



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



STERI-SILICON®

Silicon Lubricant and Releasing Spray
Sterile Cleanroom Formula

24MAY2024

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Veltek Associates, Inc.

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Product Overview

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 an ISO 7 cleanroom (Grade B), 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 with lot specific analytical, irradiation, conformance, and sterility data, tested to current USP compendium.

STERI-SILICON 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 7 cleanroom (Grade B)
- 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

Features and Benefits

- 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 analytical, irradiation, conformance, and sterility data, tested to current USP compendium
- 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

Product 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.



Chemical Specifications

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	5 years

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

Labeling

VAI's Product Labeling Colors

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 (Continued)**STERI-SILICON®***Sterile Pharmaceutical Cleanroom Formula*

Lubricates, Waterproofs, Resists rust and corrosion
Cleans, Polishes and Protects

**DANGER****Net Contents:**

Vol: 8 fl. oz. (237 mL) x 24 [Total: 1.5 Gallons (5.7 L)]

Wt: 7.41 oz. (210g) x 24 [11.1lbs (5.0kg)]

Reorder # SSIL-02

Label # SSIL-00 • Sterile • Rev 02/24

Patents: www.sterile.com/patents

Manufactured By:

Veltek Associates, Inc.

15 Lee Boulevard

Malvern, PA 19355-1234 USA

Tel: 610-644-8335

www.sterile.com

Made in USA

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Product Labeling (Continued)

STERILE PHARMACEUTICAL CLEANROOM FORMULA

INGREDIENTS:

Distillates (petroleum), hydrotreated light paraffinic (CAS # 64742-47-8).....75.0%
Carbon Dioxide (CAS # 124-38-9).....1.0%

DANGER Flammable aerosol. Pressurised container: May burst if heated. May be fatal if swallowed and enters airways. Causes skin irritation. May cause drowsiness or dizziness. May displace oxygen and cause rapid suffocation. Toxic to aquatic life with long lasting effects.

PRECAUTIONS FOR USE:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F. **IF SWALLOWED:** Immediately call a doctor. Do **NOT** induce vomiting.

In USA - For more ingredient information visit www.sterile.com

See container for lot #/Expiration Date/Red irradiation indicator

See Safety Data Sheet for first aid and additional product information.

Emergency Number: 1-866-928-0789 (toll free USA), 1-800-579-7421 (toll free Canada), 1-215-207-0061 (Americas), +44 1235 239670 (Europe), +44 1235 239671 (Middle East/Africa), +353 (0)1 809 2166 (Ireland, available to the public 08.00–22.00), 000 800 100 7479 (Hindi)

For Industrial Use Only



*STERI-SILICON
8 oz Aerosol Spray/Mist, Unattached Nozzle Extension, Sterile
SSIL-02*

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Additional Documentation

Upon request, the following additional documentation is available:

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



VAI's SCMD Family of Products

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 sales@sterile.com or visit our website at www.sterile.com. Patents: www.sterile.com/patents

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