Nycomed US Inc.

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

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

1. PRODUCT IDENTIFICATION

TRADE NAME/MATERIAL NAME: Nitro-Bid®

DESCRIPTION: Nitroglycerin Ointment
NDC #: 0281-0326-08, 0281-0326-30, 0281-0326-60
CHEMICAL NAME (for active ingredients): 1,2,3-Propanetriol Trinitrate
CHEMICAL FAMILY (for active ingredient): Aliphatic Polyhydric Alcohol Derivative
HOW SUPPLIED: Ointment
FORMULA (for active ingredient): C₃H₅N₃O₉
PRODUCT USE: Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER’S NAME: NYCOMED US INC. (Savage Labs Division)
ADDRESS: 60 Baylis Road
Melville, NY 11747
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

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, and Canadian WHMIS [Controlled Products Regulations] required information is included in appropriate sections based on the U.S. ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Product Description: This product is a pale yellow ointment with a mild petroleum jelly and lanolin odor. Health Hazards: The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing the active ingredient, Nitroglycerin, other organic nitrates, the Lanolin component or any other components of this product may experience allergic reactions to this product. Flammability Hazards: This product must be substantially heated for ignition to become a hazard. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen 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

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitroglycerin</td>
<td>56-63-0</td>
<td>2.0%</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>Proprietary</td>
</tr>
<tr>
<td>White Petrolatum</td>
<td>8009-03-8</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Lanolin</td>
<td>8006-54-0</td>
<td>Proprietary</td>
</tr>
</tbody>
</table>

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

4 FIRST-AID MEASURES

Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

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 15 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. Seek medical attention if adverse effect continues after removal to fresh air.
### 4 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.

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

**RECOMMENDATIONS TO PHYSICIANS:** This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product.

Because the hypotension associated with nitroglycerin overdose is the result of venodilatation and arterial hypovolemia, prudent therapy in this situation should be directed toward increase in central fluid volume. Passive elevation of the patient’s legs may be sufficient, but intravenous infusion of normal saline or similar fluid may also be necessary. The use of epinephrine or the arterial vasoconstrictors in this setting is likely to do more harm than good.

Methemoglobin levels are available from most clinical laboratories. The diagnosis should be suspected in patients who exhibit signs of impaired oxygen delivery despite adequate cardiac output and adequate arterial pO₂. Classically, methemoglobinemic blood is described as chocolate brown, without color change on exposure to air. When methemoglobinemia is diagnosed, the treatment of choice is methylene blue, 1–2 mg/kg intravenously.

### 5. FIRE-FIGHTING MEASURES

**FLASH POINT (closed cup):** > 110°C (230°F)

**AUTOIGNITION TEMPERATURE:** Not established.

**FLAMMABLE LIMITS (in air by volume, %):**
- Lower (LEL): Not applicable
- Upper (UEL): Not applicable

**FIRE EXTINGUISHING MATERIALS:** Use extinguishing media appropriate for surrounding fire.
- Water Spray: OK
- Carbon Dioxide: OK
- Foam: OK
- Dry Chemical: OK
- Halon: OK
- Other: Any "ABC" Class

**FIRE EXTINGUISHING MATERIALS NOT TO BE USED:** None known.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** This product must be substantially heated for ignition to become a hazard. When involved in an intense fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen oxides).

Less intense smoldering-type fires can cause Nitroglycerin to migrate and collect, leading to an explosion if sufficient heat is present. The Nitroglycerin component of this product is a powerful explosive and separation of it from the ointment vehicle is extremely hazardous. This product contains a known skin sensitizer, and so it poses a contact hazard to firefighters.

- **Explosion Sensitivity to Mechanical Impact:** Not sensitive.
- **Explosion Sensitivity to Static Discharge:** Not sensitive.

**SPECIAL FIRE-FIGHTING PROCEDURES:** 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

**SPILL AND LEAK RESPONSE:** Proper protective equipment should be used. In the event of a spill, clear the area and protect people. 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).

- **Small Spills:** Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.
- **Large Spills:** Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill areas should be restricted. 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. Dispersing mists or sprays into surrounding air and possibly inhaling them 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. Absorb spilled liquid using poly pads or other suitable absorbent material.
6. ACCIDENTAL RELEASE MEASURES (Continued)

SPILL AND LEAK RESPONSE (continued):

**Large Spills (continued):** Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Monitor area and confirm levels are below exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

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).

PART III How can I prevent hazardous situations from occurring?

7. HANDLING and USE

**WORK PRACTICES AND HYGIENE PRACTICES:** As with all chemicals, avoid getting this product ON YOU or IN YOU. 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 product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

**STORAGE AND HANDLING PRACTICES:** Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs. Ensure product is properly labeled. Store this product away from incompatible materials. Keep this product in original containers.

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

**SPECIFIC USE(S):** This product is a human pharmaceutical. Follow all industry standards for use of this product.

**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

**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 MSDS.

**EXPOSURE LIMITS/GUIDELINES:**

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EXPOSURE LIMITS IN AIR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ACGIH-TLVs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA mg/m³</td>
</tr>
<tr>
<td>Nitroglycerin</td>
<td>55-63-0</td>
<td>NE</td>
</tr>
<tr>
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</tr>
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</table>

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

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 910.132) 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 (1910.134-1998).

**EYE PROTECTION:** Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or Canadian CSA Standard Z94.3-07.

**HAND PROTECTION:** 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.
8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

BODY PROTECTION: During patient administration, use of lightweight cotton gown or other medical attire is recommended. 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 and the Canadian CSA Standard Z195-02, Protective Footwear.

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: Not established.
EVAPORATION RATE (nBuAc = 1): 0.005
FREEZING/MELTING POINT: Not established.
FROZEN PRESSURE (air = 1): Not established.
SOLUBILITY IN WATER: Not established.
SPECIFIC GRAVITY (water = 1): 0.90
ODOR THRESHOLD: Not established.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
APPEARANCE AND COLOR: This product is a pale yellow ointment with a mild petroleum jelly and lanolin odor.
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

STABILITY: This product is stable.
DECOMPOSITION PRODUCTS: Combustion: Carbon oxides and nitrogen 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.
HAZARDOUS POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Avoid heat and contact with incompatible chemicals.

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

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: Although unlikely due to form of product, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Skin contact may cause mild irritation. Eye contact may cause temporary blurred vision.

SKIN ABSORPTION: This product is designed to be absorbed through intact skin. Acute skin absorption overexposure can cause throbbing headache, confusion, moderate fever, vertigo, palpitations, visual disturbances, nausea, vomiting, colic, bloody diarrhea, fainting, air hunger, difficulty breathing, sweating, flushed skin, cold and clammy skin, methemoglobinemia (the inability of blood to adequate carry oxygen), heart block, irregular heartbeat, paralysis, coma, seizures, and death. Chronic skin absorption overexposure can cause methemoglobinemia.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product may cause nausea, vomiting, diarrhea, and symptoms such as those described under “Skin Absorption”.

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 of injection overexposure may include those described under “Skin Absorption”.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

| HEALTH HAZARD | 2 |
| FLAMMABILITY HAZARD | 1 |
| PHYSICAL HAZARD | 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
GENERAL TOXICOITY INFORMATION: Individuals who have had allergic reactions to products containing the active ingredient, Nitroglycerin, other organic nitrates, or any other components of this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance are described below:

For Males and Females: Persons using the product in therapeutic doses may experience headache, lightheadedness, fainting, crescendo angina, rebound high blood pressure, and methemoglobinemia.

IRRITANCY OF PRODUCT: This product may mildly irritate contaminated tissue.

SENSITIZATION OF PRODUCT: Individuals who have had allergic reactions to products containing the active ingredient, Nitroglycerin, other organic nitrates, Lanolin or any other components of this product may experience allergic reactions to this product. Symptoms of allergic reaction to the Lanolin component of this product can include rash, itching, swelling, and redness.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin and symptoms such as those described under “General Toxicity Information”. Accidental ingestion may cause nausea, vomiting, and diarrhea. Eye contact can cause temporary blurred vision.

Chronic: Chronic skin absorption or ingestion of this product caused by poor hygiene practices may cause methemoglobinemia.

TARGET ORGANS:


Chronic: Occupational Exposure: Skin. Therapeutic Doses: Skin, blood, circulatory system.

TOXICITY DATA: The toxicity data available for the active components of this product, Vitamins A and D, are presented in this MSDS. Additional data are available for the excipient components of this product, but are not presented in this MSDS; Contact Nycomed US, Inc. for more information.

NITROGLYCERIN:

Standard Draize Test (Skin-Rabbit) 500 mg/24 hours: Mild

TDLo (Oral-Woman) 8 µg/kg: Behavioral: headache; Cardiac: pulse rate; Gastrointestinal: nausea or vomiting

TDLo (Oral-Woman) 8 µg/kg: Cardiac: pulse rate; Vascular: BP lowering not characterized in autonomic section; Lungs, Thorax, or Respiration: other changes

TDLo (Oral-Woman) 5 mg/kg: Behavioral: general anesthetic; Cardiac: other changes; Kidney/Ureter/Bladder: incontinence

TDLo (Oral-Human) 0.0083 mg/kg: Cardiac: change in rate; Vascular: measurement of regional blood flow

TDLo (Oral-Human) 0.6 mg/kg/14 days intermittent: Cardiac: change in force of contraction, change in rate; Vascular: measurement of regional blood flow

TDLo (Intravenous-Mann) 7.14 mg/kg: Vascular: regional or general arteriole; Venous dilatation

TDLo (Intravenous-Mann) 51,429 µg/kg/2 days intermittent: Brain and Coverings: encephalitis; Sense Organs and Special Senses (Eye): miosis (papillary constriction); Sense Organs and Special Senses (Eye): corneal damage

TDLo (Skin-Woman) 32 mg/kg/20 days intermittent: Skin and Appendages: dermatitis, allergic (after topical exposure)

LDLo (Oral-Rat) 105 mg/kg: Behavioral: somnolence (general depressed activity)

LDLo (Oral-Mouse) 115 mg/kg: Behavioral: somnolence (general depressed activity)

LDLo (Oral-Arab-1:1) 1607 mg/kg

LDLo (Oral-Quinea Pig) 1450 mg/kg: Cardiac: other changes; Lungs, Thorax, or Respiration: cyanosis; Blood: methemoglobinemia-carboxyhemoglobin

LDLo (Oral-Mammal) 105 mg/kg

LDLo (Skin-Rat) > 29.200 µg/kg

LDLo (Skin-Mouse) > 35.200 µg/kg

LDLo (Skin-Rabbit) > 50 mg/kg

LDLo (Intraperitoneal-Rat) 102 mg/kg: Behavioral: ataxia; Respiration: dyspnea; Nutritional and Gross Metabolic: body temperature decrease

LDLo (Intraperitoneal-Mouse) 104 mg/kg: Behavioral: ataxia; Respiration: dyspnea; Nutritional and Gross Metabolic: body temperature decrease

LDLo (Intraperitoneal-Rabbit) 189 mg/kg

LDLo (Subcutaneous-Rat) 94 mg/kg: Behavioral: somnolence (general depressed activity)

LDLo (Subcutaneous-Mouse) 110 mg/kg: Behavioral: somnolence (general depressed activity)

NITROGLYCERIN (continued):

LDLo (Intravenous-Rat) 23,200 µg/kg: Behavioral: somnolence (general depressed activity), tremor, ataxia

LDLo (Intravenous-Mouse) 10,600 µg/kg: Behavioral: ataxia; Respiration: dyspnea; Nutritional and Gross Metabolic: body temperature decrease

LDLo (Intravenous-Mouse) 30 mg/kg

LDLo (Intravenous-Dog) 19 mg/kg: Eye: hemorrhage; Behavioral: convulsions or effect on seizure threshold; Respiration: dyspnea

LDLo (Intravenous-Rabbit) 45 mg/kg

LDLo (Unreported-Mammal) 230 mg/kg

LDLo (Intravenous-Cat) 5 mg/kg: Cardiac: change in conduction velocity; Vascular: BP lowering not characterized in autonomic section

LDLo (Subcutaneous-Cat) 150 mg/kg: Liver: other changes; Kidney/Ureter/Bladder: other changes in urine composition; Blood: normocytic anemia

LDLo (Subcutaneous-Rabbit) 400 mg/kg

TD (Oral-Rat) 438 gm/kg/2 years-continuous: Tumorigenic: equivocal tumorigenic agent by RTECS criteria; Liver: tumors; Reproductive: Tumorigenic effects: testicular tumors

TDLo (Oral-Rat) 1360 mg/kg: Brain and Coverings; other degenerative changes; Behavioral: tetany; Cardiac: cardiomyopathy including infarction

TDLo (Oral-Rat) 22.75 mg/kg/26 weeks-continuous: Cardiac: cardiomyopathy including infarction; EKG changes not diagnostic of specified effects; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects

TDLo (Oral-Rat) 4080 mg/kg/30 days-continuous: Cardiac: EKG changes not diagnostic of specified effects; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects

TDLo (Oral-Rat) 36,500 mg/kg/2 years-continuous: Tumorigenic: equivocal tumorigenic agent by RTECS criteria; Liver: tumors

TDLo (Oral-Rat) 70 mg/kg/26 weeks-continuous: Cardiac: cardiomyopathy including infarction; EKG changes not diagnostic of specified effects; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects

TDLo (Oral-Rat) 4080 mg/kg/30 days-continuous: Cardiac: EKG changes not diagnostic of specified effects, pulse rate increase, without fall in BP

NITROGLYCERIN (continued):

TDLo (Intravenous-Rat) 8 µg/kg: Vascular: BP lowering not characterized in autonomic section

TDLo (Intravenous-Rat) 1714.3 µg/kg/1 hour: Behavioral: tolerance

TDLo (Intravenous-Rat) 10 mg/kg: Behavioral: analgesia

TDLo (Intravenous-Rabbit) 340 µg/kg: Cardiac: change in rate; Vascular: BP lowering not characterized in autonomic section

TDLo (Intravenous-Cat) 1 mg/kg: Cardiac: other changes; Vascular: BP lowering not characterized in autonomic section; measurement of regional blood flow

TDLo (Intravenous-Dog) 300 mg/kg/30 days-continuous: Respiration: respiratory stimulation; Endocrine: changes in thymus weight; Blood: changes in platelet count

TDLo (Subcutaneous-Mouse) 6359 µg/kg: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

TDLo (Skin-Rat) 1500 mg/kg/30 days-continuous: Blood: pigmented or necrotized red blood cells, changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

TDLo (Skin-Rat) 25,480 mg/kg/26 weeks-continuous: Liver: other changes; Blood: pigmented or necrotized red blood cells, changes in platelet count

TDLo (Skin-Rat) 3640 mg/kg: female 17–21 days after conception lactating female 21 days post-birth: Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus), viability index (e.g., # alive at day 4 per # born alive)

TDLo (Skin-Rabbit) 400 mg/kg/5 weeks-continuous: Endocrine: changes in thymus weight; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol), changes in leukocyte (WBC) count

TDLo (Intraperitoneal-Rat) 825 mg/kg/33 days-continuous: Kidney/Ureter/Bladder: other changes in urine composition; Nutritional and Gross Metabolic: weight loss or decreased weight gain; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases

Nycomed US Inc.

11. TOXICOLOGICAL INFORMATION (Continued)
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NITROGLYCERIN (continued):

**Toxicity Data (continued):**

<table>
<thead>
<tr>
<th>Test</th>
<th>Route</th>
<th>Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDL0 (Intrapitoneal-Rat)</td>
<td>1575 mg/kg/13 weeks-intermittent</td>
<td>162 mg/kg</td>
<td>BID Litters: female 2 weeks pre-mating, 7 days after conception; Reproductive: Maternal Effects: Embryotoxicity; Effects on Embryo: Effects on Corpora Lutea; Effects on Fetuses: Embryonic Structures (e.g., placenta, umbilical cord); Specific Developmental Abnormalities (e.g., reduction in number of implants per female; total number of implants per corpora lutea); Effects on Embryo: other effects to embryo</td>
</tr>
<tr>
<td>TDL0 (Intrapitoneal-Rat)</td>
<td>775 mg/kg/15 days-intermittent</td>
<td>150 mg/kg</td>
<td>BID Litters: 2 weeks pre-mating, 7 days after conception; Reproductive: Maternal Effects: Fertility; Pre-implantation mortality (e.g., reduction number of implants per female; total number of implants per corpora lutea); Effects on Embryo: other effects to embryo</td>
</tr>
</tbody>
</table>

**Carcinogenic Information:** Studies to evaluate the carcinogenic potential of this product have not been performed. However, the Nitroglycerin component of this product is listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

- **Nitroglycerin:** MAK-38 (Substance for which in vitro tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories. Further studies are required before final classification can be made. A MAK or BAT value can be established, provided no genotoxic effects have been detected.)
- **Nitroglycerin:** USEPA, 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 active component of this product, Nitroglycerin, is rated as Pregnancy Category C (RISK CANNOT BE RULED OUT; Human evidence is lacking, but animal evidence is positive). Listed below is information concerning the effects of Nitroglycerin on animal or human reproductive systems.

- **Mutagenicity:** Studies have not been performed to evaluate the mutagenic potential of this product.
- **Embryotoxicity:** Studies have not been performed to evaluate the embryotoxic effects of this product.
- **Teratogenicity:** Studies have not been performed to evaluate the teratogenic effects of this product.
- **Reproductive Toxicity:** Long-term animal studies have not been performed to evaluate the effect on fertility of this product.

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.

**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.**

**Environmental Stability:** This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption or mobility. Environmental for components of this product are available as follows:

**Nitroglycerin:**
- Persistence and Biodegradability: If released to air, a vapor pressure of 2.0X10^-4 mm Hg at 20°C indicates Nitroglycerin will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase Nitroglycerin will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 15 days. Nitroglycerin absorbs light weakly in the environmental UV spectrum, but it is unknown weather it undergoes significant direct photolysis in the atmosphere. Particulate-phase Nitroglycerin will be removed from the atmosphere by wet and dry deposition. If released to soil, Nitroglycerin is expected to have moderate mobility based upon an estimated Koc of 180. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 4.3X10^-17 Pa*m^3/mol. If released into water, Nitroglycerin is expected to adsorb to suspended solids and sediment based upon the estimated Koc. Nitroglycerin was completely biodegraded in 13 days using river water and river water/sediment microcosms obtained from a river near a munitions facility. Volatilization from water surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 4.3X10^-17 Pa*m^3/mol. Hydrolysis may be important under alkaline conditions based on half-lives of 37 and 96 days at pH 9 and 25 and 18°C, respectively. Nitroglycerin may undergo photolysis in sunlight surface waters. The photolysis half-life for Nitroglycerin in distilled water, filtered river water and filtered pond water exposed to sunlight were 116, 57 and 73 days, respectively. Bioconcentration: An estimated BCF of 4 was calculated for Nitroglycerin, using a log Kow of 1.52 and a regression-derived equation. According to a classification scheme, this CEF suggests the potential for bioconcentration in aquatic organisms is low.

- Soil Adsorption/Mobility: The Koc of Nitroglycerin is estimated as 180, using a log Kow of 1.62 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that Nitroglycerin is expected to have moderate mobility in soil.

**Effect of Material on Plants or Animals:** 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 plant and animal life, especially in large quantities.
12. ECOLOGICAL INFORMATION (Continued)

**EFFECT OF CHEMICAL ON AQUATIC LIFE:** Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

**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 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

**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.

15. REGULATORY INFORMATION

**UNITED STATES REGULATIONS:**

**U.S. SARA REPORTING REQUIREMENTS:** The components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act, as follows:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>SARA 302 (40 CFR 355, Appendix A)</th>
<th>SARA 304 (40 CFR Table 302.4)</th>
<th>SARA 313 (40 CFR 372.65)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitroglycerin</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**U.S. SARA THRESHOLD PLANNING QUANTITY:** There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS 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):** Nitroglycerin = 10 lb (4.54 kg)

**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):** The components of this product are not on the California Proposition 65 lists.

**OTHER U.S. FEDERAL REGULATIONS:** Not applicable.

**ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):** CAUTION! MAY CAUSE ALLERGIC REACTION. MAY CAUSE SKIN AND EYE IRRITATION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, 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 from allergic reaction, 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.
Nycomed US Inc.

15. REGULATORY INFORMATION (continued)

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 DSSL/NDSL Inventory.
CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LIST: The components of this product are not on the CEPA Priorities Substances Lists.
OTHER CANADIAN REGULATIONS: Not applicable.
CANADIAN WHMIS CLASSIFICATION AND SYMBOLS:
Class D2P Poisonous and infectious material (Sensitization)

16. OTHER 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 Altana, Inc.'s knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness is 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.

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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 an substance.

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

DG 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 point 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.

DG 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 to be considered 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.

DG MAK Pregnancy Risk Group Classification (continued): 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.

EXPOSURE LIMITS IN AIR (continued):

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 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 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-hour 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-hour (TLV, PEL) or up to a 10-hour (REL) workday and a 40-hour workweek.

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 HAZARDS: 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, < 5. Eye Irritation: Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. Oral Toxicity LD<sub>50</sub> Rat > 5000 mg/kg. Dermal Toxicity LD<sub>50</sub> Rat or Rabbit: > 2000 mg/kg. Inhalation Toxicity 4-hrs LC<sub>50</sub> Rat: > 20 mg/L. 1 Slight Hazard: Minor reversible injury may occur; may irritate the skin 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<sub>50</sub> Rat: > 500–5000 mg/kg. Dermal Toxicity LD<sub>50</sub> Rat or Rabbit: > 1000–2000 mg/kg. Inhalation Toxicity LC<sub>50</sub> 4-hrs Rat: > 20–20 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 injury may occur; effects clearing in > 21 days. Oral Toxicity LD<sub>50</sub> Rat: > 50–500 mg/kg. Dermal Toxicity LD<sub>50</sub> Rat or Rabbit: > 200–1000 mg/kg. Inhalation Toxicity LC<sub>50</sub> 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.
DEFINITION OF TERMS (Continued):

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD (continued): 2 (continued) Explosives: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the container. Some fragments of the container and/or packaging may be expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. Pressured 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 2:1 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean burning time less than or equal to the mean burning time 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 decomposition at room temperature 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 where a fire hazard and either a minor blast hazard or a minor projection hazard or both, do not exist. Corrosive, Water-reactive 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: Additional rating of: No 4. Water-reactives: materials that readily ignite or react after exposure to water. 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/kg. Materials with an LC$_{50}$ 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 of 5,000 ppm to 50,000 ppm; or dusts and mists with an LD$_{50}$ for acute inhalation toxicity greater than 10 mg/kg but less than or equal to 200 mg/kg. Materials with an LC$_{50}$ 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 LC$_{50}$ 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 300 ppm but less than or equal to 5000 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 3 or 4. Materials with an LC$_{50}$ for acute oral toxicity greater than 50 mg/kg but less than or equal to 500 mg/kg. Materials with an LC$_{50}$ for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Materials with an LD$_{50}$ for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. Materials that, under emergency conditions, can cause permanent or residual injury. Gases with an LC$_{50}$ for acute inhalation toxicity greater than 1000 ppm but less than or equal to 3000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than its LC$_{50}$ for acute inhalation toxicity, if its LC$_{50}$ is less than or equal to 1000 ppm and that does not meet the criteria for either 3 or 4. Materials with an LC$_{50}$ for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC$_{50}$ for acute inhalation toxicity greater than 1000 ppm but less than or equal to 3000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than its LC$_{50}$ for acute inhalation toxicity, if its LC$_{50}$ is less than or equal to 1000 ppm and that does not meet the criteria for either 3 or 4. Materials with an LC$_{50}$ for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC$_{50}$ for acute inhalation toxicity greater than 1000 ppm but less than or equal to 3000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than its LC$_{50}$ for acute inhalation toxicity, if its LC$_{50}$ is less than or equal to 1000 ppm and that does not meet the criteria for either 3 or 4. Materials with an LC$_{50}$ for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. Materials that, under emergency conditions, can cause serious or permanent injury.
DEFINITION OF TERMS (continued):

LDo: 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.

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 Kow or Log Koc: Coefficient of Oil/Water Distribution is used to assess a substance’s behavior in the environment.

REGULATORY INFORMATION:

U.S.:


Other Information includes information on the precautionary warnings that appear on the material’s package label.

CANADA: