



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 Solution

Product Description

HYPO-CHLOR® Neutral Products are effective, ready-to-use, neutralized sodium hypochlorite solutions formulated with Water for Injection (WFI) at 0.25% or 0.52% concentrations. **HYPO-CHLOR Neutral** Products have been designed for all pharmaceutical, biopharmaceutical, biotechnology, health care, medical device, and diagnostic manufacturing cleaning 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 cleaner on numerous cleanroom surfaces with reduced consequences of corrosion, pitting, and rusting. By lowering the pH of sodium hypochlorite, the biocidal activity increases and corrosivity decreases. In addition, testing has demonstrated that **HYPO-CHLOR Neutral** Products are effective in deactivating DNase, RNase, and Endotoxins during specialized manufacturing processes.

HYPO-CHLOR Neutral Products are manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in an ISO 5 (Grade A/B, Former Class 100). 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 a lot specific Certificate of Analysis and Certificate of Sterility.

HYPO-CHLOR Neutral 0.25% and 0.52% concentrations are available sterile in a 16 oz trigger spray and a 1 gallon container. Both the 16 oz and 1 gallon come in our one-step, ready-to-use, SimpleMix® System that allows for exact and fresh solutions each and every time without handling the activator 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 activator when the product is required for use.

Quality and Manufacturing

- Formulated with Water for Injection
- Filled in an ISO 5 (Grade A/B, Former Class 100)
- 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

| HYPO-CHLOR Neutral 0.52% - 0.52% Sodium Hypochlorite formulated with Water for Injection | |
|--|----------------|
| Certificate of Analysis | Specifications |
| Assay: | 0.4 – 0.6% w/w |
| Litmus paper turns blue: | Pass |
| Addition of HCL gives off CL2 gas: | Pass |
| Yellow flame test: | Pass |
| Expiration period: | 18 months |

| HYPO-CHLOR Neutral 0.25% - 0.25% Sodium Hypochlorite formulated with Water for Injection | |
|---|-----------------------|
| Certificate of Analysis | Specifications |
| Assay: | 0.25% - 0.30% w/w |
| Litmus paper turns blue: | Pass |
| Addition of HCL gives off CL ₂ gas: | Pass |
| Yellow flame test: | Pass |
| Expiration period: | 18 months |

| Attached Activator for 0.25% and 0.52% – Neutral Aqueous Solution | |
|--|-----------------------|
| Certificate of Analysis | Specifications |
| Appearance | Colorless, Pass |
| pH: | 6.5 – 7.5 |
| Specific Gravity: | 1.2 – 1.4 |
| Expiration period once activated: | 24 hours |

Features and Benefits

- 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 Certificate of Analysis and Certificate of Sterility
- Available in our convenient, one-step, ready-to-use, SimpleMix System
- Specifically formulated as a sterile cleanroom pharmaceutical formula
- Available in two ready-to-use concentrations: 0.25% and 0.52%
- Available in 16 oz or 1 gallon containers
- Comes in a convenient 16 oz trigger spray that has the option of spray or stream
- Effective for up to 24 hours post activation
- Enhanced cleaning applications over a standard sodium hypochlorite solution
- Increased cleaning surface compatibility
- Neutralized sodium hypochlorite will significantly reduce corroding, rusting, and pitting of cleanroom surfaces
- Designed for all washable non-porous environmental surfaces
- Can be used to deactivate DNase, RNase, and Endotoxins

Uses

HYPO-CHLOR Neutral Products are for use in cleanrooms and controlled areas 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 tiles, and 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 DNase, RNase, and Endotoxins during specialized manufacturing processes.



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.

The SimpleMix® System 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 concentrated disinfectant, sporicide, or activating agent, 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 Gallon, 16oz, and 200L systems provide a sealed multi-chamber container that when activated mixes the solution to the correct use dilution. The opening on the top of the gallon size contains the concentrate and the bottom reservoir contains the VAI WFI Quality Water or Sodium Hypochlorite Solution. The 16 ounce side container houses the concentrate and the bottom reservoir houses the VAI WFI Quality Water or Sodium Hypochlorite Solution. Just open the small chamber cap, push the plunger container completely down until the bottom pops open and the bellows are compressed. 200L SimpleMix systems are activated through a hose and valve system connecting the cubicontainer of concentrate to the VAI WFI Quality Water or Sodium Hypochlorite solution. The system design permits the easy transfer of the product to the aseptic manufacturing area without concern for the transfer of contamination.



16 oz SimpleMix Bottle



1 gallon SimpleMix Bottle

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234 T: 610-644-8335 F: 610-644-8336 www.sterile.com

Rev: 18Sep2017

The Activator

HYPO-CHLOR Neutral 0.25% and 0.52% are activated via the SimpleMix System by neutralizing the pH. The activator is housed in the small chamber suspended above the sodium hypochlorite solution in the large chamber below. Once the SimpleMix plunger is pushed, the activator 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 24 hours post activation.



SimpleMix Bottle with Activator

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 | HYPO-CHLOR® Neutral 0.25%, 16 oz SimpleMix, Attached Activator, Attached Trigger, Sterile | 12 |
| SHC-NPH-0.25-02 | HYPO-CHLOR® Neutral 0.25%, 1 Gallon SimpleMix, Attached Activator, Sterile | 4 |
| SHC-NPH-0.52-16Z | HYPO-CHLOR® Neutral 0.52%, 16 oz SimpleMix, Attached Activator, Attached Trigger, Sterile | 12 |
| SHC-NPH-0.52-02 | HYPO-CHLOR® Neutral 0.52%, 1 Gallon SimpleMix, Attached Activator, Sterile | 4 |



SHC-NPH-0.25-02



SHC-NPH-0.52-16Z



SHC-NPH-0.52-02

SURFACE COMPATIBILITY TESTING 0.25%

Objective

The aim of this experiment was to evaluate the compatibility of plastic and metal surfaces with **HYPO-CHLOR Neutral 0.25%** mimicking real-life conditions.

Experimental

1. Samples of materials

The following samples were tested:

- Polypropylene coupons
- Polyethylene coupons
- Stainless steel coupons
- Galvanized steel coupons
- Brass
- Glass
- Anodized aluminum coupons
- Aluminum coupons

2. **HYPO-CHLOR Neutral 0.25%** was activated according to the label.

3. Short-term compatibility

Samples were dipped in activated **HYPO-CHLOR Neutral 0.25%** at room temperature for 10 minutes. Samples were rinsed with 70% STER-AHOL and dried at room temperature. This procedure was repeated 5 times.

4. Long-term compatibility

Samples were dipped in activated **HYPO-CHLOR Neutral 0.25%** at room temperature for 48 hours. Samples were rinsed with 70% STER-AHOL and dried at room temperature. This procedure was performed once.

5. Surface evaluation

Tested samples were evaluated for:

- Color changes – visual observation
- Structure changes – mechanical strength and elasticity for plastics only

Results

1. Short-term compatibility

HYPO-CHLOR Neutral 0.25% for 10 min. interval: GS-2015-04-143
70% STER-AHOL: Lot# 14-DSTER-708389 (Exp. 01Jul2020)



| HYPO-CHLOR Neutral 0.25% – Neutralized Sodium Hypochlorite 0.25% Formulated with Water for Injection | | | | |
|--|----------------------------------|------------------|------------------|------------------|
| Materials | Color Change & Structural Change | | | |
| | 10 min. Interval | 10 min. Interval | 10 min. Interval | 10 min. Interval |
| Polypropylene | No change | No change | No change | No change |
| Polyethylene | No change | No change | No change | No change |
| Stainless Steel | No change | No change | No change | No change |
| Galvanized Steel | No change | No change | No change | No change |
| Aluminum | No change | No change | No change | No change |
| Anodized Aluminum | No change | No change | No change | No change |
| Brass | No change | No change | No change | No change |
| Glass | No change | No change | No change | No change |

2. Long-term compatibility

HYPO-CHLOR Neutral 0.25% for 48 hours: GS-2015-04-143
70% STER-AHOL: Lot# 14-DSTER-708389 (Exp. 01Jul2020)

| HYPO-CHLOR Neutral 0.25% – Neutralized Sodium Hypochlorite 0.25% Formulated with Water for Injection | | |
|--|---|-------------------|
| Materials | Color Change | Structural Change |
| Polypropylene | No change | No change |
| Polyethylene | No change | No change |
| Stainless Steel | No change | No change |
| Galvanized Steel | Rust that was present on the steel was gone and the coupon appeared more polished | No change |
| Aluminum | Yellowish to brownish coloration | No change |
| Anodized Aluminum | Polished appearance | No change |
| Brass | White coating and appeared faded on | No change |
| Glass | No change | No change |

Conclusion

Under conditions tested, all samples except non-anodized aluminum were **HYPO-CHLOR Neutral 0.25%** compatible in the long-term study. In the short-term test, all coupons were compatible with no coloration or structural change. In the long-term study, the metal coupons appeared more polished, showing that **HYPO-CHLOR Neutral 0.25%** may be used as a disinfectant cleaning agent, except for on brass and aluminum. The brass had faded and a white color was present, meanwhile, the aluminum showed strong color change with a yellow brownish color. The structural integrity remained intact for both long and short-term tests.

SURFACE COMPATIBILITY TESTING 0.52%

Objective

The aim of this experiment was to evaluate compatibility of plastic and metal surfaces with **HYPO-CHLOR Neutral 0.52%** mimicking real-life conditions.

Experimental

6. Samples of materials

The following samples were tested:

- Polypropylene coupons
- Polyethylene coupons
- Stainless steel coupons
- Anodized aluminum coupons
- Aluminum coupons

7. **HYPO-CHLOR Neutral 0.52%** was activated according to the label.

8. Short-term compatibility

Samples were dipped in activated **HYPO-CHLOR Neutral 0.52%** at room temperature for 10 minutes. Samples were rinsed with 70% STER-AHOL and dried at room temperature. This procedure was repeated 5 times.

9. Long-term compatibility

Samples were dipped in activated **HYPO-CHLOR Neutral 0.52%** at room temperature for 48 hours. Samples were rinsed with 70% STER-AHOL and dried at room temperature. This procedure was performed once.

10. Surface evaluation

Tested samples were evaluated for:

- Color changes – visual observation
- Structure changes – mechanical strength and elasticity for plastics only

Results

3. Plastic Samples (Polypropylene and Polyethylene): no mechanical property changes – both strength and flexibility
4. Stainless Steel: no changes
5. Anodized Aluminum Surfaces: no changes
6. Aluminum: darken surfaces and off-gasing

Conclusion

Under conditions tested, all samples except non-anodized aluminum were **HYPO-CHLOR Neutral 0.52%** compatible.

CORROSIVITY STUDY 0.52% & 0.25%

Objective

To study **HYPO-CHLOR Neutral** Products corrosiveness towards variety of materials.

Experimental

The study was carried out by exposing subjected materials towards **HYPO-CHLOR Neutral 0.52%** over a period of time.

1. The following materials samples were chosen to be tested:
 - Plastic PVC
 - Vinyl Tile
 - Galvanized Steel
 - Plexiglass
 - Ceramic Tile
 - Brass
 - Rubber
2. **HYPO-CHLOR Neutral 0.52%** was activated according to the label. **HYPO-CHLOR Neutral 0.52%** used: Lot# SS-2015-04-19A.
3. The solutions of activated **HYPO-CHLOR Neutral 0.52%** was sprayed on the chosen material samples and let dry.
4. After spraying the coupons using the solution, all materials were dried and then rinsed using WFI.
5. Any change in its mechanical, texture, and color were noted for a sign of corrosion.
6. This procedure was repeated 6 times for each material.

Results

| HYPO-CHLOR Neutral 0.52% – Neutralized Sodium Hypochlorite 0.52% Formulated with Water for Injection | | | | |
|--|--------------------------------|------------|-----------|------------|
| Material | Visual | Mechanical | Texture | Compatible |
| Plastic PVC | No change | No change | No change | Yes |
| Vinyl Tile | No change | No change | No change | Yes |
| Galvanized Steel | Yellow tainted color developed | No change | No change | No |
| Plexiglass | No change | No change | No change | Yes |
| Ceramic Tile | No change | No change | No change | Yes |
| Brass | Green and red spots developed | No change | Coarsen | No |
| Rubber | No change | No change | No change | Yes |

Conclusion

Under conditions tested, all sample materials tested except for galvanized steel and brass were unchanged when exposed to **HYPO-CHLOR Neutral** 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® Neutral 0.25% and 0.52%

Neutralized Sodium Hypochlorite 0.25% & 0.52% Formulated with Water
for Injection

(Any specific product label is available upon request.)



HYPO-CHLOR Neutral Family of Products

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234 T: 610-644-8335 F: 610-644-8336 www.sterile.com

Rev: 18Sep2017

HYPO-CHLOR® Neutral 0.52% Label

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

ACTIVE INGREDIENTS:

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

Other Ingredients:

*Water 99.48%

Total **100.0%**

*USP Water for Injection



**KEEP OUT OF THE REACH OF CHILDREN
WARNING**

Net Contents: (XXoz or gallons) (XX mL or litres)

Manufactured by:

Veltek Associates, Inc.

15 Lee Blvd. Malvern, PA 19355-1234 USA

Tel: 1-610-644-8335

Fax: 1-610-644-8336

www.sterile.com**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

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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 by 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.

For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada 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 wash water or rinsate.

PHYSICAL 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 Handling: Non-refillable container. Do not reuse or refill this container to hold materials other than this product. Offer container for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration.

DIRECTIONS FOR USE

Read the label before using.

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

LOCATIONS OF USE:

For cleaning: cleanrooms 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 tiles, and stainless steel. It is compatible with most non-porous hard surface materials.

This product can be used to inactivate polynucleotides.

TO USE:

Pre-clean surfaces or item to remove heavy soil before application. Once activated, solution may be used for up to 24 hours. Discard after 24 hours.

Thoroughly wet surfaces with **HYPO-CHLOR Neutral 0.52%**. For inactivation of polynucleotides, spray or soak surfaces and allow surface to remain wet for a minimum of 10 minutes. Allow to air dry or after 10 minutes rinse and wipe dry, if desired.

Activated SimpleMix System Container as follows:

SimpleMix® System Container:

Trigger Spray Bottle lid label:

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.

See page 16 for pictorial directions.

Gallon Size Bottle lid label:

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.

See page 17 for pictorial directions.

HYPO-CHLOR® Neutral 0.25% Label

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

ACTIVE INGREDIENTS:

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

Other Ingredients:

*Water 99.75%

Total **100.0%**

*USP Water for Injection



**KEEP OUT OF THE REACH OF CHILDREN
WARNING**

Net Contents: (XXoz or gallons) (XX mL or litres)

Manufactured by:

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15 Lee Blvd. Malvern, PA 19355-1234 USA
Tel: 1-610-644-8335
Fax: 1-610-644-8336
www.sterile.com

Made in USA

FIRST AID

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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

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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 by 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.

For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada 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 wash water or rinsate.

PHYSICAL AND CHEMICAL HAZARDS:

Contact with acid releases toxic chlorine gas. Do not puncture or incinerate container. 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 Handling: Non-refillable container. Do not reuse or refill this container to hold materials other than this product. Offer container for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration.

DIRECTIONS FOR USE

Read the label before using.

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

LOCATIONS OF USE:

For cleaning: cleanrooms 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 tiles, and stainless steel. It is compatible with most non-porous hard surface materials.

This product can be used to inactivate polynucleotides.

TO USE:

Pre-clean surfaces or item to remove heavy soil before application. Once activated, solution may be used for up to 24 hours. Discard after 24 hours.

Thoroughly wet surfaces with **HYPO-CHLOR Neutral 0.25%**. For inactivation of polynucleotides, spray or soak surfaces and allow surface to remain wet for a minimum of 10 minutes. Allow to air dry or after 10 minutes rinse and wipe dry, if desired.

Activated SimpleMix System Container as follows:

SimpleMix® System Container:

Trigger Spray Bottle lid label:

8. To prepare use solution, open cap.
9. Peel off inner seal by grasping tab at far edge and pulling off.
10. Firmly push small, inner container completely down.
11. Replace cap and tighten.
12. Slowly swirl for 15 seconds.
13. Move spray nozzle to open position.
14. Follow directions for use on label.

See page 18 for pictorial directions.

Gallon Size Bottle lid label:

9. To prepare use solution, open cap.
10. Peel off inner seal by grasping far edge and pulling off.
11. Firmly push small, inner container completely down.
12. Replace cap and tighten.
13. Slowly swirl for 15 seconds.
14. Open small side spout and peel off inner seal, as above.
15. Pour solution from small side spout onto surfaces to be treated or alternate containers.
16. Follow directions for use on label.

See page 19 for pictorial directions.

16 oz SimpleMix System Directions

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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1 Gallon SimpleMix System Directions

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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Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet
 - **HYPO-CHLOR Neutral 0.52%** SDS# VEL-128
 - **HYPO-CHLOR Neutral 0.52%** Activator SDS# VEL-125
 - **HYPO-CHLOR Neutral 0.25%** SDS# VEL-133
 - **HYPO-CHLOR Neutral 0.25%** Activator SDS# VEL-132
- Sample lot specific documentation packages including Certificates of Sterility and Certificates of Analysis



SCMD

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

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