SAFETY DATA SHEET

PART I  What is the material and what do I need to know in an emergency?

 TRADE NAME/MATERIAL NAME: SurgiLube

DESCRIPTION:
Surgical Lubricant

NDC #:
0168-0205-12; 0168-0205-36; 0168-0205-37; 0168-0205-43; 0168-0205-45; 0168-0205-55

CHEMICAL FAMILY:
Propylene Glycol Mixture

HOW SUPPLIED:
Topical Gel

FORMULA:
Mixture

RELEVANT USE of the SUBSTANCE:
Pharmaceutical for Human Use

USES ADVISED AGAINST:
Other than Relevant Use

SUPPLIER/ MANUFACTURER’S NAME:
FOUGERA PHARMACEUTICALS, INC.

ADDRESS:
60 Baylis Road
Melville, NY 11747

BUSINESS PHONE/ GENERAL SDS INFORMATION:
1-631-454-7677

EMERGENCY PHONE (U.S./ Canada/ Puerto Rico): CHEMTEL: (U.S, Canada) 1(800) 255-3924 (24 hrs)
(International) +1 813 248 0585 (24 hrs)

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.


EMERGENCY OVERVIEW: Product Description: This product is a smooth, translucent gel with a slight lavender odor. Health Hazards: This product present minimal hazards in the workplace. Accidental ingestion may cause stomach upset or diarrhea. Eye contact may cause irritation. Prolonged skin contact may cause mild irritation. Flammability Hazards: If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, if necessary. Remove victim(s) to fresh air, as quickly as possible. Take copy of product label and SDS to physician or other health professional with victim(s). Reactivity Hazards: This product is not reactive. Environmental Hazards: This product has not been tested for environmental effects. Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>% w/w</th>
<th>LABEL ELEMENTS</th>
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<td>200-338-0</td>
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<tr>
<td>Water and other trace components of less than 1% concentration</td>
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<td>EU 67/548: Classification: Not applicable.</td>
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<tr>
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<td></td>
<td>GHS &amp; EU 1272/2008: Classification: Not applicable.</td>
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</tbody>
</table>

See Section 16 for full classification information of product and components.

PART II  What should I do if a hazardous situation occurs?

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: Rescuers should wear adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, if necessary. Remove victim(s) to fresh air, as quickly as possible. Take copy of product label and SDS to physician or other health professional with victim(s).

Skin Exposure: If adverse skin effects occur, discontinue use. Seek medical attention.

Eye Exposure: 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.
DESCRIPTION OF FIRST AID MEASURES (continued):

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

Ingestion: 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.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated exposure to this product.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.
AUTOIGNITION TEMPERATURE: Not applicable.
FLAMMABLE LIMITS (in air by volume, %): Not applicable.
FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.
SPECIAL HAZARDS ARISING FROM THE PRODUCT: This product contains potential skin and/or respiratory sensitizers and so presents a contact hazard to firefighters. If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides).

Explosion Sensitivity to Mechanical Impact or to Static Discharge: Not sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

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.

PROTECTIVE EQUIPMENT:
Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.
Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:
Small Spills: The product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.
Large Spills: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. Restrict access to the spill areas. For spills of amounts larger than 5 ml limit spread by gently covering with absorbent sheets, or spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.
All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.
7. HANDLING and USE

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.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

CONDITIONS FOR SAFE STORAGE: 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.

SPECIFIC END USE(S): This product is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat. Wipe equipment down with damp sponge or polypad. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water. Collect all rinsates and dispose of according to applicable waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Workplace Exposure Limits/Control Parameters:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>ACGIH-TLVs</th>
<th>OSHA-PELs</th>
<th>NIOSH-RELs</th>
<th>NIOSH</th>
<th>OTHER</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
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<tr>
<td>Hypromellose</td>
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<td>15 (total dust), 5 (resp. fract.)</td>
<td>NE</td>
<td>10 (total dust), 5 (resp. fract.)</td>
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<td>57-55-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
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NE = Not Established  See Section 16 for Definitions of Terms Used.

International Occupational Exposure Limits: Exposure limits available for some excipient components are given below.

HYPROMELLOSE:
- Russia: STEL = 10 mg/m³, JUN 2003
- New Zealand: TWA = 150 ppm (total dust), JUN 2005

PROPYLENE GLYCOL:
- Australia: TWA = 10 mg/m³ (particulates), JUL 2008
- Russia: STEL = 7 mg/m³, JUN 2003
- United Kingdom: TWA = 10 mg/m³ (particulate), 2005

PROPYLENE GLYCOL (continued):
- New Zealand: TWA = 10 mg/m³ (particulates only), JAN 2002
- New Zealand: TWA = 150 ppm (474 mg/m³) (vapor and particulates), JAN 2002
- United Kingdom: TWA = 10 mg/m³ (particulate), 2005


Respiratory Protection: Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.
8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PROTECTIVE EQUIPMENT (continued):
Skin Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Smooth gel.
MOLECULAR WEIGHT: Mixture.
ODOR: Slight lavender.
BOILING POINT: 100°C (212°F)
EVAPORATION RATE (Ether = 1): 0.02
VAPOR PRESSURE (air = 1): Not established.
FLASH POINT: Not available.
SOLUBILITY IN WATER: Soluble.
COLOR: Translucent.
MOLECULAR FORMULA: Mixture.
ODOR THRESHOLD: Not established.
FREEZING/MELTING POINT: Not established.
SPECIFIC GRAVITY @ 20°C (water = 1): 1.0
AUTOIGNITION TEMPERATURE: Not known.
OTHER SOLUBILITIES: Not known.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product can be a distinguishing characteristic to identify it in event of accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.
DECOMPOSITION PRODUCTS: Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides). Hydrolysis: None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.
POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

PART IV Is there any other useful information about this material?

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.
Inhalation: Although unlikely, due to form of product, inhalation of mist or sprays may mildly irritate the mucous membranes and upper respiratory tract. Symptoms are generally alleviated upon breathing fresh air.
Contact with Skin or Eyes: Skin contact may cause mild irritation, which is alleviated upon rinsing with soap and water. Eye contact may cause irritation, stinging, redness, and tearing.
Skin Absorption: Components of this product are not known to be absorbed via intact skin.
Ingestion: Ingestion is not a significant route of occupational exposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion exposure may include stomach upset, vomiting, and diarrhea.
Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may include those described for “Other Potential Health Effects”.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:
Acute: Accidental ingestion may cause digestive upset. Although unlikely, ingestion may irritate the respiratory system. Eye contact may cause irritation.
Chronic: None known.

TARGET ORGANS:
Acute: Occupational Exposure: Skin, eyes. Therapeutic Doses: Skin.
Chronic: Occupational Exposure: Skin. Therapeutic Doses: None known.

IRRITANT OF PRODUCT: This product may mildly to moderately irritate contaminated tissue if contact is prolonged.
SENSITIZATION OF PRODUCT: No component of this product is known to cause skin sensitization.

TOXICITY DATA: The following toxicity data available for components of this product.

HYPERMELLOSE:
LD₅₀ (Oral-Mammal-Species Unspecified) > 10,000 mg/kg
LD₅₀ (Intraperitoneal-Rat) 5200 mg/kg
TDLo (Oral-Rat) 2250 gm/kg/30 days-continuous: Gastrointestinal: hypermotility, diarrhea; Related to Chronic Data: death
11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

HYPMELLOSE (continued):
TCLo (Inhalation-Mammal-Species Unspecified) 86 mg/m³: Liver: liver function tests impaired; Kidney/Ureter/Bladder: renal function tests depressed; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases
TTC (Inhalation-Mammal-Species Unspecified) 86 mg/m³: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

PROPYLENE GLYCOL (continued):
LD₅₀ (Subcutaneous-Rat) 28,000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₅₀ (Subcutaneous-Mouse) 17,370 mg/kg: Behavioral: changes in motor activity (specific assay), muscle contraction or spasticity; Lungs, Thorax, or Respiration: cyanosis
LD₅₀ (Subcutaneous-Mouse) 17,400 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Intravenous-Rat) 6800 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Intravenous-Mouse) 8433 mg/kg
LD₃₀ (Subcutaneous-Mouse) 8000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Intravenous-Mouse) 6630 mg/kg
LD₃₀ (Intravenous-Dog) 26 mg/kg
LD₃₀ (Intravenous-Rabbit) 6500 mg/kg
LD₃₀ (Intramuscular-Rat) 14 gm/kg
LD₃₀ (Intramuscular-Mouse) 20,000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Oral-Rabbit) 20,000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Oral-Mammal) 6630 mg/kg: Behavioral: somnolence (general depressed activity), coma; Lungs, Thorax, or Respiration: respiratory stimulation
LD₃₀ (Subcutaneous-Guinea Pig) 15,500 mg/kg
LD₃₀ (Subcutaneous-Guinea Pig) 15,500 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Intravenous-Chicken) 27 gm/kg: Vascular: other changes
LD₃₀ (Intravenous-Rabbit) 4200 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Intramuscular-Mouse) 6300 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Intravenous-Dog) 6300 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Dog) 3650 mg/kg/2 years
LD₃₀ (Mouse) 1,284,800 mg/kg/2 years-intertempest: Skin and Appendages: tumors
LD₃₀ (Intraperitoneal-Rat) 19,500 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LD₃₀ (Intraperitoneal-Mouse) 100 mg/kg: female 11 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)
LD₃₀ (Intraperitoneal-Mouse) 100 mg/kg: female 15 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)
LD₃₀ (Inhalation-Rat) 2180 mg/m³/6 hours/90 days-intertempest: Behavioral: food intake (animal); Endocrine: changes in spleen weight; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: dehydrogenases
DNA inhibition (Subcutaneous-Mouse) 8000 mg/kg
Cytogenetic Analysis (Subcutaneous-Mouse) 8000 mg/kg
Cytogenetic Analysis (Hamster Fibroblast) 32 gm/L

CARCINOGENIC INFORMATION: No studies available for the product. The components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: No studies available on potential reproductive toxicity from this product. No positive human or animal data on mutagenicity, embryotoxicity, teratogenicity or reproductive toxicity for components is available.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, there are no ACGIH Biological Exposure Indices (BEIs) determined for components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for soil absorption or mobility. The following information is available for the Propylene Glycol component.

PROPYLENE GLYCOL: The Koc is estimated as 8, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests this compound is expected to have high mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. The following information is available for the Propylene Glycol component.

PROPYLENE GLYCOL: Based on a classification scheme, an estimated Koc value of 8 determined from a log Kow of -0.92 and a regression-derived equation, indicates that this material is expected to have very high mobility in soil. Volatilization of this compound from moist soil surfaces is not expected to be an important fate process given an estimated Henry’s Law constant of 1.3X10⁻⁸ atm·cu/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10⁻⁶ g/m³ that this compound is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Laboratory experiments using agricultural soils from South Carolina conducted at 22°C and a fortification of 1,000 ppm this compound, yielded 73-78% mineralization over a 51 day incubation period, suggesting that biodegradation will be an important fate process in soils.
PERSISTENCE AND BIODEGRADABILITY (continued):

PROPYLENE GLYCOL (continued): Based on a classification scheme, an estimated Koc value of 8, determined from a log Kow of -0.92 and a regression-derived equation, indicates that this compound is not expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is not expected based upon an estimated Henry’s Law constant of 1.3X10^-8 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10^-6 mg/L. Numerous screening studies using wastewater or sewage inoculum as seed, suggests that this material will be degraded readily under aqueous environments. According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, Propylene Glycol, which has a vapor pressure of 0.13 mmHg at 25°C, is expected to exist solely as a vapor in the ambient atmosphere. Vapor-phase material is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 32 hours, calculated from its rate constant of 1.2X10^-11 cu cm/molecule-sec at 25°C.

BIOACCUMULATION: This product has not been tested for bioconcentration. The following information is available for the Propylene Glycol component.

PROPYLENE GLYCOL: An estimated BCF of 3 was calculated, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

ECOTOXICITY: No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities. The following are aquatic toxicity data currently available for the Propylene Glycol component.

PROPYLENE GLYCOL:

**EC50** (Photobacterium phosphoreum, bacteria) 30 minutes = 26,800 mg/L
**EC50** (Daphnia magna, crustacea) 48 hours = 34,400 mg/L
**EC10** (Daphnia magna, crustacea) 48 hours = 50,000 mg/L
**EC50** (Daphnia magna, crustacea) 24 hours = > 10,000 mg/L
**EC10** (Daphnia magna, crustacea) 24 hours = > 10,000 mg/L
**EC50** (Nilemwa spinipes, crustacea) 96 hours = > 10,000 mg/L

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

OTHER ADVERSE EFFECTS: No component of this product is known to have ozone depletion potential.

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

DISPOSAL CONTAINERS: Waste materials must be in placed and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this product should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and is not specifically listed in Annex III under MARPOL 73/78.
15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:
U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.
U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.
U.S. CERCLA Reportable Quantities (RQ): Not applicable.
U.S. TSCA Inventory Status: This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component is listed on the California Proposition 65 lists.

CANADIAN REGULATIONS:
Canadian DSL/NDSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.
Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: The components of this product are not on the CEPA Priorities Substances Lists.
Other Canadian Regulations: Not applicable.
Canadian WHMIS Classification and Symbols: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

EUROPEAN REGULATIONS:
Safety, Health, and Environmental Regulations/Legislation Specific for the Product: Formulated, finished medicinal products for human use are subject to Directive 2001/83/EC and subsequent amendments to the directive.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE EYE IRRITATION. Avoid prolonged or repeated contact with skin and clothing. Avoid contact with eyes. Wash thoroughly after handling. Wear gloves, safety glasses, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting, seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO₂, or “alcohol” foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

CLASSIFICATION FOR COMPONENTS:
Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:
- All Components: No classification has been published or is applicable.

REFERENCE AND DATA SOURCES: Contact the supplier for information.
METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 808/441-3365 • 808/969-4846
DATE OF PRINTING: June 27, 2015

A large number of abbreviations and acronyms appear on a SDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.
CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.

DEFINITION OF TERMS
EXPOSURE LIMITS IN AIR (continued):
- DFG MAK Germ Cell Mutagen Categories (continued): 3A: Substances that have been shown to induce genetic damage in germ cells of human animals, or which produce mutagenic effects in somatic cells of mammals in vivo and have been shown to reach the germ cells in an active form. 3B: Substances that are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell in vivo; in exceptional cases, substances for which there are no in vivo data, but that are clearly mutagenic in vitro and structurally related to known in vivo mutagens. 4: Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply.

SUGRILUBE SDS
DEFINITION OF TERMS (Continued)
NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS

(continued):

DEFINITION OF TERMS (Continued):

FLAMMABILITY HAZARD (continued): 4 Materials that will rapidly or completely vaporize in air at or near normal ambient temperature or that are readily dispersed in air and will burn readily. Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F), or if it has a boiling point at or above 22.8°C (73°F). Any material that ignites in air when exposed to air. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

DEFINITION OF TERMS (Continued):

OC 50: Materials in which themselves are normally stable, even under fire conditions. Materials that are capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) or at above 0.01 W/mL and below 10 W/mL. 2 Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) or at above 10 W/mL and below 100W/mL. 3 Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but because of a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). Flash Point: Minimum temperature at which a liquid gives off sufficient vapor to form an ignitable mixture with air near the surface of the liquid, or within the test vessel used. Autoignition Point: Minimum temperature of a solid, liquid, or gas required to initiate or cause self-sustained combustion in air with no other source of ignition.UEL: Lowest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. Highest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies using similar compounds are presented. LD50: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC50: Lethal Concentration (gases) that kills 50% of the exposed animals. p(m): Concentration expressed in parts of material per million parts of air or water. ppm: Concentration expressed in weight of substance per volume of air. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TLD50: Lowest dose to cause a symptom. TCL50: Lowest concentration to cause a symptom. LEL: Lowest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. Highest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. NTP: National Toxicology Program. A elevation; 2 Other elevation; 3 Significant elevation; 4 Highest elevation.

REPRODUCTIVE TOXICITY INFORMATION:

A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the DNA of a cell will propagate errors that are inherited. A teratogen is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLM: Median threshold limit. log LC50 or log EC50: Coefficient of Oil/Water Distribution is used to describe a substance’s behavior in the environment.

REGULATORY INFORMATION:

U.S. and Canada:

This section explains the impact of various laws and regulations on the material. EPA: U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits. OSHA: U.S. Occupational Safety and Health Administration. NIOSH: National Institute of Occupational Safety and Health, which is the research arm of OSHA. WHMIS: Canadian Workplace Hazardous Materials Information System. DOT: U.S. Department of Transportation. TC: Transport Canada. SARA: Superfund Amendments and Reauthorization Act. DSL/NDSL: Canadian Domestic/Nondomestic Substances List. EPA: U.S. Environmental Protection Agency. RCRA: Resource Conservation, and Liability Act. Marine Pollutant status according to the DOT; CERCLA or Superfund; and various state regulations. This section also includes information on the precautionary warnings that appear on the material’s package label.

SURGILUBE SDS
<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 27, 2015</td>
<td>Change emergency telephone number to ChemTel.</td>
</tr>
<tr>
<td>May 20, 2015</td>
<td>Review and up-date as needed for most current format and regulations.</td>
</tr>
<tr>
<td>December 10, 2013</td>
<td>Up-date to include current GHS &amp; to add EU compliance.</td>
</tr>
<tr>
<td>October 3, 2012</td>
<td>New</td>
</tr>
</tbody>
</table>