



VELTEK ASSOCIATES, INC.

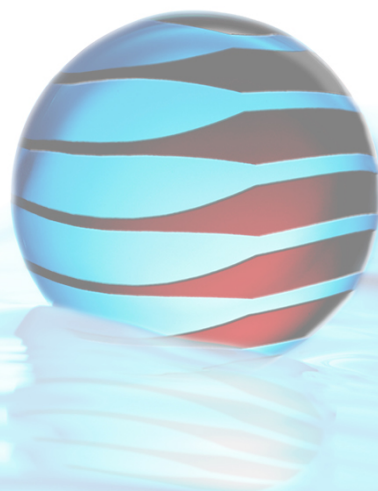
TECHNICAL DATA FILES



DECON-CLEAN®

Residue Remover and Cleaner

Sterile Pharmaceutical Cleanroom Formula



Product Description

DECON-CLEAN is designed for and processed to meet the standards required by pharmaceutical, biotechnology, healthcare, and lab animal research operations that demand a cleaning agent to remove residues left behind from disinfecting agents. **DECON-CLEAN** is an effective one-step residue remover when diluted at 1:128 (1 oz. per 1 gallon) of hard or soft water (400 ppm hard as CaCO₃). Due to **DECON-CLEAN**'s formulation it is an excellent cleaner designed for all washable, non-porous environmental surfaces. Using **DECON-CLEAN**, one can assure that noticeable and unnoticeable residues are removed, thus returning the surface to its original form. Residues left behind from disinfectants, sanitizers, and sporicidies, including Sodium Hypochlorite can be easily removed using **DECON-CLEAN**. Returning the surface to its original form assures that future decontamination will be able to penetrate to the surface.

DECON-CLEAN is available in several container sizes, including in our patented SimpleMix® System (see description below), both sterile and non-sterile. Each lot of **DECON-CLEAN** is filtered and then subsequently terminally sterilized via gamma irradiation at a 10⁻⁶ SAL. Each sterile container is double bag packaged and delivered with the lot specific Certificate of Analysis, Certificate of Irradiation and Certificate of Sterility. **DECON-CLEAN** products are completely traceable and have been completely validated for sterility and shelf life.

Please consult the end of this document for use to remove representative disinfecting agents.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered
- Gamma irradiated at a 10⁻⁶ SAL
- Sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

DECON-CLEAN Concentrate– Residue Remover and Cleaner	
Certificate of Analysis	Result
Appearance:	Clear free of suspended matter
Solubility in Water:	Completely
% Nonvolatile Matter:	</=20.0%
pH of Concentrate:	9.5-11.0
Specific Gravity @20 degrees:	1.010-1.040
Expiration Period:	2 years

Features and Benefits

- Packaged quadruple bagged in the ABCD Cleanroom Introduction System™
- Delivered with lot specific Certificate of Sterility, Certificate of Irradiation, and Certificate of Analysis
- Removes residues from sanitizers, disinfectants, and sporicidies
- Excellent cleaning characteristics
- Available in multiple container sizes including unit dose, 16 oz SimpleMix, 1 gallon SimpleMix, 11 oz aerosol, and 200L SimpleMix Drum
- Available in either sterile or non-sterile



Uses

DECON-CLEAN is designed for use in aseptic filling suites to controlled corridors and can be used for all washable, non-porous, environmental surfaces in order to return the surface to its original form after being disinfected. Examples include on aseptic connections, process lines, walls, floors, and ceilings, counter tops, and stainless steel items.

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 or sporicide 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. The 16 ounce side container houses the concentrate and the bottom reservoir houses 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. 200L SimpleMix systems are activated through a hose and valve system connecting the cubicon of concentrate to the VAI WFI Quality Water. The solution and water mix together. The system design permits the easy transfer of the product to the aseptic manufacturing area without concern for the transfer of contamination.

Ordering Information

DECON-CLEAN – Residue Remover and Cleaner		
Part number	Description	Qty/cs
DC-01	DECON-CLEAN, 1 Gallon, Concentrate, Non-Sterile	4
DC-02	DECON-CLEAN, 1 Gallon, Concentrate, Sterile	4
DC-03-4Z	DECON-CLEAN, 4 oz ,Unit Dose, Sterile	24
DCWFI-SP-11Z	DECON-CLEAN, 11 oz, Aerosol Spray Mist, Sterile	24
DC-06-16Z-01	DECON-CLEAN, 16 oz, SimpleMix, Trigger Spray, Sterile	12
DC-07-16Z-01	DECON-CLEAN, 16 oz, SimpleMix, Trigger Spray, Non-Sterile	12
DC-04-1Z	DECON-CLEAN, 1 Gallon, SimpleMix, Sterile	4
DC-05-1Z	DECON-CLEAN, 1 Gallon, SimpleMix, Non-Sterile	4
DC-100-200L-CI	DECON-CLEAN, 200L, SimpleMix Drum, Sterile	1



VAI's Product Label Colors

15 LEE BOULEVARD MALVERN, PA 19355-1234 USA
 TOLL FREE: 888.478.3745 T: 610.644.8335 WWW.STERILE.COM
VELTEK ASSOCIATES, INC.

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-TRANSPARENT	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

DECON-CLEAN
Sterile Pharmaceutical Clean Room Formula
Residue Remover and Cleaner for Hard Surfaces

PRODUCT LABELING

(All product labels are available upon request.)

Active Ingredients:

Water	86.5%
Potassium Tall Oil Soap.....	7.5%
Other ingredients	6.0%
Total.....	100.0%



DANGER
KEEP OUT OF REACH OF CHILDREN

Produced and Sterilized by:
 Veltek Associates, Inc.
 15 Lee Boulevard, Malvern, PA 19355
 610-644-8335

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Wear goggle or face shield and rubber gloves when handling. Avoid contamination of food.

FIRST AID

- EYES:** Flush thoroughly with water for at least 15 minutes.
- SKIN:** Wash affected area with soap and water.
- INGESTION:** DO NOT INDUCE VOMITING. Call a poison control center immediately.
- INHILATION:** Move to fresh air, give oxygen to exposed person if necessary.

DIRECTIONS FOR USE

Apply product generously to wet entire surface and use mechanical action to loosen residue. Squeegee off, wipe dry or rinse with clean water and dry.

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

SIMPLEMIX SYSTEM TECHNOLOGY

Directions for Use

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.

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.

200 Liter Drum Lid Label:

(note: To be used with a Veltek Associates, Inc. pump)

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.



SIMPLEMIX® SYSTEM, 200L CONTAINER OPERATION

Step #1 - Remove drum from double-bag packaging



Step #2 - Remove cubicontainer from top of drum and uncoil hoses



Step #3 - Connect Pump to center hose



Step #4 - Open Valves 1, 2, and 3



Step #5 - Start Pump



Step #6 - When cubicontainer is empty, close valves 1 and 2



Step #7 - Open Valves 5 and 6



Step #8 - Start Pump and let run for 15 minutes to mix contents



Step #9 - Stop pump, close valve 4 and open valve 3 to dispense



DECON-CLEAN

Sterile Pharmaceutical Clean Room Formula Residue Remover and Cleaner for Hard Surfaces Testing Summary

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

Discussion and Purpose of Testing

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

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

Particulate Impurities

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

Chemical Ingredient Residues

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

DECON-CLEAN as a Residue Remover

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

DECON-CLEAN's Effectiveness Test Procedure:

DECON-CLEAN® was tested against the following chemicals for effectiveness of residue removal and was found extremely effective in the control of residual levels.

DECON-AHOL® (70% and 91% RTU)
 DECON-PHENE® (1:128 Use Dilution)
 DECON-CYCLE® (1:256 Use Dilution)
 HYPO-CHLOR® (5.25%, 0.52%, and 0.25%)

STER-AHOL® (70% RTU)
 DECON-SPORE® 200 Plus (5%)
 DECON-QUAT® 100 (2:128 Use Dilution)
 STERI-PEROX® (3% and 6%)

Test Procedure

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

Chemical Residue after Drying

Chemical Tested	Results
DECON-AHOL® 70% (RTU)	ppm of isopropyl alcohol = 0 ppm*
DECON-AHOL 91% (RTU)	ppm of isopropyl alcohol = 0 ppm*
STER-AHOL® 70% (RTU)	ppm of ethanol = 0 ppm*
DECON-PHENE® (1:128 Use Dilution)	ppm of Phenols and Chlorophenols = 2 ppm
DECON-CYCLE® (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 3 ppm
DECON-QUAT® 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 3 ppm
HYPO-CHLOR® 5.25%	ppm of Sodium Chloride = 252 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 30 ppm
HYPO-CHLOR 0.25%	ppm of Sodium Chloride = 18 ppm
STERI-PEROX® 3%	ppm Hydrogen Peroxide = 1 ppm*
STERI-PEROX 6%	ppm Hydrogen Peroxide = 1 ppm*
DECON-SPORE® 200 Plus (5%)	ppm Peroxyacetic acid = 3 ppm

* No residue detectable gravimetrically

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

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

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

* Visual residue spots, not detectable gravimetrically

Testing Residue Removal Ability of DECON-CLEAN USING MECHANICAL CLEANING

After the chemical residue was established on the surface, the surface was cleaned with a **DECON-CLEAN®** application at a use dilution of 1:128 and using a VEL8-12X12 Dry Wiper with a circular mechanical cleaning action.

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

* No visual residue spots

Conclusion

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

Written By: Boris Polanuyer Date: 05Oct2015

Approved By: Kelly Rocco Date: 05Oct2015

DECON-CLEAN

Sterile Pharmaceutical Cleanroom Formula
Residue Remover and Cleaner of Hard Surfaces

Lot Specific Sterile Documentation

(Received with each shipment)

**Certificate of Analysis
Certificate of Sterility
Certificate of Irradiation**

(Please contact VAI for a sample of this documentation)



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 unidose 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