



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



HYPO-CHLOR[®] Neutral 0.25% & 0.52% **Neutralized Sodium Hypochlorite 0.25% & 0.52% Formulated with Water for Injection** **Sterile Pharmaceutical Cleanroom Formula**

Claims, product registrations, and regulatory requirements may vary based on local, regional, and/or national laws and regulations. Please contact your local sales representative for information specific to your region.

15JAN2025

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Canada

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HYPO-CHLOR Neutral Family of Products

PRODUCT OVERVIEW

HYPO-CHLOR Neutral products are an effective, neutral pH, sodium hypochlorite solution formulated with Water for Injection (WFI) at 0.25% and 0.52% concentrations. EPA and Health Canada registered **HYPO-CHLOR Neutral** products are available in our convenient, ready-to-use, SimpleMix® System, designed for all pharmaceutical, biopharmaceutical, biotechnology, health care, medical device, and diagnostic manufacturing cleaning and disinfecting rotations that demand a neutral pH sodium hypochlorite solution adequate for maintaining a clean and critical environment. This neutralized solution can be used as an improved and enhanced sodium hypochlorite, hard surface Disinfectant, Fungicide, Germicide, Virucide*, and Sporicide on numerous cleanroom surfaces. By lowering the pH of the sodium hypochlorite, the concentration of the hypochlorous acid increases and surface corrosivity decreases.

HYPO-CHLOR Neutral products are manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in an ISO 5 cleanroom (Grade A). Each lot of **HYPO-CHLOR Neutral** is sterility tested according to current USP Compendium and is completely traceable. **HYPO-CHLOR Neutral** products are delivered each time with lot specific analytical and sterility data, tested to current USP compendium.

HYPO-CHLOR Neutral 0.25% and 0.52% concentrations are available sterile in a 473 mL trigger spray, a 3.79 L container, and a 200 L drum. All container sizes come in our one-step, ready-to-use, SimpleMix System that allows for exact and fresh solutions each and every time without handling the buffer or sodium hypochlorite solution. Each sterile container is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

When used per SimpleMix System directions, **HYPO-CHLOR Neutral** products are neutralized via the attached buffer when the product is required for use.

**When used as directed*

Quality and Manufacturing

- Formulated with Water for Injection
- Filled in an ISO 5 cleanroom (Grade A)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Aseptically filled into sterile components via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish

Features and Benefits

- Canadian DIN:
 - **HYPO-CHLOR Neutral** 0.25%: 02488779
 - **HYPO-CHLOR Neutral** 0.52%: 02488612

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Features and Benefits (Continued)

- EPA Registered
 - EPA Registration Number: 68959-9
 - **HYPO-CHLOR Neutral 0.25%**: US EPA Reg. No 68959-11
 - **HYPO-CHLOR Neutral 0.52%**: US EPA Reg. No 68959-9
- Each sterile container is double bagged packaged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical and sterility data, tested to current USP compendium
- Specifically formulated as a sterile cleanroom pharmaceutical formula
- Available in two convenient, one-step, ready-to-use SimpleMix concentrations: 0.25% and 0.52%
- Available in 473 mL, 3.79 L, or 200 L containers
- Comes in a convenient 473 mL trigger spray that has the option of spray or stream
- Effective for up to 7 days post activation
- Hard Surface Disinfectant, Fungicide, Germicide, Virucide*, and Sporicide
- Enhanced cleaning applications over a standard sodium hypochlorite solution
- Increased cleaning surface compatibility
- Neutralized pH sodium hypochlorite will significantly reduce corroding, rusting, and pitting of cleanroom surfaces
- Designed for all washable non-porous environmental surfaces

**When used as directed*

Product Uses

- Cleanrooms and controlled areas in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities
- Hard non-porous, inanimate surfaces
- Aseptic filling and gowning rooms, general manufacturing areas, laboratories
- Machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves
- Plastic, glass, vinyl, glazed porcelain, laminates, glazed tiles, stainless steel

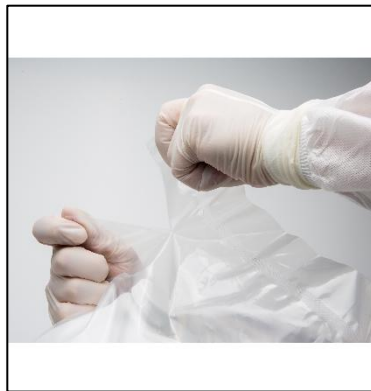
This neutral pH sodium hypochlorite solution is compatible with most non-porous hard surface materials while reducing corroding, rusting, and pitting. **HYPO-CHLOR Neutral 0.25%** and **0.52%** are safe to use daily on stainless steel surfaces. In addition, testing has demonstrated that **HYPO-CHLOR Neutral** products are effective in deactivating endotoxins during specialized manufacturing processes.

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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.



SIMPLEMIX®

The SimpleMix Technology Alternative

Veltek Associates, Inc. has developed the patented SimpleMix System Technology to eliminate measuring and additional containers. It provides for the transfer of the sterile concentrate and sterile water in a sealed container to the aseptic area. The system container is double bag packaged for easy transfer and eliminates all internal and external sterility concerns. The patented SimpleMix System provides a sealed multi-chamber container that when activated mixes the solution to the correct use dilution. The small chamber holds the concentrate, and the bottom reservoir contains the VAI® WFI Quality Water. Just open the small chamber cap, push the plunger container completely down until the bottom pops open and the bellows are compressed. The solution and water mix together. 200L SimpleMix systems are activated through a hose and valve system connecting the cubcontainer of concentrate to the VAI WFI Quality Water. The SimpleMix System design permits the easy transfer of the product to the aseptic manufacturing area without concern for the transfer of contamination.

The Buffer

HYPO-CHLOR Neutral 0.25% and 0.52% are buffered via the SimpleMix System neutralizing the pH. The buffer is housed in the small chamber suspended above the sodium hypochlorite solution in the large chamber below. Once the SimpleMix plunger is pushed, the buffer is mixed into the solution following the SimpleMix directions. Testing has shown that **HYPO-CHLOR Neutral** products are effective as neutralized cleaners for up to 7 days post activation.



SimpleMix Bottle with Activator

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SimpleMix Directions for Use

How to use the SimpleMix Trigger Spray

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container completely down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Move spray nozzle to open position.
7. Follow directions for use on label.

For pictorial directions, see page 7.

How to use the SimpleMix 3.79 L Size

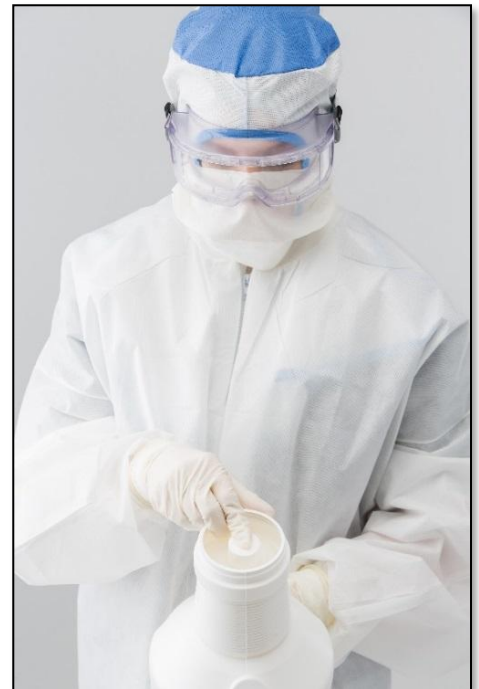
1. To prepare use solution, open cap.
2. Peel off inner seal by grasping far edge and pulling off.
3. Firmly push small, inner container completely down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.
8. Follow directions for use on label.

For pictorial directions, see page 8.

How to use the SimpleMix 200 Liter Drum

1. Close all valves.
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4.
5. START pump to empty cubic container.
6. When cubic container is empty, turn pump OFF.
7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes
10. STOP pump.
11. Close valve 4.
12. To dispense – Open valves 3 and 7. Run pump only when dispensing.
13. Follow directions for use on label.

For pictorial directions, see page 9.



SimpleMix Trigger Spray

SIMPLEMIX® 16 oz/ 473mL Aseptic Mixing System

For the Exact Formulation of 16 oz/ 473 mL Disinfectants and Sporicides

Ready-to-Use Mixing Instructions

- 1) To prepare use solution, open cap.
- 2) Peel off inner seal by grasping tab at far edge and pulling off.



- 3) Firmly push small, inner container all the way down.



- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



- 6) Move spray nozzle to open position.



- 7) Follow directions for use on label.



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SimpleMix 3.79 L

SIMPLEMIX® 1 Gallon/ 3.79L Aseptic Mixing System For the Exact Formulation of 1 Gallon/ 3.79L Size Disinfectants and Sporicides **Ready-to-Use Mixing Instructions**

- 1) To prepare use solution, open cap.
2) Peel off inner seal by grasping tab at far edge and pulling off.



- 3) Firmly push small, inner container all the way down.



- 4) Replace cap and tighten.



- 5) Slowly swirl for 15 seconds.



- 6) Open small side spout and peel off inner seal, as above.



- 7) Pour solution from small side spout onto surfaces to be treated or alternate containers.



- 8) Follow directions for use on label.

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SimpleMix Drum

SIMPLEMIX® 200 L Aseptic Mixing System For Large Scale Aseptic Manufacturing Environments **Ready-to-Use Mixing Instructions**

Remove drum from double-bag packaging.



Remove cubic container from top of drum. 1) Close all valves. 2) Uncoil hoses.



3) Connect center hose to pump between X and Y.



4) Open valve 1, then valve 2, then valve 4.



5) START pump to empty cubic container. 6) When cubic container is empty, turn pump OFF.



7) Close valve 1 and valve 2.



8) Open valve 6 and valve 5.



9) Re-start pump and mix 15 minutes. 10) Stop pump.



11) Close valve 4. 12) To dispense- Open valves 3 and 7. Run pump only when dispensing.



13) Follow directions for use on label.

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CHEMICAL SPECIFICATIONS

HYPO-CHLOR Neutral 0.25% - 0.25% Sodium Hypochlorite formulated with Water for Injection	
Certificate of Analysis	Specifications
Assay	0.25 - 0.31% w/w
Litmus paper turns blue	Pass
Addition of HCL gives off CL ₂ gas	Pass
Yellow flame test	Pass
Expiration period	2 years

HYPO-CHLOR Neutral 0.52% - 0.52% Sodium Hypochlorite formulated with Water for Injection	
Certificate of Analysis	Specifications
Assay	0.43 - 0.63% w/w
Litmus paper turns blue	Pass
Addition of HCL gives off CL ₂ gas	Pass
Yellow flame test	Pass
Expiration period	2 years

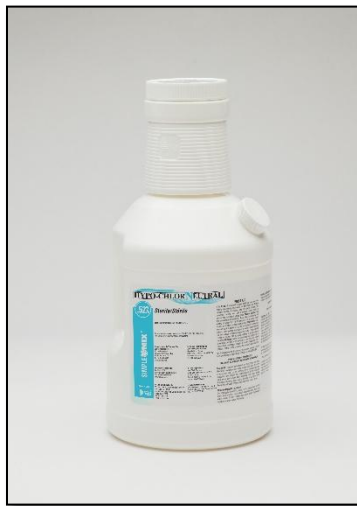
Attached Activator for 0.25% and 0.52% – Neutral Aqueous Solution	
Certificate of Analysis	Specifications
Appearance	Colorless
pH	6.5 – 7.5
Specific Gravity	1.2 – 1.4
Expiration period once activated	7 days

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ORDERING INFORMATION

HYPO-CHLOR Neutral 0.25% and 0.52% – Neutralized Sodium Hypochlorite 0.25% and 0.52% Formulated with Water for Injection		
Part Number	Description	Qty/cs
SHC-NPH-0.25-16Z-C	HYPO-CHLOR Neutral 0.25%, 473 mL SimpleMix, Attached Activator, Attached Trigger, Sterile	12
SHC-NPH-0.25-02-C	HYPO-CHLOR Neutral 0.25%, 3.79 L SimpleMix, Attached Activator, Sterile	4
SHC-NPH-0.25-200L-C	HYPO-CHLOR Neutral 0.25%, 200 L SimpleMix Drum, Attached Activator, Sterile	1
SHC-NPH-0.52-16Z-C	HYPO-CHLOR Neutral 0.52%, 473 mL SimpleMix, Attached Activator, Attached Trigger, Sterile	12
SHC-NPH-0.52-02-C	HYPO-CHLOR Neutral 0.52%, 3.79 L SimpleMix, Attached Activator, Sterile	4
SHC-NPH-0.52-200L-C	HYPO-CHLOR Neutral 0.52%, 200 L SimpleMix Drum, Attached Activator, Sterile	1



SHC-NPH-0.52-02-C



SHC-NPH-0.25-16Z-C

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LABELING

VAI's 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	COOL GREY		
DECON-AHOL WFI FORMULA 91%	WHITE	COOL GREY		
DECON-AHOL FORMULA 99%	WHITE	COOL GREY		
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		
HYPO-CHLOR Neutral 0.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.52%	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		

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Product Labeling (Continued)

HYPO-CHLOR® Neutral 0.25%

Sterile

Sodium Hypochlorite at 0.25% formulated with USP Water for Injection Quality Water • For Use in Cleanrooms and Controlled Areas • Hard Surface Disinfectant • Fungicidal • Aseptically Filtered at 0.2 µm • Ready to Use After Mixing

Active Ingredient:

**Sodium Hypochlorite.....(CAS # 7681-52-9).....0.25%

Other Ingredients:.....99.75%

Total:.....100.00%

**After mixing a decrease in % of active ingredient is expected, use within 7 days or discard any unused material.

KEEP OUT OF THE REACH OF CHILDREN WARNING

Label # SHC-NPH-0.25-00-C • Rev 10/23

Canadian DIN/DIN Canadien: 02488779

US EPA Reg. No: 68959-11 For EPA Est. No. see the final character of the lot #:

L = 68959-PA-01, C = 68959-PA-03, T = 68959-PA-02

Manufactured by: Veltek Associates, Inc.

15 Lee Blvd. Malvern, PA 19355-1234 USA

Tel: 610-644-8335

www.sterile.com • Patents: www.sterile.com/patents

Made in USA

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 to by a poison control center or doctor. Do not give anything to an 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.

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Product Labeling (Continued)

EMERGENCIES: In the case of emergency call: +1 800 579 7421 (toll-free, Canada only), +1 866 928 0789 (toll-free, US only)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. Causes skin irritation. Harmful if inhaled. Do not breathe spray mist. Do not get into eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), long sleeved shirt and long pants, socks, shoes, and waterproof or chemical-resistant gloves. 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.

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

DIRECTIONS FOR USE

Read the label before using.

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 clean rooms and controlled areas such as those in hospitals and health care institutions, and biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing, cosmetic manufacturing, and lab animal 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, Plexiglas®, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most hard non-porous surface materials. Not for use on food contact surfaces.

PREPARE USE SOLUTION: Follow SimpleMix® System Container instructions. For SimpleMix instructions, see page 5-9.

SPORICIDAL: HYPO-CHLOR Neutral .25% is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on non-porous hard surfaces in 90 minutes. Pre-clean all surfaces. Thoroughly wet surface by immersion or by flooding with the prepared use solution and allow surface to remain visibly wet for a minimum of 90 minutes. Allow surface to air dry, or after 90 minutes rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard within 7 days.

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Product Labeling (Continued)

HYPO-CHLOR® Neutral 0.52%

Sterile

Sodium Hypochlorite at 0.52% formulated with USP Water for Injection Quality Water • For Use in Cleanrooms and Controlled Areas • Hard Surface Disinfectant • Fungicidal • Aseptically Filtered at 0.2 µm • Ready to Use After Mixing

Active Ingredient:

**Sodium Hypochlorite.....(CAS # 7681-52-9).....0.52%

Other Ingredients:.....99.48%

Total:.....**100.00%**

**After mixing a decrease in % of active ingredient is expected, use within 7 days or discard any unused material.

KEEP OUT OF THE REACH OF CHILDREN WARNING

Label # SHC-NPH-0.52-00-C • Rev 10/23

Canadian DIN/DIN Canadien: 02488612

US EPA Reg. No: 68959-9 For EPA Est. No. see the final character of the lot #: L = 68959 –PA-01, C = 68959-PA-03, T = 68959-PA-02

SDS: VEL-125, VEL-128 • K-22

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Tel: 610-644-8335

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Made in USA

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 to by a poison control center or doctor. Do not give anything to an 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.

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Product Labeling (Continued)

EMERGENCIES: In the case of emergency call: +1 800 579 7421 (toll-free, Canada only), +1 866 928 0789 (toll-free, US only)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. Causes skin irritation. Harmful if inhaled. Do not breathe spray mist. Do not get into eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), long sleeved shirt and long pants, socks, shoes, and waterproof or chemical-resistant gloves. 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.

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

DIRECTIONS FOR USE

Read the label before using.

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 clean rooms and controlled areas such as those in hospitals and health care institutions, and biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing, cosmetic manufacturing, and lab animal 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, Plexiglas®, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most hard non-porous surface materials. Not for use on food contact surfaces.

PREPARE USE SOLUTION: Follow SimpleMix® System Container instructions. For SimpleMix instructions, see page 5-9.

SPORICIDAL: HYPO-CHLOR Neutral 0.52% is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on non-porous hard surfaces in 90 minutes. Pre-clean all surfaces. Thoroughly wet surface with the prepared use solution and reapply so surface remains wet for a minimum of 90 minutes; or immerse object into the use solution and soak for a minimum of 90 minutes. Allow surface to air dry, or after 90 minutes rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard within 7 days.

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TESTING SUMMARY

HYPO-CHLOR Neutral Efficacy Summary

HYPO-CHLOR Neutral 0.25% & HYPO-CHLOR Neutral 0.52% have been tested to certified AOAC efficacy standards. The products have achieved passing results supporting bactericidal, fungicidal, and sporicidal claims.

7-day hold: Based on the AOAC certified testing presented below, **HYPO-CHLOR Neutral 0.25% & HYPO-CHLOR Neutral 0.52%** are effective as a bactericide and fungicide at 10 minutes, and a sporicide at 90 minutes.

AOAC 961.02					
Acceptance Criteria: No visible growth observed in ≤ 3 replicates out of 60 (<i>S. aureus</i>) and in ≤ 6 replicate out of 60 (<i>P. aeruginosa</i>).					
Conditions: Organic Soil Load – N/A Contact Time: 10 minutes Contact Temperature: 20°C ± 1°C Contact Relative Humidity: 48% RH Performed to GLP standards	Test Organism	Carrier Population (CFU/Carrier)	Sample Lot	# Carriers	# Positive
	<i>Pseudomonas aeruginosa</i> ATCC #15442	3.4 x 10 ⁵	1	60	0/60
		2.6 x 10 ⁵	2	60	0/60
		2.7 x 10 ⁵	3	60	0/60
	<i>Staphylococcus aureus</i> ATCC # 6538	8.8 x 10 ⁵	1	60	0/60
		9.0 x 10 ⁵	2	60	0/60
		8.4 x 10 ⁵	3	60	0/60

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HYPO-CHLOR Neutral Efficacy Summary (Continued)

AOAC 961.02					
Acceptance Criteria: No visible growth observed in any carrier for each organism.					
Conditions: Organic Soil Load – N/A Contact Time: 10 minutes Contact Temperature: 20°C ± 1°C Contact Relative Humidity: 40-50% RH Performed to GLP standards	Test Organism	Carrier Population (CFU/Carrier)	Sample Lot	# Carriers	# Positive
	<i>Trichophyton interdigitale</i> ATCC #9533	8.0 x 10 ⁴	1	10	0/10
		8.5 x 10 ⁴	2	10	0/10

AOAC 955.15 & 966.04					
Acceptance Criteria: No visible growth can be detected in any of the test subculture broth tubes.					
Conditions: Organic Soil Load – N/A Contact Time: 90 minutes Contact Temperature: 20°C ± 1°C Contact Relative Humidity: 26% RH Performed to GLP standards	Test Organism	Carrier Population (CFU/Carrier)	Sample Lot	# Carriers	# Positive
	<i>Bacillus subtilis</i> ATCC #19659	5.6 x 10 ⁵	1	60	0/60
			2	60	0/60
			3	60	0/60
	<i>Clostridium sporogenes</i> ATCC #3548	5.1 x 10 ⁵	1	60	0/60
			2	60	0/60
3			60	0/60	

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HYPO-CHLOR Neutral Efficacy Summary (Continued)

24-hour hold: Based on the AOAC certified testing presented below, **HYPO-CHLOR Neutral 0.25% & HYPO-CHLOR Neutral 0.52%** are effective as a virucide and bactericide at 5 minutes.

ASTM E1053				
Acceptance Criteria: Demonstrate at least 3log₁₀ reduction in viral titer.				
Conditions: Organic Soil Load – 5.0% Fetal Bovine Serum	Test Organism	Sample Lot	Carrier Population (CFU/Carrier)	Log₁₀ Reduction per Carrier
Contact Time: 5 minutes Contact Temperature: 23°C ± 1°C Performed to GLP standards	<i>Human Adenovirus type 5, ATCC VR-5, Strain Adenoid 75</i>	1	7.05 log ₁₀	≥6.25
		2	7.05 log ₁₀	≥6.25
	<i>Poliovirus type 1 ATCC VR-1562, Strain Chat</i>	1	6.30 log ₁₀	≥5.50
		2	6.30 log ₁₀	≥5.50
	<i>Influenza A (H1N1) ATCC VR-1 469, Strain A/PR/8/34</i>	1	5.80 log ₁₀	≥5.00
		2	5.80 log ₁₀	≥5.00

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HYPO-CHLOR Neutral Efficacy Summary (Continued)

AOAC 961.02						
Acceptance Criteria: No visible growth observed in ≤ 3 replicates out of 60 (<i>S. aureus</i>) and in ≤ 6 replicate out of 60 (<i>P. aeruginosa</i>).						
Conditions: Organic Soil Load – 5.0% Fetal Bovine Serum Contact Time: 5 minutes Contact Temperature: 23°C \pm 1°C Performed to GLP standards	Test Organism	Sample Lot	Carrier Population	# Carriers	# Positive	
	<i>Pseudomonas aeruginosa</i> ATCC #15442	A		1.46 x 10 ⁵ CFU/Carrier	60	0/60
		B		1.13 x 10 ⁶ CFU/Carrier	60	0/60
		C		1.15 x 10 ⁶ CFU/Carrier	60	0/60
	<i>Staphylococcus aureus</i> ATCC # 6538	A		2.40 x 10 ⁶ CFU/Carrier	60	0/60
		B		1.26 x 10 ⁶ CFU/Carrier	60	0/60
		C		1.33 x 10 ⁶ CFU/Carrier	60	0/60

AOAC 961.02						
Acceptance Criteria: No visible growth observed in any carrier for each organism.						
Conditions: Organic Soil Load – 5.0% Fetal Bovine Serum Contact Time: 5 minutes Contact Temperature: 24°C \pm 1°C Performed to GLP standards	Test Organism	Sample Lot	Carrier Population	# Carriers	# Positive	
	<i>Trichophyton interdigitale</i> ATCC #9533	A		4.00 x 10 ⁴ CFU/Carrier	10	0/10
		B		4.00 x 10 ⁴ CFU/Carrier	10	0/10

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HYPO-CHLOR Neutral Efficacy Summary (Continued)

ASTN E1153					
Acceptance Criteria: The test substance must demonstrate a minimum 99.9% reduction of test survivors as compared to the population control.					
Conditions: Organic Soil Load – N/A	Test Organism	Carrier Population	Sample Lot	# Carriers	# Positive
Contact Time: 5 minutes Contact Temperature: 20°C ± 1°C Performed to GLP standards	<i>Enterobacter aerogenes</i> ATCC #13048	2.57×10^6 CFU/Carrier	A	5	>99.9%
			B	5	>99.9%
			C	5	>99.9%
	<i>Staphylococcus aureus</i> ATCC #6538	4.37×10^6 CFU/Carrier	A	5	>99.9%
			B	5	>99.9%
			C	5	>99.9%

ADDITIONAL DOCUMENTATION

Upon request, the following additional documentation is available:

- Product Testing Reports
- Product Labels
- Product Validation
- Safety Data Sheet
- Sample Lot Specific Documentation - Delivered with lot specific analytical and sterility data, tested to current USP compendium



VAI®'s SCMD Product Family

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 unit dose packages in ISO 5 or 7 (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.

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