



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



STERI-OIL[®] 200

Sterile Mineral Oil Lubricant
Sterile Cleanroom Formula



Product Description

VAI manufactures a sterile, USP grade, penetrating mineral oil lubricant that is processed to comply with the standards required by pharmaceutical, biotechnology, medical device, and healthcare industries. **STERI-OIL® 200** has been developed for use as a sterile lubricant in aseptic manufacturing areas and cleanrooms to reduce items from sticking, penetrate and lubricate mechanisms, and for moisture displacement. **STERI-OIL 200's** heavy consistency provides lubrication, prevents metal-to-metal contact, can withstand high friction without displacement, and reduces metal fatigue. **STERI-OIL 200** is ideal for machinery lubrication, which is an essential step for trouble free equipment operation during manufacturing.

STERI-OIL 200 is filled in ISO 5 (Grade A/B, former Class 100), filtered at 0.2 microns, and subsequently terminally sterilized to 10^{-6} sterility assurance level. Each lot of **STERI-OIL 200** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **STERI-OIL 200** is delivered each time with a lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

STERI-OIL 200 is available in a 1 oz dropper squeeze bottle that has been designed to prevent over application and for ease of use. The dropper function enables **STERI-OIL 200** to be an excellent choice for use where precise lubricant application is required and on intricate machinery parts. Each sterile container of **STERI-OIL 200** 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 at 0.2 microns
- 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-OIL 200 – Sterile Mineral Oil Lubricant	
Certificate of Analysis	Specifications
Appearance:	Bright & Clear
Viscosity, Kin @ 40°C:	64.50 – 69.70
Odor:	None
Viscosity, Saybolt @ 100°F:	340.0 – 360.0 SUS
Specific Gravity:	0.869 – 0.885
Saybolt Color:	<= 30
Expiration Period:	3 years

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 Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation
- Available in an 1 oz bottle with a dropper tip for precise application
- Bottle design prevents over use and over application
- Bottle is easy to use and easy to squeeze
- Heavy consistency ensures excellent lubrication and penetration
- Withstands high friction without displacement
- Reduces metal fatigue
- Allows for trouble free processing during manufacturing
- Specifically formulated as a sterile cleanroom formula
- 100% mineral oil

Uses

- Lubricate moving parts, machinery, and equipment for trouble free operations
- Penetrate mechanisms
- Prevent metal-to-metal contact and reduce metal fatigue
- Moisture displacement
- Reduce items from sticking
- On intricate machinery parts or where precise lubrication application is required

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-OIL 200 – Sterile Mineral Oil Lubricant		
Part Number	Description	Qty/cs.
SO200-A1Z	STERI-OIL 200, 1 oz Dropper, Sterile	250



SO200-A1Z



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		
HYP0-CHLOR 0.25%	WHITE	WHITE		
HYP0-CHLOR 0.52%	WHITE	WHITE		
HYP0-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-OIL® 200 Silicon Lubricant and Releasing Spray

(Any specific product label is available upon request.)



STERI-OIL 200

Veltek Associates, Inc.

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

DECON Rev: 28Sep2017

STERI-OIL® 200

Sterile Cleanroom Formula

ACTIVE INGREDIENTS:

White Mineral Oil (CAS#

Net Contents: 1 oz (29.6 mL)

Quan/Case: 250 x 1 oz (29.6 mL)

SDS Number: 2002-SO-01

Reorder Number: SO200-A1Z

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

Veltek Associates, Inc.
Postbus 1062
8200 BB Lelystad, Nederland
Tel: +800-00888700
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 call CARECHEM24 at 866-928-0789. For Spill/Exposure Emergency Response Service from Europe call 44 1235 239 670. For Arabic call 44 1235 239 671.



STERI-OIL 200 Dropper

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Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet # 2002-SO-01
- Product Validation
- Sample lot specific documentation packages including Certificates of Sterility, Certificate of Irradiation, and Certificate of Analysis



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

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