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

Product Description

HYPO-CHLOR® Neutral Products are effective, ready-to-use, neutral pH 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 concentration of hypochlorous acid increases and 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 16 oz trigger spray, a 1 gallon 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 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 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

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:	24 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 CL2 gas:	Pass
Yellow flame test:	Pass
Expiration period:	24 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 analytical and sterility data, tested to current USP compendium
- 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, 1 gallon, or 200 L 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

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 200 L 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. 200 L 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

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-0.25-200L	HYPO-CHLOR® Neutral 0.25%, 200 L SimpleMix Drum, Attached Activator, Sterile	1
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-0.52-200L	HYPO-CHLOR® Neutral 0.52%, 200 L SimpleMix Drum, Attached Activator, Sterile	1

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SHC-NPH-0.25-02


SHC-NPH-0.52-16Z

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 and brass 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 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

1. Samples of materials

The following samples were tested:

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

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

3. 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.

4. 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.

5. Surface evaluation

Tested samples were evaluated for:

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

Results

1. Plastic Samples (Polypropylene and Polyethylene): no mechanical property changes – both strength and flexibility
2. Stainless Steel: no changes
3. Anodized Aluminum Surfaces: no changes
4. 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	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		

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

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

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

SDS: VEL-128

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 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.

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 a corrosive resistant container with a resistant inner liner. Absorb spillage to prevent material damage. 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 of 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 19 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 20 for pictorial directions.

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.

See page 21 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:
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

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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 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.

PHYISCAL 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 of 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:

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 19 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 20 for pictorial directions.

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.

See page 21 for pictorial directions.

16 oz SimpleMix System Directions

SIMPLEMIX® 16 oz/473 mL 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.

1 Gallon SimpleMix System Directions

SIMPLEMIX® 1 Gallon/3.79 L Aseptic Mixing System

For the Exact Formulation of 1 Gallon/3.79 L 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.

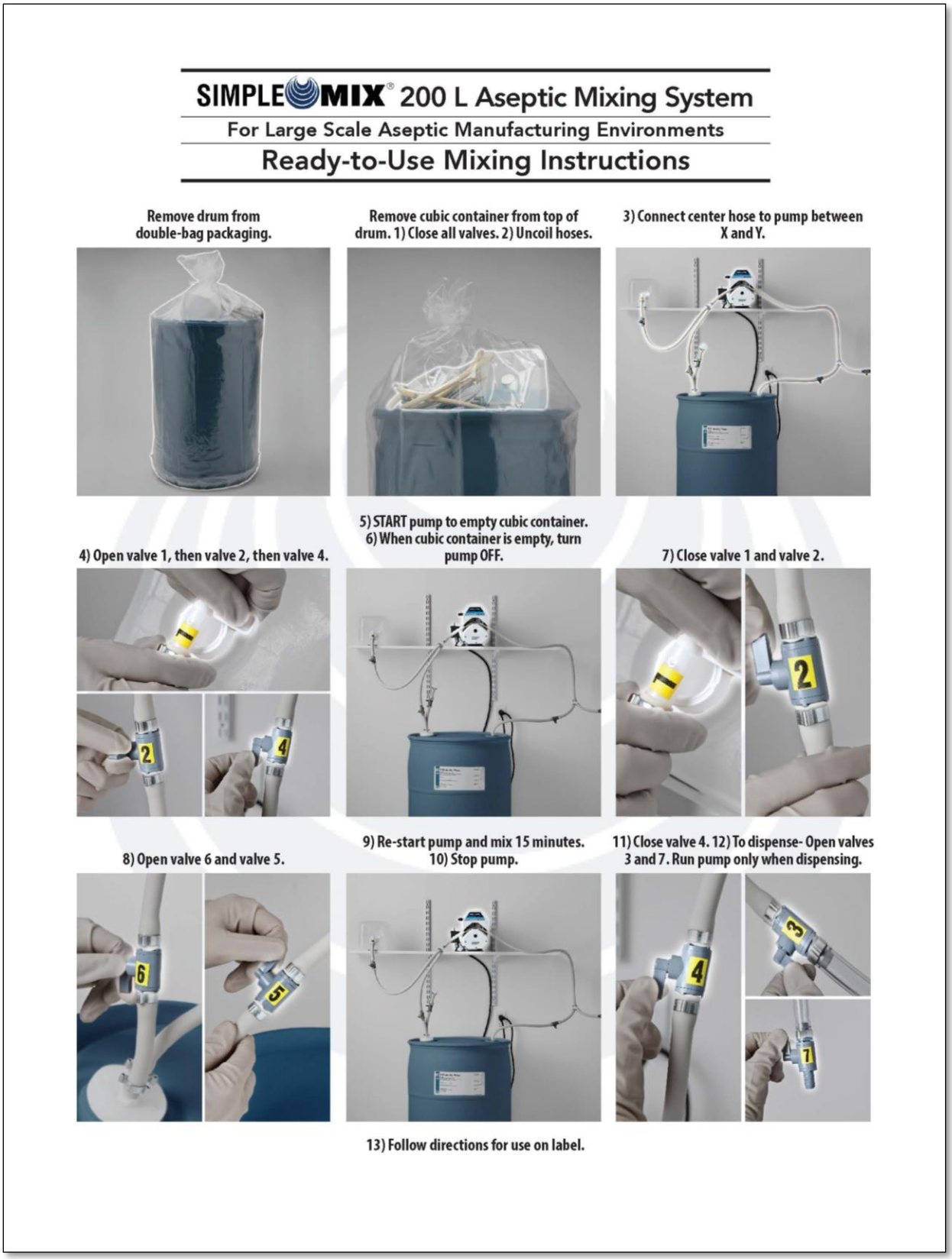
5) Slowly swirl for 15 seconds.

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.

200 L Drum SimpleMix System Directions



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 0.25%** SDS# VEL-133
    - **HYPO-CHLOR Neutral** Buffer (for 0.25% & 0.52%) SDS# VEL-125
- Sample lot specific documentation packages delivered with analytical and sterility data, tested to current USP compendium

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. To learn more about our division capabilities please visit www.sterile.com.

Patents: www.sterile.com/patents