MATERIAL SAFETY DATA SHEET
Prepared to U.S. OSHA, CMA, ANSI, and Canadian WHMIS Standards

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

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

| DESCRIPTION: | Surgical Lubricant |
| NDC #: | 0281-0205-02; 0281-0205-12; 0281-0205-36; 0281-0205-37; 0281-0205-43; 0281-0205-45; 0281-0205-55 |
| CHEMICAL NAME: | Not Applicable |
| CHEMICAL FAMILY: | Not Applicable |
| HOW SUPPLIED: | Topical Gel |
| FORMULA: | Not Applicable |
| PRODUCT USE: | Medical Device |
| SUPPLIER OF THE SAFETY DATA SHEET: | NYCOMED US INC. (Savage Labs Division) |
| ADDRESS: | 60 Baylis Road |
| BUSINESS PHONE/GENERAL MSDS INFORMATION: | +1-631-454-7677 |
| EMERGENCY PHONE (U.S./Canada/Puerto Rico): | 1-800-424-9300 (24-hr) |
| EMERGENCY PHONE (OUTSIDE U.S.): | +1-631-454-7677 |

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:  Product Description: This product is a smooth, translucent gel with a slight lavender odor. Health Hazards: The chief health hazard associated with exposure during normal use and handling is the potential for mild irritation of contaminated skin if skin contact is prolonged. Flammability Hazards: When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides). Reactivity Hazards: This product is not reactive. Environmental Hazards: This product has not been tested for environmental effects. Emergency Response 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>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypermellose</td>
<td>9004-65-3</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Water and other components. Each of the other components is present in less than 1 percent concentration (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens).</td>
<td>The remaining components do not contribute any significant additional hazards.</td>
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</table>

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

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: Rescuers should be taken for medical attention if necessary. Remove or cover gross contamination to avoid exposure to rescuers.

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must seek medical attention if any adverse effect occurs. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

Skin Exposure: If adverse skin effects occur, eliminate exposure. Flush the exposed area with running water. Seek medical advice if adverse effect occurs after flushing.

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.

Inhalation: Due to the form of the product, inhalation is unlikely.

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 3 (Hazard Identification) and 11 (Toxicological Information).

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

IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED: Treat symptoms and eliminate exposure.
5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.
AUTOIGNITION TEMPERATURE: Not established.
FLAMMABLE LIMITS (in air by volume, %): Not applicable.
FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire. Fire extinguishing materials that can be used include carbon dioxide, dry chemical powder, halon, ‘ABC’ Class, or appropriate foam.
UNSUITABLE EXTINGUISHING MEDIA: None known.
SPECIAL FIRE AND EXPLOSION HAZARDS: When involved in a fire, this material may ignite and produce irritating vapors and toxic gases (e.g., carbon oxides).
   Explosion Sensitivity to Static Discharge: Not sensitive.
ADVICE FOR FIREFIGHTERS: 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. Move containers from fire area if it can be done without risk to personnel. Water spray can be used to cool fire-exposed containers. Water fog or spray can also be used by trained firefighters to disperse this product’s vapors and to protect personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people. Trained personnel following pre-planned procedures should respond to uncontrolled releases. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Monitor area and confirm levels are bellow exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

PROTECTIVE EQUIPMENT:
   Small Spills: For incidental spills (e.g., 1 tube), wear safety glasses and gloves.
   Large Spills: For large spills (e.g., a case of tubes), protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of mists or sprays into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.

METHODS FOR CLEANUP AND CONTAINMENT:
   Small Spills: Wipe up using polyprop or sponge
   Large Spills: Absorb spilled liquid with polypads or other suitable absorbent material. Prevent material from entering sewer or confined spaces, waterways, soil or public waters.
   All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material 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.

PART III How can I prevent hazardous situations from occurring?

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: In the workplace, avoid getting this product ON YOU or IN YOU unless there is a medical need for its use. Employees must be trained to properly use this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this material must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

CONDITIONS FOR SAFE STORAGE: Ensure product is properly labeled. Store this product away from incompatible materials. Store this product in original container.

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

SPECIFIC END USE(S): This product is a human pharmaceutical. Follow all industry standards for use of this product.
7. HANDLING and USE (Continued)

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and dispose of according to applicable U.S. Federal, State, and local hazardous 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:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EXPOSURE LIMITS IN AIR</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ACGIH-TLVs</td>
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<tr>
<td></td>
<td></td>
<td>TWA</td>
</tr>
<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>NE</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>NE</td>
</tr>
</tbody>
</table>

NE = Not Established.  See Section 16 for Definitions of Terms Used.

ENGINEERING CONTROLS:

Ventilation: Ventilation should be as for standard medical product handling procedures.

PERSONAL PROTECTIVE EQUIPMENT: The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-07). Please reference applicable regulations and standards for relevant details.

Respiratory Protection: A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02. Oxygen levels below 19.5% are considered IDLH by 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 OSHA’s Respiratory Protection Standard (1910.134).


Hand Protection: None normally needed. For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate standards of Canada.

Body Protection: During patient administration, use of lightweight cotton gown or other medical attire is recommended. If necessary, refer to OSHA Technical Manual (Section VII: Personal Protective Equipment). If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee’s feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136 or Canadian CSA Standard Z195-02, Guideline on Selection, Care, and Use of Protective Footwear.

9. PHYSICAL and CHEMICAL PROPERTIES

MOLECULAR WEIGHT (single entity only): Not applicable.

PHYSICAL STATE: Smooth, translucent gel.

ODOR: Slight lavender odor.

RELATIVE VAPOR DENSITY (air = 1): Not established.

FLASH POINT: Not applicable.

UPPER EXPLOSIVE LIMIT: Not applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

EXPLOSIVE PROPERTIES: Not explosive.

BOILING POINT: 100°C (212°F).

DENSITY/SPECIFIC GRAVITY @ 20°C (water = 1): 1.0

VAPOR PRESSURE (air = 1): Not established.

PARTITION COEFFICIENT (n-octanol/water): Not established.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance and odor of this product are distinguishing characteristics to identify the product in event of accidental release.

10. STABILITY and REACTIVITY

REACTIVITY/CHEMICAL STABILITY: This product is stable.

POSSIBILITY OF HAZARDOUS POLYMERIZATION: Will not polymerize.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

INCOMPATIBLE MATERIALS: 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.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF OVEREXPOSURE 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:** Due to the form of the product, inhalation of this product is not a likely route of exposure.

**Skin Contact:** Prolonged skin contact may cause mild irritation, which is alleviated discontinuation of use.

**Eyes Contact:** Eye contact can cause irritation, stinging, redness, and tearing.

**Skin Absorption:** The components of this product are not known to be absorbed through intact skin.

**Ingestion:** Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product may cause vomiting, diarrhea and gastrointestinal upset.

**Injection:** Though not anticipated to be a significant route of overexposure 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 “General Toxicity Information”.

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to components of this product may experience allergic reactions to this product.

IRRITANCY OF PRODUCT: Prolonged skin contact may mildly irritate contaminated tissue.

SENSITIZATION OF PRODUCT: The components of this product are not known to be human skin or respiratory sensitizer.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms.

**Acute:** The primary health effect that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin if contact is prolonged. Accidental ingestion may be harmful. Eye contact will cause irritation.

**Chronic:** Prolonged skin contact may cause mild irritation.

TARGET ORGANS:

**Acute:** Occupational Exposure: Skin, eyes. Therapeutic Doses: Skin, eyes.

**Chronic:** Occupational Exposure: Skin. Therapeutic Doses: Skin.

TOXICITY DATA: Toxicity data for components of this product present in greater than 1 percent concentration are available as follows:

**HYDROXYMETHYL-GLUCOSIDE:**

- **LD₅₀ (Intraperitoneal-Rat) = 4000 mg/kg**
- **LD₅₀ (Intraperitoneal-Mouse) = 5000 mg/kg**
- **LD₅₀ (Intraperitoneal-Mammal-Species Unspecified) = 10,000 mg/kg**
- **LD₅₀ (oral, rat) = 20 g/kg**
- **TDL₀ (Intraperitoneal-Rat) = 1000 mg/kg/30 days-continuous:**
  - Gastrointestinal: hypermotility; diarrhea; Related to Chronic Data: death
  - Skin Irritancy (human) = 500 mg/7 days; mild
  - Skin Irritancy (human) = 104 mg/3 days/intermittent; moderate

**PROPYLENE GLYCOL: (continued):**

- **Eye Irritancy (rabbit) = 100 mg; mild**
- **Eye Irritancy (rabbit) = 500 mg/24 hours; mild LD₅₀ (oral, rat) = 20 g/kg**
- **LD₅₀ (oral, mouse) = 22 g/kg**
- **LD₅₀ (oral, guinea pig) = 18350 mg/kg**
- **LD₅₀ (oral, guinea pig) = 18350 mg/kg**
- **LD₅₀ (oral, guinea pig) = 18350 mg/kg**
- **LD₅₀ (skin, rabbit) = 20800 mg/kg**
- **LD₅₀ (intraperitoneal, rat) = 6660 mg/kg**
- **LD₅₀ (intraperitoneal, mouse) = 9718 mg/kg**
- **LD₅₀ (subcutaneous, rat) = 22,500 mg/kg**
- **LD₅₀ (termination, mouse) = 17,370 mg/kg**
- **LD₅₀ (intravenous, rat) = 6423 mg/kg**
- **LD₅₀ (intravenous, mouse) = 6630 mg/kg**

CARCINOGENIC POTENTIAL OF COMPONENTS: 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: The components of this product are not currently reported to produce mutagenic, embryotoxic, teratogenic, or reproductive effects in humans. Animal data are available for components of this product as follows:

**PROPYLENE GLYCOL:**

- **TDLo (intraperitoneal, mouse) = 100 mg/kg/15 days preg; Teratogenic effects**
- **TDLo (intraperitoneal, mouse) = 100 mg/kg/11 days preg; Reproductive effects**
- **DNA Inhibition (subcutaneous, mouse) = 8000 mg/kg**
- **Cytogenetic Analysis (fibroblast, hamster) = 32 g/L**

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 IN SOIL:** This product has not been tested for mobility in soil. The following information is available for some constituents.

**PROPYLENE GLYCOL:**

The Koc of Propylene Glycol 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 that Propylene Glycol is expected to have very high mobility in soil.

**PERSISTENCE AND BIODEGRADABILITY:** This product has not been tested for persistence or biodegradability. It is expected that the constituents of this product will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known. The following information is available for some constituents.

**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 Propylene Glycol is expected to have very high mobility in soil. Volatilization of Propylene Glycol 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 m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10^6 mg/L. Propylene Glycol 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 deg C and a fortification of 1,000 ppm Propylene Glycol, yielded 73-78% mineralization during a 51 day incubation period, suggesting that biodegradation will be an important fate process in soils. 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 Propylene Glycol 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 Propylene Glycol 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 Propylene Glycol 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 cm/molecule-sec at 25°C.

**ECOTOXICITY:** This product has not been tested for bioaccumulation potential. The following information is available for some constituents.

**PROPYLENE GLYCOL:**

An estimated BCF of 3 was calculated for Propylene Glycol, 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.

**MOBILITY IN SOIL:** This product has not been tested for aquatic or animal toxicity. All releases to terrestrial, atmospheric and aquatic environments should be avoided. The aquatic toxicity data for some constituents of this product are available on the following below.

**PROPYLENE GLYCOL:**

**PROPYLENE GLYCOL (continued):**

- **EC50 (Daphnia magna, crustacean) 24 hours = 50,000 mg/L**
- **LC50 (Salmo gairdneri) 96 hr = 50,000 mg/L**

**PROPYLENE GLYCOL (continued):**

- **EC50 (Pimephales promelas) 96 hr = 50,000 mg/L**
- **LC50 (Pimephales promelas) 96 hr = 50,000 mg/L**

**ECOTOXICITY:** No component of this product is known to have ozone depletion potential.

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

**13. DISPOSAL CONSIDERATIONS**

**WASTE TREATMENT/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 placed in 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 drug 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.
14. TRANSPORTATION INFORMATION

This product is not classified under any jurisdiction as Dangerous Goods and has no UN Number, Hazard Class or Packing Group or Special Precautions for User.

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA: This product is NOT classified as Dangerous Goods, per the Transportation of Dangerous Goods regulations.

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: Not applicable.

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.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The components of this product are not 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.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOLS: Not applicable.

16. OTHER INFORMATION

U.S. ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING! MAY CAUSE SKIN AND 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 Material Safety Data Sheet for additional information.

This Material Safety Data Sheet is offered pursuant to OSHA’s Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Nycomed US Inc.’s knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc.

PO Box 1961, Hilo, HI 96721

800/441-3365 • 808/969-4846

DATE OF PRINTING: September 15, 2011

DEFINITION OF TERMS

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

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

EXPOSURE LIMITS IN AIR:

CEILING LEVEL: The concentration that shall not be exceeded during any part of the working exposure.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed humans. 2: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed mammals. 3A: Substances that have been shown to induce genetic damage in germ cells of human of 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. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g. purely aneugenic substances] if research results make this seem sensible.) 5: Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

EXPOSURE LIMITS IN AIR (continued):

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. Group B: Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. Group C: There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. Group D: Classification in one of the groups A–C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

IDLH: Immediately Dangerous to Life and Health. This level represents a concentration from which one can escape within 30 minutes without suffering escape-preventing or permanent injury.

LOG: Limit of Quantitation.

MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.

NE: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

NIC: Notice of Intended Change.
Nycoderm US Inc.

DEFINITION OF TERMS (Continued):

EXPOSURE LIMITS IN AIR (Continued):

NIOSH: Threshold Limit Values. An airborne concentration of a substance that represents the conditions under which it is generally believed that nearly all workers may be repeatedly exposed to air concentrations equal to or less than the exposure limit for an 8-hour workday and a 40-hour workweek.

NIOSH CEILING: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based on the TLVs and are revised at the June, 1996, or January, 1997, OSHA PELs (58: 35338-35351 and 58: 40-1919). Both the current PELs and the vacated PELs are indicated. The phrase, 'Vacated 1989 PEL' is placed next to the PEL that was vacated by Court Order.

TWA: Time Weighted Average. This exposure concentration is based on the exposure that body burdens would accumulate if the exposure were to continue for an entire workshift (8 hours).

TLV: Threshold Limit Value. An airborne concentration of a substance that represents the conditions under which it is generally believed that nearly all workers may be repeatedly exposed to air concentrations equal to or less than the exposure limit for an 8-hour workday.

STEL: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hour TWA is within the TLV.

acute injury. Gases with a LC50 equal to or greater than 10,000 ppm (e.g., hydrogen sulfide, phosgene, and chlorine) are not considered lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD50 is less than or equal to 500 mg/kg.

irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD50 is greater than 500 mg/kg but less than or equal to 10,000 mg/kg.

irritation clearing in 8 to 10 hours. Can cause irreversible respiratory effects.

irritants. Materials that will not burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less, or that do not have a mass explosion hazard.

irritants. Materials whose LD50 is greater than 500 mg/kg but less than or equal to 5000 mg/kg.

Water Reactivity: Materials that do not react with water. Organic Peroxides: Materials that are normally stable, even under fire conditions and will not react with water. Explosives: Substances that are Non-Explosive. Compressed Gases: No 4 rating. Materials that do not react, but only under certain conditions of temperature and pressure.

Hazardous Materials Identification System HAZARD RATINGS: This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD: 0 Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. LD50 > 5000 mg/kg. Ingestion Toxicity 4. Oral Toxicity LC50 is not anticipated. PEL or REL > 5000 ppm. Ingestion Toxicity LC50 > 2000 mg/kg. Inhalation Toxicity 4 hrs LC50 > 20 mg/L. TWA or REL > 500 ppm. Inhalation Toxicity 4 hrs LC50 > 20 mg/L. TWA or REL > 500 ppm.

irritant, sensitizer. PEL or REL > 20 mg/L. TWA or REL > 50 ppm.

irritation clearing in 8 to 10 hours. Can cause irreversible respiratory effects.

irritants. Materials that will not burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less, or that do not have a mass explosion hazard.

irritants. Materials whose LD50 is greater than 500 mg/kg but less than or equal to 5000 mg/kg.

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**NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):**

**HEALTH HAZARD (continued):** 3 Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LEL of acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater its LEL for acute inhalation toxicity, if its LEL is less than or equal to 3,000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC50 for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD50 for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the skin or respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-65.5°F) that cause frostbite and irreversible tissue damage. Materials with an LEL for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. Materials that, under emergency conditions, can be lethal. Gases with an LEL for acute inhalation toxicity less than or equal to 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LEL for acute inhalation toxicity, if its LEL is less than or equal to 1000 ppm. Dusts and mists whose LC50 for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD50 for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD50 for acute oral toxicity is less than or equal to 5 mg/kg.

**FLAMMABILITY HAZARD:** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. Materials that must be preheated or exposed to air for a period of time before ignition can occur. Materials whose boiling points are below or near the ambient temperature, before ignition and combustion can occur. Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIb liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the Method of Testing for Sustained Combustibility, per 49 CFR 173, Appendix H of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations (current edition) and the related Manual of Tests and Criteria (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water content of more than 5% by weight. Combustible liquids that will not burn when exposed to the no fire point when tested by ASTM D 92, Standard Test Method for Flash and Fire Points by Cleveland Open Cup, up to the boiling point of the liquid or up to a temperature at which the sample in the test vessel is observed to ignite or to form an explosive mixture with air within the test vessel used. Commonly sold under the name of “nonspill.” Liquids with a flash point greater than 35°C (95°F) and having a boiling point at or above 37.8°C (100°F) and with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. 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. Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating will undergo a flammable or explosive reaction at normal temperatures and pressures. Materials that readily undergo decomposition or explosive reaction at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or below 0.01 W/mL and below 10 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. Materials that in themselves are readily capable of detonation or explosive decomposition or explosion reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 100 W/mL. Materials that in themselves are normally stable, even under fire conditions. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. Materials that, in themselves, are normally stable, but that can become unstable 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) at or below 0.01 W/mL and below 10 W/mL. 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) at or above 0.01 W/mL and below 100 W/mL. Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures.
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<th>Date</th>
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<tbody>
<tr>
<td>August 21, 2011</td>
<td>Remove incorrect references to propylene oxide. Add revision history section. Correction to product use. Surgilube is a medical device.</td>
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