# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078341918

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

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# SAFETY DATA SHEET

*Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, REACH, European Union CLP EC 1272/2008 and the Global Harmonization Standard*

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

## 1. SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### *TRADE NAME/MATERIAL NAME*: SurgiLube

| | |
|---|---|
| ***DESCRIPTION:*** | Surgical Lubricant |
| ***NDC #:*** | 0281-0205-12; 0281-0205-36; 0281-0205-37; 0281-0205-43; 0281-0205-45; 0281-0205-55 |
| ***CHEMICAL FAMILY:*** | Propylene Glycol Mixture |
| ***HOW SUPPLIED:*** | Topical Gel |
| ***FORMULA:*** | Mixture |
| ***RELEVANT USE of the SUBSTANCE:*** | Medical Device |
| ***USES ADVISED AGAINST*** | Other than Relevant Use |
| ***SUPPLIER/MANUFACTURER'S NAME:*** | **HR® PHARMACEUTICALS, INC.** |
| ***ADDRESS:*** | 2651 Carnegie Road<br>York, PA 17402-3706<br>www.hrpharma.com |
| ***BUSINESS PHONE/GENERAL SDS INFORMATION:*** | 1-717-252-1110 |
| ***EMERGENCY PHONE (U.S./Canada/Puerto Rico):*** | (877) 302-0111 |

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.

**EU LABELING/CLASSIFICATION:** According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

***EMERGENCY OVERVIEW: Product Description:*** This product is a smooth, translucent get 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. 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 Considerations:*** Emergency responders should wear appropriate protection for situation to which they respond.

## 3. COMPOSITION and INFORMATION ON INGREDIENTS

| CHEMICAL NAME | CAS # | EINECS # | % w/w | **LABEL ELEMENTS**<br>**EU Classification (67/548/EEC)**<br>**GHS & EU Classification (1272/2008 EC)**<br>**Risk Phrases/Hazard Statements** |
|---|---|---|---|---|
| Hypromellose | 9004-65-3 | Not Listed | Proprietary | EU 67/548: Classification: Not applicable.<br>GHS & EU 1272/2008: Classification: Not applicable. |
| Propylene Glycol | 57-55-6 | 200-338-0 | Proprietary | EU 67/548: Classification: Not applicable.<br>GHS & EU 1272/2008: Classification: Not applicable |
| Water and other trace components of less than 1% concentration | | | Proprietary | EU 67/548: Classification: Not applicable.<br>GHS & EU 1272/2008: Classification: Not applicable. |

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.

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

## 4. FIRST-AID MEASURES (Continued)

**DESCRIPTION OF FIRST AID MEASURES (continued):**

***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.

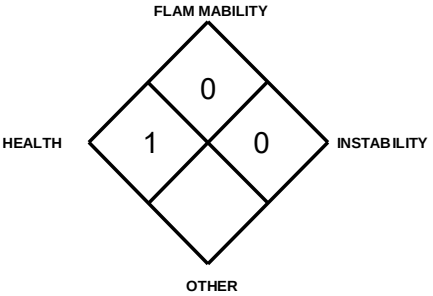
***FLAMMABLE LIMITS (in air by volume, %):*** Not applicable.

***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).

**NFPA RATING**




Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

**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.

# PART III *How can I prevent hazardous situations from occurring?*

## 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:***

| *CHEMICAL NAME* | *CAS #* | *EXPOSURE LIMITS IN AIR* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | *ACGIH-TLVs* | | *OSHA-PELs* | | *NIOSH-RELs* | | *NIOSH* | *OTHER* |
| | | *TWA mg/m³* | *STEL mg/m³* | *TWA mg/m³* | *STEL mg/m³* | *TWA mg/m³* | *STEL mg/m³* | *IDLH mg/m³* | *mg/m³* |
| Hypromellose<br>Exposure limits given are for celluloses | 9004-65-3 | 10 | NE | 15 (total dust), 5 (resp. fract.) | NE | 10 (total dust), 5 (resp. fract.) | NE | NE | NE |
| Propylene Glycol | 57-55-6 | NE | NE | NE | NE | NE | NE | NE | AIHA WEEL: TWA = 10 |

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

**PROPYLENE GLYCOL:**
Australia: TWA = 10 mg/m³ (particulates), JUL 2008
Australia: TWA = 150 ppm (474 mg/m³) (total), JUL 2008

**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
Russia: STEL = 7 mg/m³, JUN 2003
United Kingdom: TWA = 10 mg/m³ (particulate), 2005
United Kingdom: TWA = 150 ppm (474 mg/m³) (total vapor), 2005

***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, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132)*, equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

***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.
***COLOR:*** Translucent.
***MOLECULAR WEIGHT:*** Mixture.
***MOLECULAR FORMULA:*** Mixture.
**ODOR:** Slight lavender.
***ODOR THRESHOLD:*** Not established.
***BOILING POINT:*** 100°C (212°F)
***FREEZING/MELTING POINT:*** Not established.
***EVAPORATION RATE (Ether = 1):*** 0.02
***pH:*** 4.0-7.0
***VAPOR PRESSURE (air = 1):*** Not established.
***SPECIFIC GRAVITY @ 20°C (water = 1):*** 1.0
**FLASH POINT:** Not available.
**AUTOIGNITION TEMPERATURE:** Not known.
***SOLUBILITY IN WATER:*** Soluble.
***OTHER SOLUBILITIES:*** Not known.
***COEFFICIENT WATER/OIL DISTRIBUTION:*** Not established.
***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".

**HAZARDOUS MATERIAL IDENTIFICATION SYSTEM**

| | |
|---|---|
| **HEALTH HAZARD** (BLUE) | 1 |
| **FLAMMABILITY HAZARD** (RED) | 0 |
| **PHYSICAL HAZARD** (YELLOW) | 0 |

**PROTECTIVE EQUIPMENT**

| EYES | RESPIRATORY | HANDS | BODY |
|---|---|---|---|
|  | SEE SECTION 8 |  | SEE SECTION 8 |

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate
**3** = Serious **4** = Severe * = Chronic hazard

***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, inhalation 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.

***IRRITANCY 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.

## 11. TOXICOLOGICAL INFORMATION (Continued)

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

**HYPROMELLOSE:**

$LD_{50}$ (Oral-Mammal-Species Unspecified) > 10,000 mg/kg
$LD_{50}$ (Intraperitoneal-Rat) 5200 mg/kg
$LD_{50}$ (Intraperitoneal-Mouse) 5 gm/kg
TDLo (Oral-Rat) 2250 gm/kg/30 days-continuous: Gastrointestinal: hypermotility, diarrhea; Related to Chronic Data: death
TCLo (Inhalation-Mammal-Species Unspecified) 86 $mg/m^3$: Liver: liver function tests impaired; Kidney/Ureter/Bladder: renal function tests depressed; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases
TCLo (Inhalation-Mammal-Species Unspecified) 86 $mg/m^3$: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

**PROPYLENE GLYCOL:**

Standard Draize Test (Skin-Human) 500 mg/7 days: Mild
Standard Draize Test (Skin-Human) 104 mg/3 days-intermittent: Moderate
Standard Draize Test (Skin-Man) 10%/2 days
Standard Draize Test (Skin-Child) 30%/96 hours-continuous: Moderate
Open Irritation Test (Skin-woman) 30%/96 hours: Mild
TDLo (Oral-Child) 79 gm/kg/56 weeks-intermittent: Brain and Coverings: changes in surface EEG; Behavioral: general anesthetic, convulsions or effect on seizure threshold
TDLo (Skin-Human) 10 pph: Skin and Appendages: dermatitis, allergic (after topical exposure)
TDLo (Parenteral-Infant) 10 gm/kg/3 days-continuous: Nutritional and Gross Metabolic: other changes
TDLo (Skin-Human) 5 mg/kg/7 days-intermittent: Skin and Appendages: primary irritation (after topical exposure)
TDLo (Skin-Human) 4.5 mg/kg/3 days-intermittent: Skin and Appendages: primary irritation (after topical exposure)
TDLo (Skin-Human) 10 pph/48 hours-continuous: Skin and Appendages: dermatitis, allergic (after topical exposure)
TDLo (Skin-Man) 0.03 mL/kg/22 days-intermittent: Skin and Appendages: cutaneous sensitization, experimental (after topical exposure)
TDLo (Intravenous-Woman) 5167 mg/kg/13 days-continuous: Nutritional and Gross Metabolic: metabolic acidosis
Standard Draize Test (Eye-Rabbit) 100 mg: Mild
Standard Draize Test (Eye-Rabbit) 500 mg/24 hours: Mild
$LD_{50}$ (Oral-Rat) 20 gm/kg
$LD_{50}$ (Oral-Mouse) 20,300 mg/kg: Behavioral: ataxia, tetany; Lungs, Thorax, or Respiration: respiratory depression $LD_{50}$ (Oral-Mouse) 22 gm/kg
$LD_{50}$ (Oral-Rabbit) 18,500 mg/kg
$LD_{50}$ (Oral-Dog) 22 gm/kg
$LD_{50}$ (Oral-Dog) 22,000 mg/kg: Behavioral: ataxia, tetany; Lungs, Thorax, or Respiration: respiratory depression
$LD_{50}$ (Oral-Guinea Pig) 18,350 mg/kg
$LD_{50}$ (Oral-Guinea Pig) 19,000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression $LD_{50}$ (Oral-Quail) > 2080 mg/kg
$LD_{50}$ (Skin-Rabbit) 20,800 mg/kg
$LD_{50}$ (Skin-Rabbit) 20,800 mg/kg: Behavioral: ataxia, tetany; Lungs, Thorax, or Respiration: respiratory depression
$LD_{50}$ (Intraperitoneal-Rat) 6660 mg/kg
$LD_{50}$ (Intraperitoneal-Mouse) 9718 mg/kg: Lungs, Thorax, or Respiration: chronic pulmonary edema; Kidney/Ureter/Bladder: changes in both tubules and glomeruli; Blood: changes in spleen
$LD_{50}$ (Intraperitoneal-Mouse) 11,400 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
$LD_{50}$ (Subcutaneous-Rat) 22,500 mg/kg

**PROPYLENE GLYCOL (continued):**

$LD_{50}$ (Subcutaneous-Rat) 28,000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
$LD_{50}$ (Subcutaneous-Mouse) 17,370 mg/kg: Behavioral: changes in motor activity (specific assay), muscle contraction or spasticity; Lungs, Thorax, or Respiration: cyanosis
$LD_{50}$ (Subcutaneous-Mouse) 17,400 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
$LD_{50}$ (Intravenous-Rat) 6800 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
$LD_{50}$ (Intravenous-Rat) 6423 mg/kg
$LD_{50}$ (Intravenous-Mouse) 8000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
$LD_{50}$ (Intravenous-Mouse) 6630 mg/kg
$LD_{50}$ (Intravenous-Dog) 26 gm/kg
$LD_{50}$ (Intravenous-Rabbit) 6500 mg/kg
$LD_{50}$ (Intramuscular-Rat) 14 gm/kg
$LD_{50}$ (Intramuscular-Rat) 20,000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LDLo (Oral-Rabbit) 20,000 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LDLo (Intramuscular-Rabbit) 6300 mg/kg: Behavioral: somnolence (general depressed activity), coma; Lungs, Thorax, or Respiration: respiratory stimulation
LDLo (Subcutaneous-Guinea Pig) 15,500 mg/kg
LDLo (Subcutaneous-Guinea Pig) 15,500 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LDLo (Intravenous-Chicken) 27 gm/kg: Vascular: other changes
LDLo (Intravenous-Rabbit) 4200 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
LDLo (Intramuscular-Mouse) 6300 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
TDLo (Oral-Rat) 88,269 mg/kg/30 days-intermittent: Endocrine: hyperglycemia Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases, transaminases
TDLo (Oral-Rat) 84 mL/kg/30 days-continuous: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol) Blood: changes in leukocyte (WBC) count; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects
TDLo (Oral-Dog) 3650 mg/kg/2 years-intermittent: Blood: normocytic anemia, other hemolysis with or without anemia
TDLo (Skin-Mouse) 1,284,800 mg/kg/2 years-intermittent: Skin and Appendages: tumors
TDLo (Intraperitoneal-Rat) 19,500 mg/kg: Behavioral: ataxia, tetany Lungs, Thorax, or Respiration: respiratory depression
TDLo (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)
TDLo (Intraperitoneal-Mouse) 100 mg/kg: female 15 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)
TCLo (Inhalation-Rat) 2180 $mg/m^3$/6 hours/90 days-intermittent: 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 that this compound is expected to have very 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.

## 12. ECOLOGICAL INFORMATION (Continued)

***PERSISTENCE AND BIODEGRADABILITY (continued):***

**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 m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/liter. 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 during a 51 day incubation period, suggesting that biodegradation will be an important fate process in soils.

**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:**

$EC_{50}$ (*Photobacterium phosphoreum*, bacteria) 30 minutes = 26,800 mg/L
$EC_{50}$ (*Daphnia magna*, crustacean) 48 hours = 34,400 mg/L
$EC_{100}$ (*Daphnia magna*, crustacean) 48 hours = 50,000 mg/L
$EC_{50}$ (*Daphnia magna*, crustacean) 24 hours = > 10,000 mg/L
$EC_{100}$ (*Daphnia magna*, crustacean) 24 hours = > 10,000 mg/L
$EC_{50}$ (*Nitocra spinipes*, crustacean) 96 hours = > 10,000 mg/L

**PROPYLENE GLYCOL (continued):**

$LC_{50}$ (*Carassius auratus*) 24 hours = > 5,000 mg/L
$LC_{50}$ (*Lebistes reticulatus*, guppy) 48 hours > 10,000 mg/L
$LC_{50}$ (*Salmo gairdneri*) 24 hours = 50,000 mg/L
$LC_{50}$ (*Pimephales promelas*) 96 hr = 54,900 mg/L
$LC_{50}$ (Artemia salina) 24 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 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 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.

## 14. TRANSPORTATION INFORMATION (Continued)

***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.

***Chemical Safety Assessment:*** No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

## 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, $CO_2$, 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.

***67/548/EEC EU LABELING/CLASSIFICATION:*** According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

***CLASSIFICATION FOR COMPONENTS:***

***Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:***

**All Components:** No classification has been published or is applicable.

***Full Text EU 67/548/EEC:***

**All Components:** No classification has been published or is applicable.

REVISION DETAILS: May 2015: Up-date of entire SDS to the current Global Harmonization Standard format.

REFERENCES 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.



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# DEFINITION OF TERMS

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.

## 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.

**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.

**LOQ:** 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.

**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 in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). 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.

**SKIN:** Used when a there is a danger of cutaneous absorption.

**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-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

**TLV:** Threshold Limit Value. An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

**TWA:** Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek. **WEEL:** Workplace Environmental Exposure Limits from the AIHA.

## 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. *Skin Irritation*: Essentially non-irritating. Mechanical irritation may occur. PII or Draize = 0. *Eye Irritation*: Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. *Oral Toxicity $LD_{50}$ Rat*: > 5000 mg/kg. *Dermal Toxicity $LD_{50}$ Rat or Rabbit*: > 2000 mg/kg. *Inhalation Toxicity 4-hrs $LC_{50}$ Rat*: > 20 mg/L. **1)** Slight Hazard: Minor reversible injury may occur; may irritate the stomach if swallowed; may defat the skin and exacerbate existing dermatitis. *Skin Irritation*: Slightly or mildly irritating. PII or Draize > 0 < 5. *Eye Irritation*: Slightly to mildly irritating, but reversible within 7 days. Draize > 0 ≤ 25. *Oral Toxicity $LD_{50}$ Rat*: > 500–5000 mg/kg. *Dermal Toxicity $LD_{50}$ Rat or Rabbit*: > 1000–2000 mg/kg. *Inhalation Toxicity $LC_{50}$ 4-hrs Rat*: > 2–20 mg/L. **2** *Moderate Hazard*: Temporary or transitory injury may occur; prolonged exposure may affect the CNS. *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize ≥ 5, with no destruction of dermal tissue. *Eye Irritation*: Moderately to severely irritating; reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. *Oral Toxicity $LD_{50}$ Rat*: > 50–500 mg/kg. *Dermal Toxicity $LD_{50}$ Rat or Rabbit*: > 200–1000 mg/kg. *Inhalation Toxicity $LC_{50}$ 4-hrs Rat*: > 0.5–2 mg/L. **3** Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may cause destruction of dermal tissue, skin burns, and dermal necrosis. PII or Draize > 5– 8, with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation

## HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **4 (continued):** permanent damage may result from single or repeated exposure; extremely toxic; irreversible injury may result from brief contact. *Skin Irritation*: Not appropriate. Do not rate as a 4, based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a 4, based on eye irritation alone. *Oral Toxicity $LD_{50}$ Rat*: ≤ 1 mg/kg. *Dermal Toxicity $LD_{50}$ Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity $LC_{50}$ 4-hrs Rat*: ≤ 0.05 mg/L.

FLAMMABILITY HAZARD: **0** Minimal Hazard: Materials that will not burn in air when exposure to a temperature of 815.5°C (1500°F) for a period of 5 minutes. **1** Slight Hazard: Materials that must be pre-heated before ignition can occur. Material requires considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. This usually includes the following: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C (200°F) (i.e. OSHA Class IIIB); and Most ordinary combustible materials (e.g. wood, paper, etc.). **2** Moderate Hazard: 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 in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres with air. This usually includes the following: Liquids having a flash-point at or above 37.8°C (100°F); Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp); and Solids and semisolids (e.g. viscous and slow flowing as asphalt) that readily give off flammable vapors. **3** Serious Hazard: Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions. This usually includes the following: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 38°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. OSHA Class IB and IC); Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air (e.g., dusts of combustible solids, mists or droplets of flammable liquids); and Materials that burn extremely rapidly, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). **4** Severe Hazard: Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and that will burn readily. This usually includes the following: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. OSHA Class IA); and Materials that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below (pyrophoric).

PHYSICAL HAZARD: **0** *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 Rating. *Pyrophorics*: No Rating. *Oxidizers*: No 0 rating. *Unstable Reactives*: Substances that will not polymerize, decompose, condense, or self-react.). **1** *Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. *Explosives*: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives*: Substances that may decompose condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. Substances that readily undergo hazardous polymerization in the absence of inhibitors. **2** *Water Reactivity*: Materials that may react violently with water. *Organic Peroxides*: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives*: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases*: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group II oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. **3** *Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.3 explosives. Explosive substances

# *DEFINITION OF TERMS (Continued)*

persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity $LD_{50}$ Rat*: > 1–50 mg/kg. *Dermal Toxicity $LD_{50}$ Rat or Rabbit*: > 20–200 mg/kg. *Inhalation Toxicity $LC_{50}$ 4-hrs Rat*: > 0.05–0.5 mg/L. **4** Severe Hazard: Life-threatening; major or

that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I oxidizers.

PHYSICAL HAZARD (continued): **3 (continued):** Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. Liquids: any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. **4** *Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability 4. *Oxidizers*: No 4 rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

## NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an $LC_{50}$ for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an $LC_{50}$ for acute inhalation toxicity greater than 200 mg/L. Materials with an $LD_{50}$ for acute dermal toxicity greater than 2000 mg/kg. Materials with an $LD_{50}$ for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. **1** Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an $LC_{50}$ for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an $LC_{50}$ for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an $LD_{50}$ for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an $LD_{50}$ for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **2** Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an $LC_{50}$ for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its $LC_{50}$ for acute inhalation toxicity, if its $LC_{50}$ is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an $LC_{50}$ for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an $LD_{50}$ for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose $LD_{50}$ for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. **3** Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an $LC_{50}$ for 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 $LC_{50}$ for acute inhalation toxicity, if its $LC_{50}$ is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an $LC_{50}$ for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an $LD_{50}$ for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the 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 (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an $LD_{50}$ for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. **4** Materials that, under emergency conditions, can be lethal. Gases with an $LC_{50}$ 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 $LC_{50}$ for acute inhalation toxicity, if its $LC_{50}$ is less than or equal to 1000 ppm. Dusts and mists whose $LC_{50}$ for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose $LD_{50}$ for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose $LD_{50}$ for acute oral toxicity is less than or equal to 5 mg/kg.

FLAMMABILITY HAZARD: **0** 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 according with Annex D of NFPA 704. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, 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 according 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 or 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 noncombustible liquid/solid content of more than 85% by weight. Liquids that have 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 being tested shows an obvious physical change. Combustible pellets 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. **2** 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 could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative

FLAMMABILITY HAZARD (continued): **2 (continued):** diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal, and hemp. Solids and rated by the closed cup flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and 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) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite 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.

INSTABILITY HAZARD: **0** 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. **1** 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 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) at or above 10 W/mL and below 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require 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. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive 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) 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 Temperature: Minimum temperature of a solid, liquid, or gas required to initiate or cause self-sustained combustion in air with no other source of ignition. LEL: Lowest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. UEL: 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 with similar compounds are presented. $LD_{50}$: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. $LC_{50}$: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. $mg/m^3$: 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. TDLo: Lowest dose to cause a symptom. TCLo: Lowest concentration to cause a symptom. TDo, LDLo, and LDo, or TC, TCo, LCLo, and LCo: Lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** IARC: International Agency for Research on Cancer. NTP: National Toxicology Program. RTECS: Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** BEI: ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

## REPRODUCTIVE TOXICITY INFORMATION:

A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An embryo toxin 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 teratogen is a chemical that causes damage to a developing fetus, 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:

EC: Effect concentration in water. BCF: 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 $K_{OW}$ or log $K_{OC}$: Coefficient of Oil/Water Distribution is used to assess 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/Non-Domestic Substances List. TSCA: U.S. Toxic Substance Control Act. CERCLA: Comprehensive Environmental Response, Compensation, 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.

## ***REVISION HISTORY***

| **Date** | **Changes** |
|---|---|
| October 6, 2015 | Update Manufacturer's name, address and phone. |
| September 6, 2015 | Update CHEMTEL number. |
| July 22, 2015 | Make correction to NDC# from Fougera (0168) to Savage Labs (0281). Relevant use of the substance corrected to Medical Device. |
| June 27, 2015 | Change emergency telephone number to ChemTel. |
| May 20, 2015 | Review and up-date as needed for most current format and regulations. |
| December 10, 2013 | Up-date to include current GHS & to add EU compliance. |
| October 3, 2012 | New |