

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078942192

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

078942193 078942194 078942195



## Safety Data Sheet

Preparation Date: 02/06/2020

Revision Date: 02/06/2020

Revision Number: 01

### Section 1 - Chemical Product and Company Identification

**PRODUCT IDENTIFIER/TRADE/MATERIAL NAME:** Clomipramine Hydrochloride Tablets

**DESCRIPTION:** Clomipramine Hydrochloride Tablets 5 mg, 20 mg, 40 mg, and 80 mg

**OTHER DESIGNATIONS:** NDC 86039-113-30, NDC 86039-114-30, NDC 86039-115-30, NDC 86039-116-30

**IPUAC NAME FOR ACTIVE INGREDIENT:** 3-(2-chloro-5,6-dihydrobenzo[b][1]benzazepin-11-yl)-N,N-dimethylpropan-1-amine.

**CHEMICAL CLASS FOR ACTIVE INGREDIENT:** Dibenzazepine

**THERAPEUTIC CLASS:** Tricyclic antidepressant

**HOW SUPPLIED:** Brown, modified capsule shaped tablets.

**FORMULA:**  $C_{19}H_{23}ClN_2 \cdot HCl$  M.W. = 351.31

**PRODUCT USE:** To treat separation anxiety in dogs greater than 6 months of age, inappropriate barking or destructive behavior, as well as inappropriate elimination.

**MANUFACTURED FOR:**

Mizner Bioscience, LLC  
225 NE Mizner Blvd, Suite 760  
Boca Raton, FL 33432

**EMERGENCY TELEPHONE NUMBER:** (561)-570-1875

**Section 2 - Hazards 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 exempted 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 supplied as a brown, meat flavored, capsule shaped tablet.

**Health Hazards:** In the workplace, exposure via inhalation and eye or skin contact may cause irritation. Overdose in humans causes anticholinergic effects including effects on the central nervous (e.g., convulsions) and cardiovascular (e.g., arrhythmia, tachycardia) systems.


**Flammability Hazards:** This product requires substantial pre-heating before ignition occurs. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides (NO<sub>x</sub>), and hydrogen chloride gas).

**Reactivity Hazards:** This product is not reactive.

**Environmental Hazards:** Release of large quantity to the environment may be harmful to plants and animals and aquatic organisms.

**Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

**Section 3 - Composition / Information on Ingredients**

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL CLASSIFICATION EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
<b>ACTIVE INGREDIENT</b>				
Clomipramine Hydrochloride	17321-77-6	241-344-3		<b>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)</b> Acute toxicity, Oral (Category 4), H302 Reproductive toxicity (Category 2), H361 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410 <b>GHS Label elements, including precautionary statements</b>  Pictogram   Signal word Warning <b>Hazard statement(s)</b> H302 Harmful if swallowed. H361 Suspected of damaging fertility or the unborn child. H410 Very toxic to aquatic life with long lasting effects. <b>Precautionary statement(s)</b> P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P264 Wash skin thoroughly after handling. P270 Do not eat, drink, or smoke when using this product. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage. P405 Store locked up. P501 Dispose of contents/ container to an approved waste disposal plant.  <b>Hazards not otherwise classified (HNOC) or not covered by GHS</b> none
<b>EXCIPIENTS</b>				
Colloidal Silicon Dioxide	112945-52-5	601-216-3	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Crospovidone Polyplasdone	9003-39-8	618-363-4	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable
Dry Beef Flavor	Not listed	Not listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable
Lactose Monohydrate	64044-51-5	613-418-9	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Povidone K-30	616-45-5	210-483-1	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.

**Section 4 - First Aid Measures**

**DESCRIPTION OF FIRST AID MEASURES:** Contaminated individuals must be taken for medical attention if any adverse effects occur. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

**SKIN EXPOSURE:** No specific effect is expected from skin contact. If this product contaminates the skin and adverse effect occurs, begin decontamination with running water. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

**EYE EXPOSURE:** If this product enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect continues after flushing.

**INHALATION:** If dusts of this product are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.

**INGESTION:** This product is intended to be swallowed; however, if an overdose occurs **CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION.** If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. 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 emergency medical attention.

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** Persons with a history of hypersensitivity to clomipramine hydrochloride or other tricyclic antidepressants. Persons taking monoamine oxidase inhibitors (MAOIs). Persons being treated with linezolid or intravenous methylene blue should be aware of an increased risk of serotonin syndrome.

**INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED:** Treat symptoms and eliminate exposure. Persons with hypersensitivity reaction should receive immediate medical attention. Persons developing hypersensitivity reactions should receive immediate medical attention.

**Section 5 - Fire Fighting Measures**

**FLASH POINT:** Not available.

**AUTOIGNITION TEMPERATURE:** Not available.

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

**FIRE EXTINGUISHING MEDIA:** Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

**UNSUITABLE FIRE EXTINGUISHING MEDIA:** None known.

**SPECIAL HAZARDS ARISING FROM THE SUBSTANCE:** This product must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including aluminum, carbon, sodium, sulfur, magnesium, and nitrogen oxides, and hydrogen chloride).

**Explosion Sensitivity to Mechanical Impact:** Not applicable.

**Explosion Sensitivity to Static Discharge:** Not sensitive.

**SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS:** Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and thoroughly rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

**Section 6 - Accidental Release Measures**

**PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:** Spill kits, clearly labeled, should be kept in or near preparation and operational 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, a small scoop to collect glass fragments (if applicable) and two large waste disposal bags. Absorbents should be able to be incinerated. Avoid generating dusts of this material during spill response procedures as described below.

**PROTECTIVE EQUIPMENT:**

**Small Spills/Spills in Hoods:** Personnel wearing nitrile or other appropriate gloves, lab coat or other protective clothing and eye protection should immediately clean incidental spills of less than 5 mL.

**Large Spills:** Use proper protective equipment, including double nitrile or appropriate gloves and protective clothing (i.e., disposable Tyvek coveralls). When there is any danger of airborne dusts being generated, use a 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:**

**Cleanup of Small Spills:** Solids should be gently covered with wet 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.

**Spills in Hoods:** Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the HEPA filter of a hood is contaminated, label the unit "Do not use-contaminated" and have trained personnel wearing appropriate protective equipment change and dispose of the filter properly as soon as possible.

**Large Spills:** Restrict access to the spill areas. For spills of greater than 5 mL, limit spread by gently covering with absorbent sheets, spill-control pads or pillows. Be sure not to generate dusts. The dispersion of dusts 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 material and report spill per regulatory requirements.

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

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

**Section 7 - Handling and Storage**

**PRECAUTIONS FOR SAFE HANDLING:** All employees who handle this material should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat or drink while handling this material. After handling this material, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Open containers slowly on a stable surface in areas that have been designated for use of this material. Minimize all exposures to this material. Avoid generation of dusts. Areas in which this material is used should be wiped down, so that this material does not accumulate.

**CONDITIONS FOR SAFE STORAGE:** Containers of this material 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). 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. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.

**SPECIFIC END USE(S):** This product is an animal 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. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water.



## Section 8 - Exposure Controls / Personal Protection

### EXPOSURE LIMITS/CONTROL PARAMETERS:

**Ventilation and Engineering Controls:** General: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately.

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELS		NIOSH	OTHER
		TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	IDLH mg/m <sup>3</sup>	mg/m <sup>3</sup>
Clomipramine Hydrochloride	17321-77-6	NE	NE	NE	NE	NE	NE	NE	NE
Colloidal Silicon Dioxide	112945-52-5	NE	NE	NE	NE	6 mg/m <sup>3</sup>	NE	NE	NE
Crospovidone Polyplasdone	9003-39-8	10 Inhalable fraction 3 resp. fract.	NE	15 (total dust) 5 (resp. fract.)	NE	NE	NE	NE	NE
Dry Beef Flavor	Not listed	NE	NE	NE	NE	NE	NE	NE	NE
Lactose Monohydrate	61044-51-5	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate	557-04-0	10	NE	10	NE	NE	NE	NE	OSHA PEL 15 (total dust), 5 (resp. fract.)
Microcrystalline Cellulose	9004-34-6	NE	NE	15 (total dust) 5 (resp. fract.)	NE	NE	NE	NE	NE
Povidone K-30	616-45-5	NE	NE	NE	NE	NE	NE	NE	NE

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

**INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS:** In addition to the exposure limit values cited in this section, other exposure limits have been established by various countries for the components of this product. Below are available limits for the active ingredient and excipient components. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

**MICROCRYSTALLINE CELLULOSE:**

Australia: TWA = 10 mg/m<sup>3</sup>  
 Belgium: TWA = 10 mg/m<sup>3</sup>  
 Canada-Ontario: TWA = 10 mg/m<sup>3</sup>  
 Canada-Quebec: TWA = 10 mg/m<sup>3</sup>  
 France: TWA = 10 mg/m<sup>3</sup> Inhalable aerosol  
 Ireland: TWA = 10 mg/m<sup>3</sup> Inhalable fraction  
 Ireland: STEL = 20 mg/m<sup>3</sup> Inhalable fraction 15 minute reference period  
 Ireland: TWA = 4 mg/m<sup>3</sup> Respirable fraction  
 Latvia: TWA = 2 mg/m<sup>3</sup>

**MICROCRYSTALLINE CELLULOSE (continued):**

New Zealand: TWA = 10 mg/m<sup>3</sup> Inhalable dust, no asbestos  
 Singapore: TWA = 10 mg/m<sup>3</sup>  
 South Korea: TWA = 10 mg/m<sup>3</sup>  
 Spain: TWA = 10 mg/m<sup>3</sup> Inhalable aerosol  
 Switzerland: TWA = 10 mg/m<sup>3</sup> respirable aerosol  
 United Kingdom: TWA = 10 mg/m<sup>3</sup> Inhalable aerosol  
 United Kingdom: STEL = 20 mg/m<sup>3</sup> Inhalable aerosol  
 United Kingdom: TWA = 4 mg/m<sup>3</sup> respirable aerosol

**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), equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-02), 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.*



## Safety Data Sheet

Preparation Date: 02/06/2020

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**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. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. 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.

**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.

### Section 9 - Physical & Chemical Properties

The following information is for the product as a whole.

Appearance	light brown speckled modified capsule shaped tablets	Vapor pressure	Not applicable
Physical State	Solid	Vapor density	Not applicable
Odor:	Meaty	Relative density	Not applicable
Melting point/freezing point	Not available	Solubility(ies)	Miscible.
Initial boiling point and boiling range	Not available	Partition coefficient (n-octanol/water)	Not available
Flash point	Not applicable	Auto-ignition temperature	Not available
Evaporation rate	Not applicable	Decomposition temperature	Not available.
Flammability (solid, gas)	Not available	Viscosity	Not applicable.
Upper/lower flammability or explosive limits		Explosive properties	Not available.
Flammability limit – lower (%)	Not available	Oxidizing properties	Not available.
Flammability limit – upper (%)	Not available		

The following information is for the active ingredient, clomipramine hydrochloride.

Appearance	Form: powder.	Vapor pressure	No data available
Odor	odorless	Vapor density	No data available
Odor Threshold	No data available	Relative density	No data available
pH	3.5 - 5 at 100 g/l	Water solubility	125 g/l - soluble
Melting point/freezing point	Melting point/range: 189 - 192 °C (372 - 378 °F)	Partition coefficient: n- octanol/ water	No data available
Initial boiling point and boiling range	No data available	Auto-ignition temperature	350 °C (662 °F)
Flash Point:	No data available	Decomposition temperature:	No data available
Evaporation rate	No data available	Viscosity	No data available
Flammability (solid, gas)	No data available	Explosive properties	No data available
Upper/lower flammability or explosive limits	No data available	Oxidizing properties	No data available

### Section 10 - Chemical Stability & Reactivity Information

**REACTIVITY/CHEMICAL STABILITY:** Stable under normal conditions.

**DECOMPOSITION PRODUCTS:** *Combustion:* Products of thermal decomposition may include carbon, sodium, sulfur, magnesium, and nitrogen oxides, and hydrogen chloride. *Hydrolysis:* None known.

**MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:** Incompatible with strong oxidizing agents, and strong acids.

**POSSIBILITY HAZARDOUS POLYMERIZATION:** Will not occur.

**CONDITIONS TO AVOID:** Exposure to or contact with extreme temperatures, incompatible chemicals.

**Section 11 - Toxicological Information**

**SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE:** The main route of occupational exposure to this product is via inhalation of dusts and skin contact. The anticipated symptoms of exposure, by route of exposure are described further in this section.

**INHALATION:** Inhalation of airborne dusts of this product may slightly irritate the nose, throat, and lungs. In addition, inhalation may result in adverse effects as described under 'Other Potential Health Effects'.

**CONTACT WITH SKIN or EYES:** It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness. Symptoms of eye contact can include redness, pain, and watering (mechanical irritation).

**SKIN ABSORPTION:** No data is available on potential absorption of this material through intact skin.

**INGESTION:** Ingestion of this product (i.e., through poor hygiene practices) may be harmful or toxic by ingestion. Ingestion may cause anticholinergic effects including effects on the central nervous (e.g., convulsions) and cardiovascular (e.g., arrhythmia, tachycardia) systems. Other effects may occur as described under 'Other Potential Health Effects'.

**INJECTION:** Not a potential route of exposure.

**OTHER POTENTIAL HEALTH EFFECTS:**

Other potential health effects may include: suicide risk, serotonin syndrome, angle-closure glaucoma, seizures, and drug rash with eosinophilia and systemic symptoms (DRESS).

**HEALTH EFFECTS OR RISKS FROM EXPOSURE:**

**Acute:** Airborne dusts from product may cause irritation if inhaled and in contact with skin or eyes. Accidental ingestion may be harmful or cause toxic effects. Acute exposure may cause effects described in "Other Potential Health Effects".

**Chronic:** Chronic exposure may lead to symptoms described under 'Other Potential Health Effects'. No chronic effects have been reported from workplace exposure.

**TARGET ORGANS:** It is anticipated that for Occupational Exposure the target organs are: Acute: Skin, eyes, respiratory system. Chronic: None reported. In therapeutic use, this product may have an impact on the body systems listed under 'Other Potential Health Effects'.

**Section 12 - Ecological Information**

**ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.**

**MOBILITY:** This product has not been tested for mobility in soils. No predicted values are available.

**PERSISTENCE AND BIODEGRADABILITY:** This product has not been tested for persistence and biodegradability. No predicted values are available.

**BIO-ACCUMULATION POTENTIAL:** This product has not been tested for bio-accumulation potential.

**ECOTOXICITY:** At high levels, this product may be harmful or fatal to contaminated plant and animal-life (especially if large quantities are released). This product has not been tested for aquatic toxicity. No aquatic toxicity data are available for components of this product.

**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.

**OTHER ADVERSE EFFECTS:** The components of this product are not listed as having ozone depletion potential.

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

**Section 13 - Disposal Considerations**

**WASTE TREATMENT/DISPOSAL METHODS:** 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. All protective clothing, gloves, and disposable materials used in the manufacture or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. 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. Incineration or other approved methods of disposal are recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

**DISPOSAL CONTAINERS:** Unless the waste is going to an approved landfill, the 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.

**U.S. EPA WASTE NUMBER:** Not applicable.

**EWC WASTE CODE:** Wastes from Human or Animal Health Care or Related Research: 18 01 09: Medicines Other Than Those Mentioned in 18 01 08.

**Section 14 - Transportation Information**

**U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS:** This product is not classified as dangerous goods, per U.S. DOT regulations, under 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 is not classified as Dangerous Goods, by 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 is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

**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

**Section 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:** 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 lbs. (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 under Food and Drug Administration standards; it is not subject to requirements under TSCA.

**CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):** No component of this product is on the California Proposition 65 Lists. US Federal Regulations.

**CANADIAN REGULATIONS:**

**CANADIAN DSL INVENTORY STATUS:** This product is regulated by the Therapeutic Products Program (TPP) of Health Canada; it is exempt from the requirements of CEPA.

**CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:** The components of this product are not on the CEPA Priorities Substances Lists.

**CANADIAN WHMIS CLASSIFICATION AND SYMBOL:** 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 COMMUNITY REGULATIONS:**

**SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT:** When formulated in a finished medicinal product for human use, this material is 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.

**Section 16 - Other Information**

**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 exempted from classification and other criteria of 1272/2008.

**EU LABELING AND CLASSIFICATION 67/548/EEC:** 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.

**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.

**REVISION DETAILS:** New

**DEFINITION OF TERMS**

For information on medical terms used in this SDS consult an on-line database such as Medline Plus:

<http://www.nlm.nih.gov/medlineplus/druginformation.html>.

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

**EXPOSURE LIMITS IN AIR:**

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

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

**ACGIH** - American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits. **TLV** - Threshold Limit Value - an airborne concentration of a substance which 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 Time Weighted Average (**TWA**), the 15-minute Short Term Exposure Limit, and the instantaneous Ceiling Level (**C**). Skin absorption effects must also be considered.

**DFG MAK Germ Cell Mutagen Categories:** **1:** Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed humans. **2:** Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed mammals. **3A:** Substances which have been shown to induce genetic damage in germ cells of human or 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 which 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 which 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.

**EXPOSURE LIMITS IN AIR (continued):**

**DFG MAK Pregnancy Risk Group Classification: Group A: (continued):**

**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-Permissible Exposure Limit:** 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 there is a danger of cutaneous absorption.

**STEL-Short Term Exposure Limit:** 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:** 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.

**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. PII or Draize = "0". *Eye Irritation:* Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. 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; slightly or mildly irritating. *Skin Irritation:* Slightly or mildly irritating. *Eye Irritation:* Slightly or mildly irritating. *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:* > 2-20 mg/L; **2 (Moderate Hazard):** Temporary or transitory injury may occur. *Skin Irritation:* Moderately irritating; primary irritant; sensitizer. PII or Draize > 0, < 5. *Eye Irritation:* Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. Draize > 0, < 25. *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>*



**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM****HAZARD RATINGS (continued):****HEALTH HAZARD (continued):**

*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 destroy dermal tissue, cause skin burns, dermal necrosis. PII or Draize > 5-8 with destruction of tissue. *Eye Irritation:* Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD<sub>50</sub> Rat.* > 1-50 mg/kg. *Dermal Toxicity LD<sub>50</sub> Rat or Rabbit.* > 20-200 mg/kg. *Inhalation Toxicity LC<sub>50</sub> 4-hrs Rat.* > 0.05-0.5 mg/L.); **4** (Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure. *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<sub>50</sub> Rat.* < 1 mg/kg. *Dermal Toxicity LD<sub>50</sub> Rat or Rabbit.* < 20 mg/kg. *Inhalation Toxicity LC<sub>50</sub> 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 require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. Including:

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] (e.g. OSHA Class IIIB, or; 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 in air, Including: 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; Solids and semisolids 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, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] [e.g. 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]; 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 which will burn readily, including: 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] [e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C [130°F] or below [e.g. pyrophoric]).

**PHYSICAL HAZARD: 0** (*Water Reactivity:* Materials that do not react with water. *Organic Peroxides:* Materials that are normally stable, even

**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM****HAZARD RATINGS (continued):****PHYSICAL HAZARD (continued):**

under fire conditions and will not react with water. *Explosives:* Substances that are Non-Explosive. *Unstable Compressed Gases:* No Rating. *Pyrophorics:* No Rating. *Oxidizers:* No "0" rating allowed. *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. *Explosives:* Division 1.5 & 1.6 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; *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 explosive hazard. 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 – Explosive substances where the explosive effect 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:* Packaging Group II *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. *Unstable Reactives:* Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential 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 1.2 – Explosive substances 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:* Packaging Group I *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,

**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM****HAZARD RATINGS (continued):****PHYSICAL HAZARD (continued):**

condense or self-react at ambient temperature and/or pressure and have a moderate potential 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-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 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<sub>50</sub> for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC<sub>50</sub> for acute inhalation toxicity greater than 200 mg/L. Materials with an LD<sub>50</sub> for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD<sub>50</sub> 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<sub>50</sub> for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC<sub>50</sub> for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD<sub>50</sub> 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<sub>50</sub> 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 temporary incapacitation or residual injury. Gases with an LC<sub>50</sub> 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<sub>50</sub> for acute inhalation toxicity, if its LC<sub>50</sub> 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<sub>50</sub> for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD<sub>50</sub> 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<sub>50</sub> for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. Dusts and mists with an LC<sub>50</sub> for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD<sub>50</sub> 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<sub>50</sub> for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **3** (materials that, under emergency conditions, can cause serious or permanent injury): Gases and vapors whose LC<sub>50</sub> for acute inhalation toxicity is greater than

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

1,000 ppm but less than or equal to 3,000 ppm. Dusts and mists whose LC<sub>50</sub> for acute inhalation toxicity is greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials whose LD<sub>50</sub> for acute dermal toxicity is greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials whose LD<sub>50</sub> for acute oral toxicity is greater than 5 mg/kg but less than or equal to 50 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC<sub>50</sub> for acute inhalation toxicity, if its LC<sub>50</sub> is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials that are respiratory irritants. Cryogenic gases that cause frostbite and irreversible tissue damage. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials that are corrosive to the skin. **4** (materials that, under emergency conditions, can be lethal): Gases and vapors whose LC<sub>50</sub> for acute inhalation toxicity less than or equal to 1,000 ppm. Dusts and mists whose LC<sub>50</sub> for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD<sub>50</sub> for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD<sub>50</sub> for acute oral toxicity is less than or equal to 5 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC<sub>50</sub> for acute inhalation toxicity, if its LC<sub>50</sub> is less than or equal to 1000 ppm.

**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 accordance with Annex D. **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 accordance with Annex D. 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 *Recommendation 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 non-combustible liquid/solid content of more than 85 percent 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 a 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). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent. Most ordinary combustible materials. **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 diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly

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

but that generally do not form explosive mixtures in air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** 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, though unaffected by ambient temperatures, are readily ignited under almost all conditions: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that, on account of their physical form or environmental conditions, can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with a representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are 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 percent 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 estimated 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 estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL.

Materials that readily undergo violent chemical change at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) 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 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. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures.

**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 vapors to form an ignitable mixture with air. Auto ignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

**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. Definitions of some terms used in this section are: **LD<sub>50</sub>** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC<sub>50</sub>** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m<sup>3</sup>** 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. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, and **LDo**, or **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Sub rankings (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:****REPRODUCTIVE TOXICITY INFORMATION:**

A **mutagen** is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An **embryotoxin** is a chemical which 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 which causes damage to a developing fetus, but the damage does not propagate across generational lines. A **reproductive toxin** is any substance which interferes in any way with the reproductive process.

**United States FDA Pharmaceutical Pregnancy Categories:**

**Pregnancy Category A:** Adequate and well-controlled human studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).

**Pregnancy Category B:** Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.

**Pregnancy Category C:** Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. **Pregnancy Category D:** There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. **Pregnancy Category X:** Studies in animals or humans have demonstrated fetal abnormalities

**REPRODUCTIVE TOXICITY INFORMATION****(continued):**

and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits. **Pregnancy Category N:** FDA has not classified this drug.

**ECOLOGICAL INFORMATION:**

EC is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. **TL<sub>m</sub>** = median threshold limit; Coefficient of Oil/Water Distribution is represented by **log K<sub>OW</sub>** or **log K<sub>OC</sub>** and is used to assess a substance's behavior in the environment.

**REGULATORY INFORMATION:****U.S. and CANADA:**

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

**EUROPEAN and INTERNATIONAL:**

**The DFG:** This is the Federal Republic of Germany's Occupation Health Agency, similar to the U.S. OSHA. **EU** is the European

**EUROPEAN and INTERNATIONAL (continued):**

Community (formerly known as the EEC, European Economic Community). **EINECS:** This is the European Inventory of Now-Existing Chemical Substances. The **ARD** is the European Agreement Concerning the International Carriage of Dangerous Goods by Road and the **RID** are the International Regulations Concerning the Carriage of Dangerous Goods.