



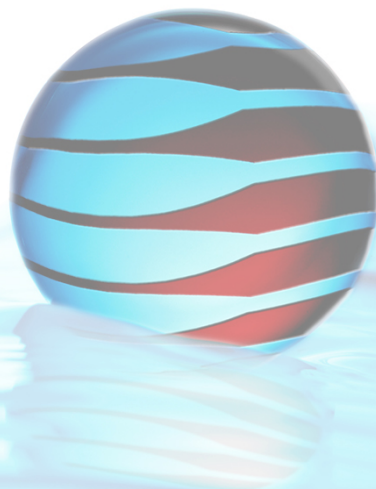
VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DEC-GLASS[®]

**Glass and Plexiglass Residue Remover and Cleaner
Sterile Cleanroom Pharmaceutical Formula**



Product Description

DEC-GLASS is designed for pharmaceutical and biotechnology cleaning cycles that demand a sterile glass and plexiglass cleaner capable of removing residues from disinfecting agents. **DEC-GLASS** is an effective one-step, ready-to-use, residue remover, glass and plexiglass cleaner that is formulated with USP Water for Injection. **DEC-GLASS** is an excellent cleaner designed for all washable, porous and non-porous environmental surfaces. Using **DEC-GLASS**, one can assure that noticeable and unnoticeable residues, smudges, oils and dirt build up are removed, thus returning the surface to its original form. Return of the surface to the original form assures that future decontamination operations will address surfaces and not the existing residues.

DEC-GLASS is available in a 16 oz. trigger spray bottle. Terminal sterilization is achieved by first filtering the solution at 0.2 microns, secondly, double bag packaging each container, and then subsequently sterilizing the entire contents via gamma irradiation. **DEC-GLASS** is delivered each time with the lot specific Certificate of Analysis, Certificate of Sterility and Certificate of Irradiation. **DEC-GLASS** is completely traceable and has been completely validated for sterility and shelf life.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered at 0.2 microns
- Gamma irradiated to a sterility assurance level of 10^{-6}
- Sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

DEC-GLASS – Glass and Plexiglass Cleaner	
Certificate of Analysis	Result
Specific Gravity	0.985-1.01
pH:	5.0-8.0
Expiration Period:	3 years

Features and Benefits

- Packaged quadruple bagged in the ABCD Cleanroom Introduction System™
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility
- Specifically formulated as a glass cleaner and degreaser
- Ready-to-use residue remover for glass and plexiglass
- Formulated with USP Water for Injection
- Designed for all washable environmental surfaces
- Removes noticeable and unnoticeable residues, smudges, oils, and dirt buildup
- Comes in a convenient 16 oz trigger spray that has the option of spray or mist

Uses

DEC-GLASS Sterile solution is used for the cleaning of glass, plexiglass, environmental, hard, non-porous surfaces, and many other applications that require the use of a streak free sterile glass cleaner that incorporates detergency characteristics with no remaining residue. Use where there is build-up of previous disinfectants, oil, or residue as residue remover.

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 a bag. 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 the outer bag prior to entering a cleaner area. In this packaging system each container is individually packaged into two easy tear bags, and all the individually packaged containers are then bulk packaged into two additional bags.



Ordering Information

DEC-GLASS – Glass and Plexiglass Cleaner		
Part Number	Description	Qty/cs.
DG-03-16Z-E	DEC-GLASS, 16oz, Trigger Spray, Sterile	12



Veltek Associates, Inc.

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

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VAI Product Label Colors

15 LEE BOULEVARD MALVERN, PA 19355-1234 USA
TOLL FREE: 888.478.3745 T: 610.644.8335 WWW.STERILE.COM
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VELTEK DEC PRODUCT LABEL COLORS

PRODUCT NAME	BOTTLE/CAN COLOR	LABEL BACKGROUND COLOR	BAR & USER INFO COLOR	TEXT COLOR
DEC-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-AHOL WFI 60%	WHITE	LIGHT BLUE		
DEC-AHOL WFI 91%	WHITE	LIGHT BLUE		
DEC-AHOL WFI 99%	WHITE	LIGHT BLUE		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DEC-HAND STERILE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-HAND NON-STERILE	CLEAR	LIGHT BLUE		
DEC-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
STERI-OIL	WHITE	WHITE		
STERI-BUFFER	CLEAR	PRINTED BOTTLE		
DEC-CYCLE	WHITE	LIGHT BLUE		
DEC-CLEAN	WHITE	LIGHT BLUE		
DEC-QUAT 100	WHITE	LIGHT BLUE		
DEC-QUAT 200C	WHITE	LIGHT BLUE		
DEC-QUAT 200V	WHITE	LIGHT BLUE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	MEDIUM BLUE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DEC-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DEC-GLASS	WHITE	LIGHT BLUE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		

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DEC-GLASS

**Sterile Glass and Plexiglass Residue Remover and Cleaner
Sterile Pharmaceutical Cleanroom Formula**

PRODUCT LABELING

All product labels are available upon request.

Ingredients:

Sodium Lauryl Sulfate	0.1%
Isopropyl Alcohol	1.7%
USP Water for Injection.....	98.2%
Total	100.0%

(*note – Sodium Lauryl Sulfate will not appear on the product label. Due to the amount present in the final product and its non-hazardous classification, it is not required to be listed on the label.)

Container and Sterilized and Distributed by:

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355 USA

610-644-8335

European Office: Postbus 1062, 8200 BB Lelystad, Nederland

Tel: 00-800-00888700

HAZARD STATEMENTS

Avoid all unnecessary exposure. Wear protective gloves. Safety glasses. Wear suitable protective clothing. In case of inadequate ventilation wear respiratory protection. Do not eat, drink or smoke during use.

PRECAUTIONARY STATEMENTS

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

See Safety Data Sheet and/or leaflet for additional product information.

For Spill/Exposure Emergency Response from Europe call +44-1235-239-670. For Arabic call +44-1235-239-671, for Chinese call +86-10-5100-3039.

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For Industrial Use Only**STUDY: Comparison of cleaning efficiency of old and new DEC-GLASS formula**

The aim of this experiment was to compare cleaning efficiency of old and new VAI DEC-GLASS formula.

Experimental

Glass coupons 5"x3" were weighed and loaded with different VAI disinfectants. They were dried overnight and cleaned using the old and the new VAI **DEC-GLASS** formula.

DEC-GLASS as a Residue Remover:

DEC-GLASS has been developed to clean glass and Plexiglas surfaces within the ISO 5 (Grade A/Class 100) aseptic manufacturing operation. The patented formula assures the removal of VAI's DEC-SPORE 200 Plus, DEC-CYCLE®, HYPO-CHLOR®, DEC-QUAT 200® and other disinfectants. Once broken down, these residues or remnants of chemicals may be mopped, sponged, wiped or rinsed free from the surface.

DEC-GLASS Effectiveness Test Procedure:

DEC-GLASS was tested against the following chemicals for effectiveness of residue removal and was found extremely effective in the control of residual levels. All disinfectants were used as is, without a dilution.

DEC-SPORE 200 Plus®

DEC-CYCLE®

HYPO-CHLOR® (5.25%)

DEC-QUAT 200®

Test Procedure:**Controls:**

1. Glass coupons were defined for the test.
2. Each chemical was prepared and the surface was completely exposed to the chemical in separate tests.
3. The chemical was permitted to completely dry.
4. Testing was conducted in a fume hood.
5. All safety precautions were taken referencing safety. This includes gowning, gloves and a NIOSH approved chemical mask.
6. The samples were clearly marked as controls/ chemical tested and delivered to the laboratory for gravimetric testing.
7. Results establish baselines residues were assessed and reported.

Testing Residue Removal Ability of DEC-GLASS 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 **DEC-GLASS** application as a RINSE ONLY. Once cleaning was performed testing proceeded from step #4 as listed above. Cleaning efficiency was measured both visually and gravimetrically.

Disinfectant	DEC-GLASS Old Formula			DEC-GLASS New Formula		
	Residue before cleaning, mg	Residue after cleaning, mg	Cleaning efficiency, %	Residue before cleaning, mg	Residue after cleaning, mg	Cleaning efficiency, %
DEC-SPORE 200 PLUS	86	0	100	111	0	100
DEC-CYCLE	122	0	100	281	0	100
HYPO-CHLOR 5.25%	40	0	100	145	0	100
DEC-QUAT 200C	64	0	100	116	0	100



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)



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

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