



PRODUCT INFORMATION LEAFLET



STERI-OIL^{®md} 200

STERILE LUBRICATING MINERAL OIL PHARMACEUTICAL CLEAN ROOM FORMULA

Veltek Associates, Inc.

In USA: 15 Lee Boulevard • Malvern, PA 19355-1234 • Tel: (610) 644-8335

In the EU: Postbus 1062, 8200 BB Lelystad, Nederland, +800 00888700

Fax: (610) 644-8336 • E-mail: vai@sterile.com • 07 Nov 2014



PRODUCT DESCRIPTION

STERI-OIL 200 is sterile USP mineral oil for use as a lubricant within aseptic manufacturing areas. The use of a sterile lubricant is important to prevent contamination in environmentally controlled areas.

STERI-OIL 200:

- Contributes to machine life
- Provides lubrication
- Prevents metal to metal contact
- Withstands high friction without displacement
- Reduces metal fatigue
- Reduces items from sticking
- Penetrates and lubricates mechanisms
- Can be used for moisture displacement
- Brightens and polishes
- Contains no acids or abrasives

QUALITY AND MANUFACTURING

- Filled in ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 micron
- 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

INGREDIENTS

White Mineral Oil – Food Grade (Aliphatic - paraffinic and naphthenic hydrocarbons CAS#8042-47-5).....100%

PACKAGE SIZE

1 Ounce Squeeze Bottle

PRODUCT USES

STERI OIL 200 may be used in clean rooms and controlled areas such as those in health care institutions, laboratories, biopharmaceutical, pharmaceutical, medical device, and diagnostic manufacturing facilities. This product may be used on non-food contact, non-porous, inanimate, hard surfaces in areas such as aseptic filling and gowning rooms, general manufacturing areas, and laboratories. It is compatible with most hard surface materials such as stainless steel, chrome, brass, copper, aluminum, other metals, laminate, plastic, and glass.

STERI-OIL 200 can be used on moving parts such as hinges, wheels, turntables, and machinery. It can also be used on shelves, carts, metal trim, wall panels, floor panels, doors, tools, tables, counters, and laminar-flow benches.

LOT SPECIFIC DOCUMENTATION

STERI-OIL 200 is aseptically filtered, double bag packaged, and sterilized by gamma irradiation. It is delivered with the following lot specific documentation:

- Certificate of Analysis
- Certificate of Sterility
- Certificate of Irradiation

For a sample of this documentation or for other **technical data supplements** such as Product TDR, Validation Report, or Specific Test Reports, please contact VAI.

CONTACT VAI

For Sales and Service, please contact VAI toll free:

In USA: 888-478-3745

In EU: +800 00888700

Or visit us on the web at www.sterile.com

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PRECAUTIONARY STATEMENTS

- **Keep Out Of Reach Of Children**
- Do not get on skin or in eyes.
- Product is irritating to eyes and respiratory tract.
- Do not take internally
- Not for personal use.
- Not for use on or around food or food utensils.
- Do not inhale vapor/mist.
- Use good industrial hygiene practices in handling this material.
- Wash thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Avoid release to the environment.
- May be fatal if swallowed and enters airways.
- Causes mild skin irritation.
- Causes moderate eye irritation.

Physical And Chemical Hazards:

This product may be irritating to the eyes, skin, gastrointestinal tract, and respiratory system. If ingested, product can act as a laxative. If swallowed, material can be aspirated into lungs. Inhalation of mist or vapor may cause aspiration pneumonia.

Flammable: Flash point 168.3°C. Keep away from heat and flame. Negligible fire hazard at lower temperatures.

Fire Extinguishing Media: Dry chemical, alcohol-resistant foam, carbon dioxide, water fog.

PERSONAL PROTECTIVE EQUIPMENT

Eyes/Face: Wear safety glasses or goggles.

Skin: Suitable work clothes to cover exposed skin.

Hands: Chemical resistant gloves.

Respiratory Protection: In case of inadequate ventilation wear respiratory protection for oils.

DIRECTIONS FOR USE

Read the label and leaflet before using.

The use of this product on sterile surfaces in aseptic controlled areas should always be done by trained individuals using good aseptic technique and sterilized cloths or wipes. In non-sterile areas, clean non-sterile materials may be used for application and removal.

1. Pre-clean and dry surface or item to remove heavy soil before application.
2. Apply STERI-OIL 200 to surface by drops or by using a cloth or wipe.
3. Wipe lightly to lubricate surface and allow parts or components to move freely.
4. If desired, polish surface to a smooth clear film.
5. Wipe off excess.
6. Re-cap original container securely.

FIRST AID

Eyes: Immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists, get medical attention.

Inhalation: Immediately remove the affected person to fresh air. Call a physician if symptoms develop or persist. Give artificial respiration if not breathing. Call a physician immediately.

Skin: Flush with large amounts of water. Wash with soap and water. Wash contaminated clothing before reuse. If irritation persists, get medical attention.

If Swallowed: Get immediate medical attention or advice. **Do not induce vomiting.** If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration.

SAFETY HAZARD INFORMATION

For a complete summary of the chemical and physical safety and exposure hazards to users, see **Safety Data Sheet VEL-2002-SO-01-EU**. A copy of the SDS was shipped with this product. If an additional copy is needed contact VAI USA Customer Service or download it from the website www.sterile.com. If an immediate copy is needed outside business hours, call the Emergency Response Service listed below.

For spill/exposure emergency response service in English and EU languages- telephone CARECHEM24 toll free in USA and Canada: 866 -928-0789, or in EU: +44 1235 239 670, for Arabic language +44 1235 239 671.

GHS Substance/Preparation Classification according to EC Regulation No. 1272/2008:
Not Classified.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Keep out of reach of children.

Storage: Keep the container tightly closed and in a cool, well-ventilated place. Eliminate all sources of ignition and heat. Keep container tightly closed. Store in the original container.

Disposal: Improper disposal of excess product is a violation of Laws. Dispose of unused contents and container in accordance with local regional national or international regulations. Never place unused product down any indoor or outdoor drain.

Container Handling: Non-refillable container. Do not reuse or refill this container. Offer for recycling, or dispose of in a sanitary landfill.

CHEMICAL COMPATIBILITY

Chemical Stability: Stable.

Conditions to Avoid: Keep away from heat, ignition sources and incompatible materials.

Incompatibility: Strong oxidizers.

Hazardous Decomposition: Oxides of carbon.

Hazardous Polymerization: Will not occur.

ENVIRONMENTAL EXPOSURE CONTROLS

Environmental Precautions: Avoid dispersal of spilled material, runoff and contact with soil, waterways, drains, and sewers. Do not allow the spilled product to enter public drainage system or open water courses.

Persistence & Degradation: Product is expected to degrade in a matter of days to weeks.

Bioaccumulative Potential: Product is not expected to bioaccumulate.

Containment Procedures: Stop the flow of material, if this is without risk. Block any potential routes to water systems with dikes or absorbents. Remove sources of ignition.

Clean-Up Procedures: Ventilate the contaminated area. Wear appropriate protective equipment and clothing during clean-up. Absorb with an inert material and shoveled into an appropriate container for disposal.

Evacuation Procedures: Isolate area. Surface may become slippery. Treat with inert material such as sand. Keep unnecessary personnel away.

Document translation to foreign language available upon request.

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