

VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-GLASS®

Glass and Plexiglass Residue Remover and Cleaner Sterile Cleanroom Pharmaceutical Formula

Claims, product registrations, and regulatory requirements may vary based on local, regional, and/or national laws and regulations. Please contact your local sales representative for information specific to your region.



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16 oz Attached Trigger Spray DG-03-16Z



PRODUCT OVERVIEW

DECON-GLASS is designed for pharmaceutical and biotechnology cleaning cycles that demand a sterile glass and plexiglass cleaner capable of removing residues from disinfecting agents. **DECON-GLASS** is an effective one-step, ready-to-use, residue remover, glass and plexiglass cleaner that is formulated with USP Water for Injection. **DECON-GLASS** is an excellent cleaner designed for all washable, porous and non-porous environmental surfaces. Using **DECON-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.

DECON-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. **DECON-GLASS** is delivered each time with a lot specific analytical, irradiation, and sterility data, tested to current USP compendium. **DECON-GLASS** is completely traceable and has been completely validated for sterility and shelf life.

Quality and Manufacturing

- Filled in an ISO 7 cleanroom (Grade B)
- Filtered at 0.2 microns
- Formulated with USP Water for Injection (<0.25 EU/mL)
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated to a sterility assurance level of 10⁻⁶
- Lot sterility tested according to the current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System[®]
- Individually labeled with lot number and 5-year expiration
- Delivered with lot specific analytical, irradiation, and sterility data, tested to current USP compendium
- Specifically formulated as a glass cleaner and degreaser
- Designed for all washable environmental surfaces
- Streak free and incorporates detergency characteristics
- Low remaining residue



Product Uses

- Environmental, hard, non-porous surfaces
- Glass, plexiglass
- Applications that require the use of a streak free sterile glass cleaner
- Use where there is a build-up of pervious disinfectants, oil, or residue as a 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.







CHEMICAL SPECIFICATIONS

DECON-GLASS – Glass and Plexiglass Cleaner					
Certificate of Analysis	Specification	Result			
pH	5.0 - 8.0	7.0			
Sodium Lauryl Sulfate	< 0.1%	0.08%			
Specific Gravity (@20°C)	0.985 - 1.01	0.997			
Isopropyl Alcohol	< 3.0%	2.4%			

ORDERING INFORMATION

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



LABELING

VAI Product Label Colors

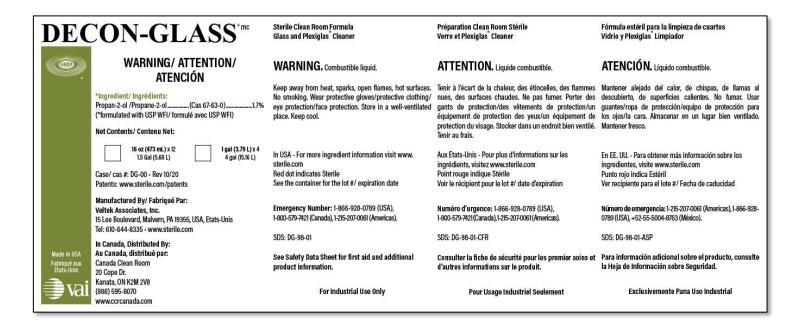
Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DECON-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
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

DECON-GLASS

Sterile Glass and Plexiglass Residue Remover and Cleaner



Case Label DG-00 Rev10/20

Any specific product label is available upon request.



16 oz Attached Trigger Spray DG-03-16Z



Product Labeling (Continued)

DECON-GLASS

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

Ingredients:

Sodium Lauryl Sulfate	0.1%
Isopropyl Alcohol	
USP Water for Injection	
Total	

(*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

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.

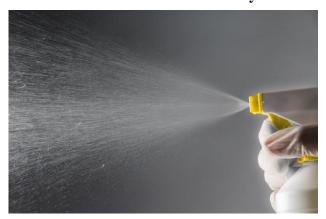
INHILIATION: Move to fresh air, give oxygen to exposed person if necessary.

RECOMMENDATIONS FOR USE

Use only as directed. Use in well ventilated area. Spray small amount to wet surface, clean with cloth. Polish with another clean, dry cloth. Do not use on pots, pans, or eating utensils.

For Spill/Exposure Emergency Response Service call CHARECHEM24 at 866-928-0789.

For Industrial Use Only



16 oz Attached Trigger Spray DG-03-16Z



ADDITIONAL DOCUMENTATION

Upon request, the following additional documentation is available:

- Product Testing Reports
- Product Labels
- Product Validation
- Safety Data Sheet
- Sample documentation packages delivered with lot specific analytical, irradiation, and sterility data, tested to current USP compendium



VAI®'s SCMD Product Family

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.

For more information call 610-644-8335, email <u>sales@sterile.com</u> or visit our website at <u>www.sterile.com</u>. Patents: <u>www.sterile.com/patents</u>