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DECON-Clean®

Sterile Pharmaceutical Clean Room Formula

**CLEANER AND RESIDUE REMOVER
(for hard surface)**



SEE THE NEW

Veltek

SimpleMix®

SYSTEM



Veltek Associates, Inc.

15 Lee Boulevard • Malvern, PA 19355-1234

Tel: (610)644-8335 Fax: (610)644-8336 E-mail: vai@sterile.com VL-701-98-3 07/16/04

DECON-Clean[®] Sterile Pharmaceutical Clean Room Formula

PRODUCT DESCRIPTION

DECON-Clean is designed for pharmaceutical and biotechnology operations that demand a cleaning agent to remove residues 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) DECON-Clean is filtered at 0.2 microns and then subsequently terminally sterilized. DECON-Clean 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. Return of the surface to the original form assures that future decontaminating operations will address surfaces and not the existing residues. DECON-Clean is available in 4 oz. bottles 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, Certificate of Irradiation and Sterility Report. DECON-Clean products are completely traceable and have been completely validated for sterility and shelf life.

The SimpleMix[®] System Technology Alternative:

As a innovating step to address this problematic situation, Veltek Associates, Inc has developed the SimpleMix[®] System Technology. The system provide for the transfer of the sterile disinfectant and sterile water in a sealed container to the aseptic area. The system container is double bag packaged for easy transfer and eliminated all internal and external concerns for the use of a sterile, compliant disinfectant or sporicide.

The Patent Pending SimpleMix[®] System provides a sealed multi-chamber container that when activated mixes the two solutions. The top part contains the concentrate disinfectant or sporicide and the bottom part contains the USP WFI Quality Water. **Just open the cap, pull the tab and they instantly mix together.** The system design permits the easy transfer of the sterile disinfectant or sporicide and sterile water to the aseptic manufacturing area without concern for the transfer of contamination. See **VAI Technical Document (SMix-01 Rev. 02/03)**

Uses: DECON-Clean Sterile is a cleaning solution used for the removal of residue buildup from chemicals on walls, ceilings, floors and stainless items.

<u>Order#</u>	<u>Description</u>	<u>Quan/cs.</u>
DC-01	DECON-Clean 1 Gallon Non-Sterile	4
DC-02	DECON-Clean 1 Gallon Sterile	4
DC-03-4Z	DECON-Clean 4 oz. Sterile	24
DC-04-1Z	DECON-Clean SimpleMix Sterile 1 gallon	4
DC-05-1Z	DECON-Clean SimpleMix Non-Sterile 1 gallon	4

Available Technical Data Supplements (Upon Request)

SC-001: Sterile Chemical Product Guide

VL-701: DECON-Clean Technical Data Report

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SPECIFICATIONS

<u>Specification</u>	<u>DECON-Clean</u>
Filtration:	0.2 Micron Absolute
Processing:	Filled in a GMP Class 100 area
Sterilization:	Gamma Radiation at 10 ⁻⁶ SAL Level
Appearance:	Clear Pigmented
Odor:	Lemon (Citrus)
Residue and De-greasing Removal Properties:	Excellent
pH Use Dilution:	9.5-11.0
Biodegradable:	Yes
Class of Wetting Agent:	Anionic
Detergency:	Excellent
Solubility(water):	Excellent
Wetting ability:	Excellent
Specific Gravity:	1.01-1.15
Flash & Fire Points:	110 Degrees F, SETA
Non-volatile Residue:	0.05 mg.(0.01%)
Storage Stability:	Excellent
Freeze-thaw stability:	Excellent-if frozen, thaw and mix well
Weight/Gallon:	11.6 lb/gal.
Irradiation Dose:	25.0 – 50.0 kGy
Testing/Parameters:	USP Sterility Testing and Certificate of Analysis

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(for hard surface)**

PRODUCT LABELING

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(CENTER PANEL)

DECON-Clean®

Sterile Pharmaceutical Clean Room Formula

**RESIDUE REMOVER
(for hard surfaces)**

ACTIVE INGREDIENTS:

Detergent.....	2.50%
2-Butoxyethanol.....	10.00%
Potassium Hydroxide.....	2.50%
Terrasodium Pyrophosphate.....	2.50%
Inert Ingredients.....	82.50%

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Keep Out of Reach of Children

DANGER

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DIRECTIONS FOR USE

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

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of Reach of Children. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink large quantities of water. Call a Physician.

USE: Mix 1 oz. of DECON-Clean with 1 gallon of water. (1:128)

Contents 1 gallon (128 ounces) or 8 ounces

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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 existent chemical residues. All chemicals leave a residual on the surfaces that they come in contact. 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 existent 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 existent 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 the 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-PHASE[®], DECON-CYCLE[®], PHENE-AHOL[®], DECON-Clean[®], DECON-QUAT 100[®], HYPO-CHLOR[®], STERI-PEROX[®], DECON-SPORE 100[®], DECON-SPORE 200[®], and DECON-SPORE 200[®] PLUS products. Elements in the formulation of the above listed VAI products are broken down by the DECON-Clean mixture. Once broken down, these residues or remnants of chemicals may be mopped, sponged, wiped or rinsed free from the surface.

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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)	STER-AHOL (70% RTU)
DECON-PHENE (1:128 Use Dilution)	DECON-PHASE (1:256 Use Dilution)
DECON-CYCLE (1:256 Use Dilution)	PHENE-AHOL (70% ETOH-0.21% Phenol)
DECON-QUAT 100 (2:128 Use Dilution)	HYPO-CHLOR (5.25%, 0.52%, and 0.25%)
STERI-PEROX (3% and 6%)	DECON-SPORE 100 (0.86%)
DECON-SPORE 200 PLUS 5%	DECON-SPORE 200 (1:32 Use Dilution)

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.

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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-PHASE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 727 ppm
DECON-CYCLE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 731 ppm
PHENE-AHOL ((70% ETOH/Phenol RTU	ppm of Phenols and Chlorophenols = 0.016 ppm*
DECON-QUAT 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 133 ppm
HYPO-CHLOR 5.25%	ppm of Sodium Chloride = 49,768 ppm
HYPO-CHLOR 0.52%	ppm of Sodium Chloride = 651 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
DECON-SPORE 100 (0.86%)	ppm Peroxyacetic acid = 7 ppm
DECON-SPORE 200 (1:32 Use Dilution)	ppm Peroxyacetic acid = 4 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-PHASE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 48 ppm
DECON-CYCLE (1:256 Use Dilution)	ppm of Phenols and Chlorophenols = 41 ppm
DECON-QUAT 100 (2:128 Use Dilution)	ppm of Ammonium Chloride = 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
DECON-SPORE 100 (0.86%)	ppm Peroxyacetic acid = <2 ppm
DECON-SPORE 200 (1:32 Use Dilution)	ppm Peroxyacetic acid = <2 ppm

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

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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:

<u>Chemical Tested</u>	<u>Results:</u>
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-PHASE (1:256 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 of Ammonium Chloride = 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*
DECON-SPORE 100 (0.86%)	ppm Peroxyacetic acid = 0.00 ppm*
DECON-SPORE 200 (1:32 Use Dilution)	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*

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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 (filtered at 0.2 um.) is further recommended as the levels of all existent residues is further reduced.

The following Testing Study was conducted by:

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

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DECON-Clean[®]

**Sterile Pharmaceutical Clean Room Formula
Residues Remover**

MATERIAL SAFETY DATA SHEET

COMPLIES WITH OSHA HAZARD COMMUNICATION STANDARD 29 CFR 1910.1200

(Complies with Commission Directive 91/155/EEC amended by 2001/58/EC)



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DECON-Clean®

MATERIAL SAFETY DATA SHEET

COMPLIES WITH OSHA HAZARD COMMUNICATION STANDARD 29 CFR 1910.1200
(Complies with Commission Directive 91/155/EEC amended by 2001/58/EC)

I. Identification of Substance:

Product Name: DECON-Clean® Sterile

MSDS #: DC-01-98

Description: Cleaner, Residue Remover

MSDS Information	Manufacturer Information	Emergency Telephone Information
Date Prepared: November 6, 2002	Veltek Associates, Inc.	Notify your Supervisor
Prepared by:	15 Lee Boulevard	Emergencies Chemtrec (800) 424-9300
Art Vellutato, Jr.	Malvern, PA 19355	24-hour service
V.P. Technical Support Operations	TEL: (610)644-8335	
Reviewed by:		Effective Date: November 6, 2002
Art Vellutato, Sr.		Date Supercedes: 03/26/98
Technical Director		

II. Composition/Data on Components:

Description: Clear Pigmented Liquid with Characteristic Odor

Chemical Name	CAS#	WT%	PEL	TWA-TLV	STEL-TLV	Carcinogen
Water	7732-18-5	80%	NA	NA	NA	No
2-Butoxyethmol	111-76-2	10%	25 ppm	25 ppm	NA	No
Potassium Hydroxide	1310-43-5	2.5%	NA	C2mg/M3	NA	No
Potassium Soap	81720-44-1	2.5%	NA	NA	NA	No
Terrasodium Pyrophosphate	1310-43-5	5%	NA	NA	NA	No

HIMIS RATING *Concentrate* HEALTH 1 REACTIVITY 0 FLAMMABILITY 2 PERSONAL B
HIMIS RATING *Diluted 1:128 (1 oz. per gal)* HEALTH 1 REACTIVITY 0 FLAMMABILITY 0 PERSONAL B

HAZARD RATINGS: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Extreme A = Safety Glasses B = Safety Glasses & Gloves

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III. Hazards Identification:

Effects of Overexposure: Primary Route of Entry:

Skin: Skin irritant. May cause moderate reddening and swelling.

Eyes: Eye irritant. Liquid and Mist may damage eyes causing cornea damage.

Inhalation: Vapors and Mist may cause irritation to mucous membranes in nose, throat, and lungs.

Ingestion: Irritating and corrosive to the mouth and throat. May cause headaches, nausea, abdominal pain, vomiting, and diarrhea. Excessive amounts may cause collapse

IV. First Aid Measures:

Skin: Flush with Water. Seek medical attention if irritation persists.

Eyes: Flush with Plenty of Water keeping eyelids open. Seek medical attention if irritation persists.

Inhalation: Get to Fresh Air. Seek medical attention if irritation persists.

Ingestion: Do Not Induce Vomiting. Drink large quantities of Water. Immediately seek medical attention.

V. Firefighting Measures:

Flash Point (Method Used): N/A

Upper Exposure Limit: N/A

Extinguishing Media: N/A

Special Firefighting Procedures: Non-Flammable

Unusual Fire and Explosion Hazards: N/A

FLASH POINT (°F): NA

FLAMMABLE LIMITS: NA

EXTINGUISHING MEDIA: Water Fog, Alcohol Foam, Dry Chemical, CO₂

SPECIAL FIRE FIGHTING PROCEDURES: will not burn

UNUSUAL FIRE AND EXPLOSION HAZARDS: will not burn or explode

VI. Accidental Release Measures:

Mop up or otherwise absorb and hold for disposal. Dispose of in accordance with applicable laws

VII. Handling and Storage:

PRECAUTIONARY LABELING: See carton label for precautions

OTHER HANDLING AND STORAGE CONDITIONS: Do not Store above 120°F or below 32°F. Will Freeze. Do not store in sunlight.

VIII. Exposure Control and Personal Protection:

Respiratory Protection: Use in well ventilated area.

Protective Gloves: Waterproof

Eye Protection: Safety goggles or glasses

Ventilation: Provide local exhaust to keep TLV below acceptable limits

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IX. Physical and Chemical Properties:

Boiling Point: 210°F
Vapor Pressure: 20 mm Hg @ 68°F
Solubility in Water: Complete
Specific Gravity: 1.010
pH: 9.5 – 11.0

X. Stability and Reactivity

Stability: Stable
Incompatibility: (Materials to Avoid): Strong Acids Hazardous Polymerization: None
Hazardous Decomposition Products: Alkaline Vapors in fire
STABILITY: Stable
STABILITY-CONDITIONS TO AVOID: Stable
HAZARDOUS DECOMPOSITION PRODUCTS: None
HAZARDOUS POLYMERIZATION: Will not occur
HAZARDOUS POLYMERIZATION-COND. TO AVOID: Will not occur

XI. Toxicological Information:

POISON CRITERIA:	<u>Oral</u>	<u>Dermal</u>	<u>Inhalation</u>
		5840mg/kg/Rat	1300mg/kg/Rabbit 1200mg/L/Rat

XII. Ecological Information:

Consult local authorities pertaining to the release of material to the environment.

XIII. Disposal Considerations:

Disposal: Container disposal regulation may vary with amount of liquid content remaining in container. Refer to latest Federal and State Regulations regarding proper disposal of ALL containers. If needed, consult manufacturer for assistance to obtain proper disposal guidelines for your area

XIV. Transport Information:

DOT SHIPPING NAME: Cleaner **HAZARD CLASS:** None **ID NUMBER:** Not Regulated

XV. Regulations:

PLEASE CONSULT YOUR STATE AND LOCAL AUTHORITY FOR INGREDIENTS LISTED AS PERTAINING TO REPORTING REQUIREMENTS FOR HAZARDOUS SUBSTANCE LIST.

No special regulation other than transportation and disposal (see section VII and section IX). Conform to Federal, State and Local Regulations for disposal. Follow usage instructions on container.

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XVI. Other Information:

Avoid Contact with Eyes, Skin and Clothing Keep Out of Reach of Children
Keep Container Closed during Storage
For industrial use only.

**NA-Not Applicable, NE-Not Established, NSR-No Special Requirement,
ND-Not determined for this product**

The Information herein is given in good faith. No warranty, expressed or implied is made. Any use of these data and information must be determined by the user to be in accordance with applicable Federal, State and Local Laws and Regulations. The information contained in this form is confidential and is submitted solely for your organization's internal use. MSDS #: MSDS-2002-DG-01 (Rev 2 – 04/2002)

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**CLEANER AND RESIDUE REMOVER
(for hard surface)**

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)

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