

In the United States: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

In Canada: This product is to be used only in accordance with the directions on the label. It is an offence to use this product in a way that is inconsistent with the directions on the label.

This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

LOCATIONS OF USE: Disinfects and sanitizes clean rooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile and stainless steel. It is compatible with most non-porous hard surface materials.

Use this product while wearing personal protection such as eye protection goggles or face shield,

protective clothing and chemical resistant gloves. Use with adequate ventilation and spray away from eyes and face. **HYPO-CHLOR**® 5.25% is ready to use, or it may be diluted to **HYPO-CHLOR** 0.52% with distilled water, as desired by the user, as follows:

Amount of Product	Amount of Water
6 ⅓ ounces (190mL)	½ gallon (1.9L)
12 ⅔ ounces (380mL)	1 gallon (3.79L)

Hold container upright 15-20 cm (6-8 inches) from surface when applying or apply with saturated cloth or immerse item in a basin.

DISINFECTION:
Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with **HYPO-CHLOR** 5.25% and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth wiper.

SANITIZATION:
Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with **HYPO-CHLOR** 5.25% and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes wipe dry with sterilized cloth wiper.

FUNGICIDAL:
Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with **HYPO-CHLOR** 5.25% and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth wiper.
Rinsing may be done with sterile water, if needed.

Opening a sterile 1 gallon **HYPO-CHLOR** 5.25%, SHC-02-5.25

EFFICACY TEST SUMMARY

Claims made for this product grouping are based on testing performed using standardized methods and specified type strains under GLP conditions by ATS Labs located in Eagan, Minnesota, USA. Claims include disinfectant, sanitizer and fungicide for hard inanimate non-porous environmental surfaces such as tools, equipment, floors and walls under the following conditions.

HYPO-CHLOR 0.52%

Sodium Hypochlorite and Water for Injection Solution

Test as Disinfectant

The following ready to use product **HYPO-CHLOR** 0.52% is bactericidal according to the AOAC Use Dilution Test Germicidal and Detergent Sanitizing Action on hard inanimate surfaces in EPA OPP Disinfectants for Use on Hard surfaces, DIS/TSS-1 and Supplemental Recommendations DIS/TSS-2, in Official Methods of analysis of the AOAC when not more than 1 out of 60 carriers are positive for growth in 10 minutes, and, for Canada ; Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices CAN/CGSB-2 161-97 is met when not more than 2 out of 60 carriers are positive for growth in 10 minutes. (Total carriers = 180 per organism.)

[Note: False positives were confirmed by a new test of the same material showing no positives.]

HYPO-CHLOR 0.52% (5200ppm)				
Organism	**Carrier Population**	**Sample Lot (All >60 days old)**	**# Carriers**	**# Positive**
Pseudomonas aeruginosa ATCC #15442	7.5 X 10^6 CFU/Carrier	A	60	0/60
	6.3 X 10^6 CFU/Carrier	B	60	0/60
		C	60	0/60
Salmonella enterica ATCC #10708	4.5 X 10^6 CFU/Carrier	A	60	0/60
	8.3 x 10^5 CFU/Carrier	B	60	0/60
	8.3 x 10^5 CFU/Carrier	C	60	**3/60
	1.75 X 10^6 CFU/Carrier	**C	60	0/60
Staphylococcus aureus ATCC #6538	7.2 X 10^6 CFU/Carrier	A	60	0/60
	6.2 X 10^6 CFU/Carrier	B	60	0/60
		C	60	0/60

**confirmed false positive, new test performed.

HYPO-CHLOR 0.25%

Sodium Hypochlorite and Water for Injection Solution

Test as Disinfectant

The following ready to use product **HYPO-CHLOR** 0.25% is bactericidal according to the AOAC Use Dilution Test on hard inanimate surfaces in EPA OPP Disinfectants for Use on Hard surfaces, DIS/TSS-1 and Supplemental Recommendations DIS/TSS-2, Germicidal Spray Products as Disinfectants, 961.02 in Official Methods of analysis of the AOAC for Canada; Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices CAN/CGSB-2 161-97 when not more than 2 out of 60 carriers are positive for growth in 20 minutes. (Total carriers = 180).)

Additional data (*) was generated for **HYPO-CHLOR** 0.25%, per US EPA requirement, in the above referenced AOAC Use Dilution Test Germicidal Spray Method, using contact time of 10 minutes (actual test time – 9 minutes 40 seconds). This harmonizes the contact time for disinfection to 10 minutes using all supplied dilutions of this product at or above 0.25%. (See note on last page.)

*The test results at 10 minutes are shown for 3 additional lots *D, *E, and *F (Total carriers = 180).

HYPO-CHLOR® 0.25% (2500ppm) in 20 minutes and (*)10 minutes				
Organism	**Carrier Population**	**Sample Lot (All >60 days old)**	**# Carriers**	**# Positive**
Pseudomonas aeruginosa ATCC #15442	9.6 X 10^6 CFU/Carrier	A	60	0/60
		B	60	0/60
		C	60	1/60
	*1.52 X 10^6 CFU/Carrier	*D	60	0/60
		*E	60	0/60
		*F	60	0/60
Salmonella enterica ATCC #10708	5.1 X 10^6 CFU/Carrier	A	60	0/60
		B	60	0/60
		C	60	0/60
	*9.07 X 10^4 CFU/Carrier	*D	60	0/60
		*E	60	0/60
		*F	60	0/60
Staphylococcus aureus ATCC #6538	1.54 X 10^7 CFU/carrier	A	60	1/60
		B	60	***3/60
		C	60	0/60
	1.07 X 10^7CFU/Carrier	***B	60	0/60
	*6.87 X 10^5 CFU/Carrier	*D	60	0/60
		*E	60	0/60
		*F	60	0/60

***confirmed false positive, new test performed.

Test as Fungicide

Testing performed per the AOAC UDT/GST method in The Official Methods of Analysis of the AOAC showed Killing of 10 out of 10 carriers by 3 separate lots of this product in the presence of 5% organic soil load. For Canada Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices CAN/CGSB-2 161-97, this requirement was also met.

HYPO-CHLOR 0.25% (2500ppm)				
Organism	**Carrier Population**	**Sample Lot (All >60 days old)**	**# Carriers**	**# Positive**
Trichophyton mentagrophytes ATCC 9533	2.60 X 10^5 CFU/Carrier	A	10	0/10
		B	10	0/10
		C	10	0/10

HYPO-CHLOR 0.52% & HYPO-CHLOR 0.25%

Sodium Hypochlorite and Water for Injection Solutions

Test as Sanitizer

Testing per ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Germicidal Spray Method in the presence of 5% organic soil and for Canada Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices CAN/CGSB-2 161-97 showed sanitization was achieved in 5 minutes. Five carriers per lot per organism were used. All lots tested were > 60 days old. This product is considered a sanitizer when test results show a reduction of at least 99.9% (3 Log10) in the average numbers of each test microorganism on test carriers within 5 minutes. (Total Carriers = 30/organism)

HYPO-CHLOR 0.52% (5200ppm)				
Organism	**Avg Carrier Population**	**Sample Lot**	**Avg Survivors/Carrier**	**Percent Kill**
Staphylococcus aureus ATCC #6538	1.1 x10^8 CFU/Carrier	A	<2.51x10^1	>99.9
		B	<2.51x10^1	>99.9
		C	<2.51x10^1	>99.9
Enterobacter aerogenes ATCC #13048	1.37 x10^9 CFU/Carrier	A	<2.51x10^1	>99.9
		B	<2.51x10^1	>99.9
		C	<2.51x10^1	>99.9
HYPO-CHLOR® 0.25% (2500ppm)				
Organism	**Avg Carrier Population**	**Sample Lot**	**Avg Survivors/Carrier**	**Percent Kill**
Staphylococcus aureus ATCC #6538	1.2x10^7 CFU/Carrier	A	<2.51x10^1	>99.9
		B	<2.51x10^1	>99.9
		C	<2.51x10^1	>99.9
Klebsiella pneumonia ATCC #4352	2.48x10^8 CFU/Carrier	A	<2.51x10^1	>99.9
		B	<2.51x10^1	>99.9
		C	<2.51x10^1	>99.9

HYPO-CHLOR 5.25%

Sodium Hypochlorite and Water for Injection Solution

Sanitizer, Disinfectant, & Fungicide

HYPO-CHLOR 5.25% (52,500ppm) - All claims above are applicable at full strength and when diluted with water to the levels specified above.

See notes below.

Notes

In USA:

HYPO-CHLOR 5.25% (~52,500ppm) and **HYPO-CHLOR** 0.52% (~5,200ppm) are, per standard practice of the US EPA, considered to have *at least* the efficacy of the lowest tested strength of the product, when the diluent used for the product is the same diluent in all strengths. In this case, the diluent for all strengths of this product is water and acceptable test results were obtained for all claims using **HYPO-CHLOR** 0.25%.

Therefore, all the results above apply to **HYPO-CHLOR** 5.25% and to **HYPO-CHLOR** 0.52% and also apply to all aqueous dilutions of the product more concentrated than 0.25%.

[However, for many industries or special uses, contact time for lesser (more dilute) aqueous dilutions or contact times shorter than those shown above, should be determined by the user to be effective for the user's purpose before general use.]

In Canada:

HYPO-CHLOR 5.25% (hypochlorite solution) is a Category IV Monograph item for use on hard surfaces, in Canada under Health Canada Therapeutic Product Directorate. It is recognized as an effective antimicrobial/disinfectant and at all concentrations >100 ppm sodium hypochlorite.

Therefore, in Canada, all dilutions of **HYPO-CHLOR** 5.25% in water that are prepared to yield a concentration above 100ppm would be possible for use. The above test results demonstrate efficacy of dilution levels well above 100ppm.

[However, for many industries or special uses, contact times for lesser (more dilute) aqueous dilutions or contact times shorter than those shown above, should be determined by the user to be effective for the user's purpose before general use.]

See the product label for directions for use.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet
    - **HYPO-CHLOR** 0.25% SDS# VEL-127
    - **HYPO-CHLOR** 0.52% SDS# VEL-126
    - **HYPO-CHLOR** 5.25% SDS# HC-98-01
- In-use Validation
- Product Validation
- Sample lot specific documentation packages including Certificates of Sterility and Certificates of Analysis

VAI's Sterile Chemical Manufacturing Division - SCMD manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. Overall, VAI's capabilities for manufacturing products include the ability to fill aerosol, bulk, and unitdose packages in ISO 5 (Grade A/B). Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal. VAI's operations mirror current GMP's and enforces the adherence to USP specifications. VAI is an EPA and FDA registered facility. To learn more about our division capabilities please visit www.sterile.com.

Patents: www.sterile.com/patents