HYPO-CHLOR®

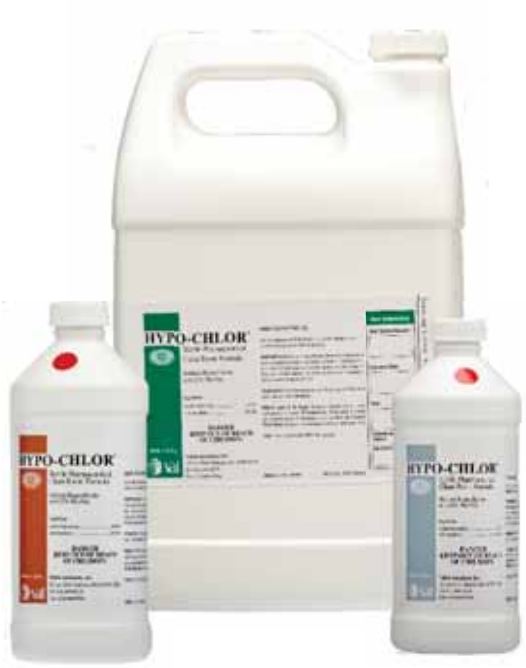
5.25%, 0.52% & 0.25%

Sodium Hypochlorite Solution

HYPO-CHLOR-hc-01-w

Rev 16 January 2013

Technical Data File



Veltek Associates, Inc. 15 Lee Boulevard Malvern, PA 19355-1234 USA T: 610.644.8335 F: 610.644.8336 www.sterile.com

HYPO-CHLOR
Sterile Clean Room Formula

PRODUCT DESCRIPTION

HYPO-CHLOR is designed for pharmaceutical and biotechnology operations that demand a sterile sodium hypochlorite solution. HYPO-CHLOR is an effective one step, ready to use product that is available in premixed concentrations of 5.25%, 0.52% and 0.25%. Formulation of HYPO-CHLOR is accomplished with Water For Injection (WFI). HYPO-CHLOR is tested in accordance with current USP guidelines in development of the Certificate of Analysis and Sterility Test Results.

HYPO-CHLOR is produced sterile by aseptic filtration at 0.2 microns. The product is available in 16 oz. bottles with trigger sprayers, 13-OUNCE UNIT DOSE BOTTLES (mix with 2 gallons of water to make a 0.25% solution and 1 gallon of water to make a 0.52% solution) and 1-gallon containers both sterile and non-sterile. Each container is double bag packaged and delivered each time with the lot specific Certificate of Analysis and Sterility Report. HYPO-CHLOR products are completely traceable and have been completely validated for sterility and shelf life.

HYPO-CHLOR is also available in a 200 liter drum, ready-to-use. This product is available in both 0.52% and 0.25% solutions. Both solutions are aseptically filled, sterility tested to current USP compendium and double-bag packaged for easy transportation into your controlled areas. 200 Liter HYPO-CHLOR comes complete with sterile tubing attached to the drum, simply fasten it to the pump and it is ready to be dispensed.

ORDERING INFORMATION

Order#	Description	Quan/cs.
SHC-01-5.25	HYPO-CHLOR 1 Gallon Non-Sterile @ 5.25%	4
SHC-02-5.25	HYPO-CHLOR 1 Gallon Sterile @ 5.25%	4
SHC-02-0.52	HYPO-CHLOR 1 Gallon Sterile @ 0.52%	4
SHC-02-0.25	HYPO-CHLOR 1 Gallon Sterile @ 0.25%	4
SHC-13Z-5.25	HYPO-CHLOR 13 oz. Unit dose Sterile @ 5.25%	12
SHC-16Z-5.25	HYPO-CHLOR 16 oz. Sterile @ 5.25%	12
SHC-16Z-0.52	HYPO-CHLOR 16 oz. Sterile @ 0.52%	12
SHC-16Z-0.25	HYPO-CHLOR 16 oz. Sterile @0 .25%	12
SHC-10-200L-0.52	HYPO-CHLOR 200 Liter Sterile @ 0.52%	1
SHC-10-200L-0.25	HYPO-CHLOR 200 Liter Sterile @ 0.25%	1

Available Technical Data Supplements (Upon Request)

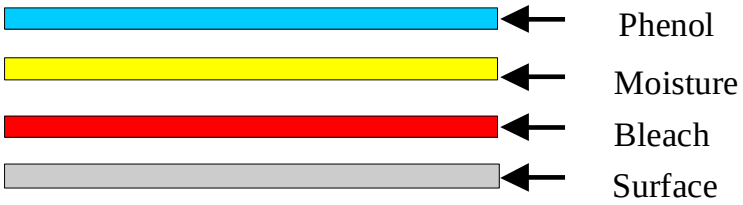
SC-001: Sterile Chemical Product Guide
VL-801: HYPO-CHLOR Technical Data Report

Using HYPO-CHLOR Sterile

The purpose of this section of the report is to explain the "appropriate use" of the product in a clean room operation. The biggest concern with HYPO-CHLOR relates to residues and deterioration of the surface. This problematic situation relates to remaining residues. **If handled appropriately, this concern can be eliminated from the scope.**
There are two problems with sodium hypochlorite. The first is what concentration should be used and the second is the deterioration of the surface. The first, concentration, points to industry standards that look at a 0.52% solution over a 5.25%. The concentration of 0.52% is suitable for clean room and leaves less of a residue that 5.25%.

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

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



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

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

HYPO-CHLOR

Sterile Pharmaceutical Clean Room Formula

SPECIFICATIONS

Specification	HYPO-CHLOR
Filtration:	0.2 Micron Absolute
Appearance:	Colorless to yellow liquid
Odor:	Chlorine-like
Percentage of Sodium Hypochlorite:	5.25%, 0.52% or 0.25%
Biodegradable:	Yes
Class of Wetting Agent:	Anionic
Detergency:	Excellent
Solubility(water):	Miscible
Wetting ability:	Excellent
Specific Gravity:	1.07
Litmus Test Addition of HCI(Yellow):	Passes
Addition of HCI gives off CI2 Gas:	Passes
Storage Stability:	Excellent
Freeze-thaw stability:	Excellent-if frozen, thaw & mix well
Testing/Parameters:	Current USP compendium Assay and Sterility tested.
Documents with Each Lot:	Certificate of Analysis and the Certificate of Sterility

HYPO-CHLOR

Sterile Pharmaceutical Clean Room Formula

5.25%, 0.52% AND 0.25%
STERILE SODIUM HYPOCHLORITE

PRODUCT LABELING

Any Specific Product Label is Available Upon Request.

vai
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VELTEK PRODUCT LABEL COLORS

PRODUCT NAME	BOTTLE/CAN COLOR	LABEL BACKGROUND COLOR	BAR & USER INFO COLOR	TEXT COLOR
DECON-AHOL WFI 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI 70% SQUEEZE BOTTLE	WHITE SEMI-TRANPARENT	COOL GREY		
DECON-AHOL WFI 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI 60%	WHITE	WHITE		
DECON-AHOL WFI 91%	WHITE	WHITE		
DECON-AHOL WFI 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		

REV. 06 JUNE 2012

HYPO-CHLOR

Sterile Pharmaceutical Clean Room Formula

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

TECHNICAL REPORT

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

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

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

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

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

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

DECON-Clean as a Residue Remover:
DECON-Clean has been developed to cope with the removal of residues within the class 100 aseptic manufacturing operation. The patented formula assures the breakdown of VAI's DECON-AHOL®, STER-AHOL®, DECON-PHENE®, DECON-CYCLE®, DECON-Clean®, DECON-QUAT 100®, DECON-QUAT 200C, DECON-QUAT 200V, HYPO-CHLOR, STERI-PEROX®, Cage2Wash®, Process2Clean®, and DECON-SPORE 200® Plus products. Once broken down, these residues or remnants of chemicals may be mopped, sponged, wiped or rinsed free from the surface.

DECON-Clean's Effectiveness Test Procedure:
DECON-Clean was tested against the following chemicals for effectiveness of residue removal and was found extremely effective in the control of residual levels.

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

Test Procedure:
Controls:

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

Results:

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

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

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

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

Results:

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

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

Testing Residue Removal Ability of DECON-Clean® USING MECHANICAL CLEANING

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

Results:

Chemical Tested	Results:
DECON-AHOL® 70% (RTU)	ppm of isopropyl alcohol = 0 ppm*
DECON-AHOL 91% (RTU)	ppm of isopropyl alcohol = 0 ppm*
STER-AHOL® 70% (RTU)	ppm of ethanol = 0 ppm*
DECON-PHENE® (1:128 Use Dilution)	ppm of Phenols and Chlorophenols = 0.00 ppm*
DECON-CYCLE® (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 0.00 ppm*
DECON-QUAT® 100 (2:128 Use Dilution)	ppm Peroxyacetic acid = 0.00 ppm*
HYPO-CHLOR 5.25%	ppm of Sodium Chloride = 2 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 0.00 ppm*
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 0.00 ppm *
STERI-PEROX® 3%	ppm Hydrogen Peroxide = 0.000 ppm*
STERI-PEROX 6%	ppm Hydrogen Peroxide = 0.000 ppm*
DECON-SPORE® 200 Plus 5%	ppm Peroxyacetic acid = 0.00 ppm*

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

Possible Residues from DECON-Clean

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

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

Results DECON-Clean Residues After Rinsing Chemical Tested
DECON-Clean (1:128) w/Rinse Results: ppm of combined residues = 0.00 ppm*

Conclusion:

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

The following Testing Study was conducted by:

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

HYPO-CHLOR

Sterile Pharmaceutical Clean Room Formula

5.25%, 0.52% AND 0.25%
STERILE SODIUM HYPOCHLORITE

Lot Specific
Sterile Documentation

(received with each shipment)

Certificate of Analysis
Certificate of Sterility

(Please contact VAI for a sample of this documentation)

Room Type/Surface	Minimum Frequency*	Method	Application	Product (Must be STERILE)
ISO 5 Primary Engineering Controls				
• LAFW • BSC • CAI • CACI	• Beginning of each shift _____ • Before each batch • Every 30 minutes during compounding • When spills occur • When surface contamination is known/suspected	Wipe Wipe	Cleaning/Disinfecting Disinfecting Disinfecting	1. Decon-Quat 200C followed by: 2. Decon-Ahol 70% IPA Decon-Ahol 70%IPA
	Monthly or quarterly based in response to EM micro monitoring results	Wipe	Cleaning Sporicidal	1. Decon-Clean followed by: 2. Decon-Spore 200 Plus Or 0.52% Hypo-Chlor Or 6% Steri-Perox
	During use as required	Wipe		Decon-Ahol 70% IPA
ISO 7 & 8 - Buffer Area & Anteroom				
Counters, Work surfaces, door plates, handles, gowning benches	Daily	Wipe	Cleaning/Disinfecting	Decon-Quat 200C
Floors	Daily (when no aseptic operations are in progress)	Mop	Cleaning/Disinfecting	Decon-Quat 200C
	Monthly or quarterly based in response to EM micro monitoring results	Mop	Cleaning Sporicidal	1. Decon-Clean followed by: 2. Spore 200 Plus Or 0.52% Hypo-Chlor Or 6% Steri-Perox **
Walls & Ceilings	Monthly	Mop	Cleaning/Disinfecting	Decon-Quat 200C
	Quarterly or yearly based in response to EM micro monitoring results	Mop	Cleaning Sporicidal	1. Decon-Clean followed by: 2. Spore 200 Plus Or 0.52% Hypo-Chlor Or 6% Steri-Perox **
Storage Shelving	Monthly	Wipe	Cleaning/Disinfecting	Decon-Quat 200C
In-coming Supplies	As needed	Wipe	Disinfecting	Decon-Ahol 70% IPA Or 6% Steri-Perox Saturated Wipe

*Always refer to site specific SOP's for cleaning and disinfection instructions. ** Consider MSDS PEL before applying.

Product Dilutions/Applications

Product	Dilution	Application
Decon-Ahol 70% IPA	RTU	Disinfecting
6% Steri-Perox	6% RTU	Sporicidal
Decon-Quat 200C	1:128 RTU	Cleaning/Disinfecting
Decon-Spore 200 Plus	6.4:128 RTU	Sporicidal
0.52% Hypo-Chlor	0.52% RTU	Sporicidal
Decon-Clean	1:128 RTU	Cleaning
6% Saturated Steri-Perox Wipe	RTU	Decontamination
Wipedown HC	-	Sterile non-shedding drywipe

NOTE: All products used in the critical classified area must be sterile.