

**Safety Data Sheet (SDS)**

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 03/14/2024

Reviewed on 03/02/2024

**1 Identification**

- **Product Identifier**
- **Trade Name:** Surgilube®
- **Product Number:**  
0281-0205-12; 0281-0205-36; 0281-0205-37; 0281-0205-43; 0281-0205-45; 0281-0205-55; 0281-0205-02;  
0281-0205-57
- **Relevant identified uses of the substance or mixture and uses advised against:** Medical Device
- **Product Description:** Topical Gel
- **Details of the Supplier of the Safety Data Sheet:**
- **Manufacturer/Supplier:**  
HR HealthCare  
2600 Eastern Blvd.  
Suite 201  
York, PA 17402  
Phone: 877-302-1110  
Fax: 717-685-2590  
www.hrhealthcare.com
- **Emergency telephone number:** (717) 252-1110

**2 Hazard(s) Identification**

- **Classification of the substance or mixture:**



Skin Irritation 2 H315 Causes skin irritation.

Eye Irritation 2B H320 Causes eye irritation.

- **Label elements:**
- **Hazard pictograms:**



- **Signal word:** Warning
- **Hazard statements:**  
H315+H320 Causes skin and eye irritation.
- **Precautionary statements:**

P264+P265	Wash thoroughly after handling. Do not touch eyes.
P280	Wear protective gloves.
P302+P352	If on skin: Wash with plenty of water.
P321	Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P337+P317	If eye irritation persists: Get medical help.
- **Unknown acute toxicity:**  
This value refers to knowledge of known, established toxicological or ecotoxicological values.  
0 % of the mixture consists of component(s) of unknown toxicity.
- **Classification system:** NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

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**Trade Name: Surgilube®****· NFPA ratings (scale 0 - 4)****· HMIS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Physical Hazard = 0

**· Hazard(s) not otherwise classified (HNOC):** None known**3 Composition/Information on Ingredients****· Non-hazardous components:**

7732-18-5	Water, distilled water, deionized water	Proprietary%
9004-65-3	Hydroxypropyl Methylcellulose	Proprietary%

**· Chemical characterization: Substance****· Description:** Mixture of substances listed below with non-hazardous additions.**· Dangerous Components:**

CAS: 57-55-6	Propylene Glycol	Proprietary%
RTECS: TY 2000000		

**· Additional information:**

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

**4 First-Aid Measures****· Description of first aid measures****· General information:** If symptoms persist, call a physician.**· After inhalation:**

If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

**· After skin contact:** If skin irritation occurs, consult a doctor.**· After eye contact:**

If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

**· After swallowing:**

If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

**· Information for doctor****· Most important symptoms and effects, both acute and delayed:** No further relevant information available.**· Indication of any immediate medical attention and special treatment needed:** Treat symptomatically.**5 Fire-Fighting Measures****· Extinguishing media****· Suitable extinguishing agents:** Use fire fighting measures that suit the environment.

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- **For safety reasons unsuitable extinguishing agents:** No further relevant information.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters**
- **Special protective equipment for firefighters:**  
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

**6 Accidental Release Measures**

- **Personal precautions, protective equipment and emergency procedures:**  
Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product. Spills may be slippery.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust). Dispose of the collected material according to regulations.
- **Reference to other sections:**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

· <b>PAC-1:</b>		
57-55-6	Propylene Glycol	30 mg/m <sup>3</sup>
· <b>PAC-2:</b>		
57-55-6	Propylene Glycol	1,300 mg/m <sup>3</sup>
· <b>PAC-3:</b>		
57-55-6	Propylene Glycol	7,900 mg/m <sup>3</sup>

**7 Handling and Storage**

- **Handling**
- **Precautions for safe handling:**  
All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**  
Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F) [USP Controlled Room Temperature]. Protect from freezing. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s):** No further relevant information available.

**\* 8 Exposure Controls/Personal Protection**

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**

· <b>Components with occupational exposure limits:</b>
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**57-55-6 Propylene Glycol**

WEEL	Long-term value: 10 mg/m <sup>3</sup>
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- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
- **Exposure controls:**
- **Personal protective equipment**
- **General protective and hygienic measures:**  
The usual precautionary measures for handling chemicals should be followed.  
Wash hands before breaks and at the end of work.
- **Breathing equipment:**  
Exposure should be avoided by use of proper ventilation. Where exposure is likely to be prolonged or is unknown, wear approved respiratory protection. Confirmation of which respirator is most suitable for the intended application should be obtained from the respiratory protection supplier.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

- **Material of gloves:**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material:**  
The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.
- **Eye protection:**



Goggles recommended during refilling.

- **Limitation and supervision of exposure into the environment:** None

**\* 9 Physical and Chemical Properties**

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

<b>Form:</b>	Gel
<b>Color:</b>	Translucent

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- **Odor:** Slight lavender
- **Odor threshold:** Not determined.
- **pH-value @ 20 °C (68 °F):** 4-7
- **Change in condition**
  - Melting point/Melting range:** Not determined.
  - Boiling point/Boiling range:** 100 °C (212 °F)
- **Flash point:** None
- **Flammability (solid, gaseous):** Not applicable.
- **Auto igniting:** Not applicable.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not self-igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
  - Lower:** Not determined.
  - Upper:** Not determined.
- **Vapor pressure @ 20 °C (68 °F):** ≤23 hPa (≤17.3 mm Hg)
- **Density @ 20 °C (68 °F):** 1 g/cm<sup>3</sup> (8.345 lbs/gal)
- **Relative density:** Not determined.
- **Vapor density:** Not determined.
- **Evaporation rate:** Not determined.
- **Solubility in / Miscibility with:**
  - Water:** Fully miscible.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic:** Not determined.
  - Kinematic:** Not determined.
- **Other information:** No further relevant information available.

**10 Stability and Reactivity**

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Product is stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Avoid heat, light, and contact with incompatible chemicals.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**  
If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides).

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**Trade Name: Surgilube®****\* 11 Toxicological Information**

- **Information on toxicological effects:**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

**57-55-6 Propylene Glycol**

Oral	LD50	20,000 mg/kg (Rat)
Dermal	LD50	20,800 mg/kg (rabbit)
Inhalative	LC50/96 hours	52,930 mg/l (Pimephales)
	Intravenous	6,630 mg/kg (mouse)
		6,423 mg/kg (Rat)
		6,500 mg/kg (rabbit)

- **Primary irritant effect:**
- **On the skin:** No irritating effect.
- **On the eye:** Irritating effect.
- **Additional toxicological information:**
- **Carcinogenic categories:**

- **IARC (International Agency for Research on Cancer):**

None of the ingredients are listed.

- **NTP (National Toxicology Program):**

None of the ingredients are listed.

- **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

**12 Ecological Information**

- **Toxicity:**

- **Aquatic toxicity:**

**57-55-6 Propylene Glycol**

EC50 &gt;10,000 mg/l (Daphnia)

- **Persistence and degradability:** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **Results of PBT and vPvB assessment:**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

**13 Disposal Considerations**

- **Waste treatment methods**
- **Recommendation:**  
Observe all federal, state and local environmental regulations when disposing of this material.

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Name: Surgilube®

- **Uncleaned packaging**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**14 Transport Information**

- **UN-Number:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material.
- **UN proper shipping name:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material.
- **Transport hazard class(es):**
- **DOT, ADR/ADN, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material.
- **Packing group:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material.
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material.

**15 Regulatory Information**

· **Safety, health and environmental regulations/legislation specific for the substance or mixture:**

No further relevant information available.

· **SARA (Superfund Amendments and Reauthorization):**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

· **Hazardous Air Pollutants**

None of the ingredients are listed.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

· **New Jersey Right-to-Know List:**

57-55-6 Propylene Glycol

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**Name: Surgilube®****· New Jersey Special Hazardous Substance List:**

None of the ingredients are listed.

**· Pennsylvania Right-to-Know List:**

57-55-6 Propylene Glycol

**· Pennsylvania Special Hazardous Substance List:**

None of the ingredients are listed.

**· Carcinogenic categories:****· EPA (Environmental Protection Agency):**

None of the ingredients are listed.

**· TLV (Threshold Limit Value established by ACGIH):**

None of the ingredients are listed.

**· NIOSH-Ca (National Institute for Occupational Safety and Health):**

None of the ingredients are listed.

**· GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

**· Hazard pictograms:****· Signal word:** Warning**· Hazard statements:**

H315+H320 Causes skin and eye irritation.

**· Precautionary statements:**

P264+P265 Wash thoroughly after handling. Do not touch eyes.

P280 Wear protective gloves.

P302+P352 If on skin: Wash with plenty of water.

P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before reuse.

P337+P317 If eye irritation persists: Get medical help.

**· National regulations:**

The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.

**· Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**16 Other Information**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

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**Trade Name: Surgilube®****Contact:****Abbreviations and acronyms:**

- ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
- ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- NFPA: National Fire Protection Association (USA)
- HMIS: Hazardous Materials Identification System (USA)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: National Institute for Occupational Safety and Health
- OSHA: Occupational Safety & Health Administration
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Skin Irritation 2: Skin corrosion/irritation – Category 2
- Eye Irritation 2B: Serious eye damage/eye irritation – Category 2B

**\* Data compared to the previous version altered.**SDS created by MSDS Authoring Services [www.msdsauthoring.com](http://www.msdsauthoring.com) +1-877-204-9106