VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

STERI-SILICON®

Silicon Lubricant and Releasing Spray
Sterile Cleanroom Formula

Product Description

VAI manufactures a sterile silicon lubricant and releasing spray that is processed to comply with the standards required by pharmaceutical, biotechnology, medical device, and healthcare industries. **STERI-SILICON®** has been developed for use as a sterile silicon lubricant in aseptic manufacturing areas and cleanrooms to speed up operations in heat sealing, packaging, and general processing. **STERI-SILICON** is an excellent choice for machinery lubrication which is essential for trouble free equipment operations during manufacturing of products, for stopping squeaks, to release sticking objects, and for protecting and prolonging machinery life. **STERI-SILICON** is colorless with excellent thermal stability and is inert.

STERI-SILICON is filled in ISO 5 (Grade A/B, former Class 100), filtered, and subsequently terminally sterilized to 10^{-6} sterility assurance level. Each lot of **STERI-SILICON** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **STERI-SILICON** is delivered each time with a lot specific Certificate of Conformance, Certificate of Sterility, and Certificate of Irradiation.

STERI-SICLION is available in an 8 oz aerosol. This high quality, carbon dioxide propelled, aerosol spray can precipitates in a broad spray/mist without aspiration of the room's air during use. Non-aspiration ensures that the master reservoir of **STERI-SILICON** remains sterile from the first drop to the last drop. Included with each can of **STERI-SILICON** is one nozzle extension that allow operators to use in hard to reach places or on intricate mechanical parts. Each sterile container of **STERI-SILICON** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

STERI-SILICON – Silicon Lubricant and Releasing Spray	
Certificate of Conformance	**Specifications**
Density:	0.7619 – 0.8489 g/cc
Refractive Index:	1.4148 – 1.4610
Color:	Clear/ Water White Liquid
Odor:	Mild or Bland Petroleum Distillate
Irradiation Specified Dose (kGy)	Min: 25.0, Max: 50.0
Expiration Period:	3 years

Features and Benefits

Nozzle Extension

- Each sterile container is double bagged packaged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Conformance, Certificate of Sterility, and Certificate of Irradiation
- Available in an 8 oz aerosol that will not aspirate the room's air
- Delivered with one unattached nozzle extension per bottle for use in hard to reach areas or when lubricating intricate machinery and equipment parts
- Specifically formulated as a sterile cleanroom formula
- Allows for trouble free processing during manufacturing
- Speeds up operations and prevents objects from sticking
- Protects and prolongs life of equipment
- Colorless, has excellent thermal stability, and is inert

Uses

- Spray on parts to stop squeaks
- Lubricate moving parts, machinery, and equipment for trouble free operations
- Speed up heat sealing, packaging, and processing
- Release sticking objects
- Use on chains, rollers, delivery chutes, hinges, latches, belts, rubber moldings, and drawers

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.

Ordering Information

STERI-SILICON – Silicon Lubricant and Releasing Spray		
Part Number	**Description**	**Qty/cs.**
SSIL-02	STERI-SILICON, 8 oz Aerosol Spray/Mist, Unattached Nozzle Extension, Sterile	24

SSIL-02

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	WHITE		
DECON-AHOL WFI FORMULA 91%	WHITE	WHITE		
DECON-AHOL FORMULA 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		

PRODUCT LABELING

STERI-SILICON®
Silicon Lubricant and Releasing Spray

(Any specific product label is available upon request.)

STERI-SILICON

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

STERI-SILICON®

Sterile Cleanroom Formula

ACTIVE INGREDIENTS:
Aliphatic Hydrocarbons (CAS# 64742-47-8)
Polydimethylsiloxane (CAS# 63148-62-9)
Carbon Dioxide (CAS# 124-38-9)

KEEP OUT OF THE REACH OF CHILDREN

Contents under pressure. Store in a cool, well ventilated area, out of sunlight. Eliminate sources of ignition. Do not store, incinerate, or heat material above 120°F (49°C).

Non-flammable, Cleans Polishes and Protects.

Lubricates, Waterproofs, Resists rust and corrosion.

Net Contents: 8 oz (237 mL)
SDS Number: SIL-01112
Reorder Number: SSIL-02

Container and Product Sterilized and Distributed by:

Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355-1234 USA
Tel: 1-610-644-8335
Fax: 1-610-644-8336
www.sterile.com
In Canada: Distributed By:
Canada Clean Room (CCR) www.ccrkanata.com

Made in USA, Lubricant, For Industrial Use Only

FIRST AID

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.

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

For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada in English, French, and Spanish (and 23 other languages), call CARCHEM24 toll free at 866-928-0789.

Recommendations for Use

Use only as directed. Use in well ventilated area. Shake before using. Do not use on pots, pans, or eating utensils.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Product Validation
- In-use Validation Report
- Safety Data Sheet # SIL-01112
- Sample lot specific documentation packages including Certificates of Sterility, Certificate of Irradiation, and Certificate of Conformance

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 unitdose 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.

Patents: www.sterile.com/patents