



MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA and ANSI Standards

1. PRODUCT IDENTIFICATION

TRADE/MATERIAL NAME: Elspar®

DESCRIPTION: Asparaginase

NDC DESIGNATIONS: NDC# 67386-411-51

CHEMICAL NAME: L-Asparagine Amidohydrolase, Type EC-2 derived from *Escherichia coli*

CHEMICAL FAMILY: Amidohydrolase

HOW SUPPLIED: 10,000 IU as lyophilized powder in single-use vial for Intramuscular or Intravenous Use

FORMULA: C₁₃₇₇H₂₂₀₈N₃₈₂O₄₄₂S₁₇

PRODUCT USE:

Pharmaceutical for Human Use

SUPPLIER:

LUNDBECK INC.

ADDRESS:

Four Parkway North
Deerfield, IL 60015, United States

BUSINESS PHONE/GENERAL MSDS INFORMATION:

1 (866) 337-6996

EMERGENCY PHONE (U.S./NORTH AMERICA):

CHEMTREC: 1-800-424-9300 (U.S. and Canada)

info@lundbeck.com

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:

Product Description: This product is supplied as an odorless, white, lyophilized powder.

Health Hazards: The chief health hazard associated with overexposures during normal occupational use and handling is irritation of contaminated tissues. There are reports of anaphylactic reactions from persons taking therapeutic doses of products containing L-Asparaginase. **Flammability Hazards:** This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including e.g., carbon oxides, nitrogen oxides, and sulfur oxides).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for the situation to which they respond.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following information describes the symptoms of exposure by route of exposure.

ACUTE TOXICITY - DERMAL: Not determined.

ACUTE TOXICITY - INHALATION: Inhalation of airborne dusts may temporarily irritate the respiratory system and cause chills, fever, slight respiratory distress, and diarrhea.

CORROSIVITY: Not corrosive.

DERMAL IRRITATION: Not irritating.

EYE IRRITATION: Not determined. Eye contact may cause mechanical irritation.

SENSITIZATION: Persons who are hypersensitive to this product or to other *Escherichia coli*-derived L-Asparaginases may have an allergic reaction to this drug.

SKIN ABSORPTION: Not determined.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product may cause irritation, nausea, diarrhea, vomiting, chills, dizziness, chest pain, heart failure, and pulmonary edema.

INJECTION: If accidentally injected, symptoms of acute injection overexposure can include central nervous system thrombosis, pancreatitis, glucose intolerance, coagulopathy, hyperglycemia, hyperbilirubinemia, and elevated transaminases. Persons who are hypersensitive to this product or to other *Escherichia coli*-derived L-Asparaginases may have an allergic reaction to this drug. Symptoms of an allergic reaction include anaphylactic reactions, skin rashes, hives, joint pain, and respiratory distress.

2. HAZARD IDENTIFICATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-*Therapeutic Doses:*

Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included the following: central nervous system thrombosis, pancreatitis, glucose intolerance, coagulopathy, hyperglycemia, hyperbilirubinemia, and elevated transaminases.

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 irritation of contaminated tissues or symptoms described under "Ingestion" if swallowed. In the event of acute exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result.

Chronic: Persons who are hypersensitive to this product or to other *Escherichia coli*-derived L-Asparaginases may have an allergic reaction to this drug. In the event of chronic exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result. See Section 11 (Toxicological Information, for additional information).

TARGET ORGANS: **Acute:** Occupational Exposure: None known. Therapeutic Doses: Liver, pancreas. **Chronic:** Occupational Exposure: None known. Therapeutic Doses: Liver, pancreas, respiratory system.



HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	1
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FLAMMABILITY HAZARD	(RED)	1
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PHYSICAL HAZARD	(YELLOW)	0
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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

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% w/v
L-Asparaginase (active ingredient)	9015-68-3	31%
Mannitol	87-78-5	69%

4. FIRST-AID MEASURES

Persons developing hypersensitivity reactions to preparations containing L-Asparaginase should receive immediate medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of container label, Product Insert and MSDS to physician or health professional with the affected individual.

SKIN EXPOSURE: Basic hygiene should prevent any problems. If contact with the skin causes irritation, rinse with running water. Remove contaminated clothing, taking care not to contaminate eyes. If an adverse reaction occurs, seek medical attention.

EYE EXPOSURE: If product contacts the eyes rinse eyes thoroughly. If irritation occurs, open victim's eyes while under gently running water. Use sufficient force to open eyelids and then "roll" while flushing eyes. Minimum flushing is for 15 minutes if the exposure has resulted in an adverse effect, seek medical attention.

INHALATION: In unlikely event that inhalation occurs and adverse effect occurs, 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.

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: There is no information on pre-existing medical conditions that may be aggravated by occupational exposure to this product. With therapeutic use, pre-existing hypersensitivity to L-Asparaginase, pancreatitis, and liver impairment may be aggravated by clinical use of 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. Treatment of overdosage is mainly supportive.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS (in air by volume, %):

Lower (LEL): Not applicable.

Upper (UEL): Not applicable.

FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding fire. Fire extinguishing materials that can be used against fires of this product include carbon dioxide, dry chemical powder, halon, 'ABC' Class, or appropriate foam.

FIRE EXTINGUISHING MATERIALS NOT TO BE USED: None known.

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product must

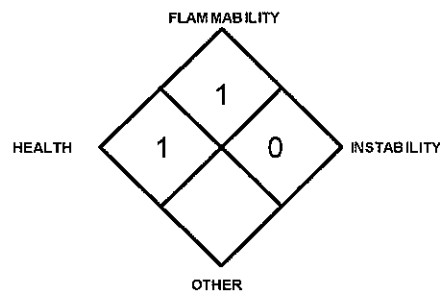
be substantially pre-heated before ignition can occur. When involved in a fire, the products of combustion or thermal decomposition can include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, and sulfur oxides). Accumulated dusts of this product can create a serious hazard of explosion. If the fire scene includes high levels of airborne dusts from this product, firefighters should take great care as an explosive ignition may occur.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Although this product is not sensitive to static discharge, dusts of organic compounds, such as this material may generate, can be ignited by static discharge especially if large amounts of dusts are allowed to accumulate. All equipment in used in the handling of this material should be electrically grounded.

SPECIAL FIRE-FIGHTING PROCEDURES: No special procedures are necessary. Firefighters should follow normal fire response procedures consistent with surrounding materials. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water before being returned to service.

NFPA RATING



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

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. Eliminate all sources of ignition before cleanup begins. Use non-sparking tools. 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: Small spills of this product (1 vial) outside a hood should be cleaned immediately by personnel wearing gowns and double latex or nitrile disposable gloves and eye protection. Wipe up spilled material carefully.

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 airborne powder being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of particles into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.** Sweep up or vacuum spilled solid (an explosion-proof vacuum should be used). 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).

7. HANDLING and USE

NOTE: Consistent with the OSHA Bloodborne Pathogen regulation (29 CFR 1910.1030), ensure that safe work practices involving medical sharps are followed.

SAFE WORK AND HYGIENE PRACTICES: THIS MATERIAL IS AN ANTINEOPLASTIC AGENT; use careful work practices consistent with anti-neoplastic agents. Post hazard and warning information in the work area about this compound. Communication of health and safety hazards of this compound must be given to employees prior to working with them. Follow SPECIFIC USE INSTRUCTIONS supplied with compound. Conduct all open manipulations in a Class II Biological Safety Cabinet and use adequate personal protective equipment to minimize all exposure to this material in powdered and reconstituted form. During decontamination, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS for the cleanup of a small spill. If airborne exposure to this material is possible during spill clean-up, wear appropriate respiratory protection (including PAPR or SCBA).

7. HANDLING and USE (Continued)

SAFE WORK AND HYGIENE PRACTICES (continued): As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics in work areas where this product is handled or stored. Personnel preparing drugs of this class should wear double chemical resistant, impervious gloves, safety goggles, outer garments and shoe covers. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces and inhalation of aerosols and dusts (see Section 8 for further details). Wash hands thoroughly after removing protective gloves that are worn for handling Elspar® or equipment and containers of this compound.

STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Special attention must be paid in avoiding releasing airborne particles of this material. Potentially hazardous operations associated with the use of this product include withdrawal of needles from drug vials, drug transfers using syringes and needles, and expulsion of air from drug-filled syringes. Ensure vials are properly labeled. All equipment in used during the handling of this material that involves bulk amounts should be electrically grounded and intrinsically safe. All needles, syringes, vials, and other disposable items should be disposed of properly as chemotherapeutic medical sharps. Store this product away from incompatible materials (see Section 10, Stability and Reactivity). Store at 2-8°C (36-46°F) according to Package Labeling instructions.

SPECIFIC USE(S): This product is for use as a chemotherapy treatment. Follow all industry standards for use of this product.

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

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber gloves, goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. All needles, syringes, vials, and other disposable items should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION, ENGINEERING, AND OCCUPATIONAL EXPOSURE CONTROLS: No open handling of powder or solutions of this product should occur. Admixtures or manipulations of this drug should be carried out in a cytotoxic drug safety cabinet or Class I or II Biological Safety Cabinet. The cabinet should be regularly cleaned following the manufacturer's recommendations and those of the NSF. HEPA filters in the safety cabinet should be changed per recommendations of the manufacturer or the NSF. The safety cabinet should be tested and certified as recommended by the National Sanitation Foundation in Standard Number 49.

EXPOSURE LIMITS/GUIDELINES: Total dust guidelines would not be appropriate for an exposure limit for an active pharmaceutical compound. If OSHA were evaluating exposure, they would probably apply 5a1 and a fraction of pharmaceutical dose, not the total dust standard which would not be protective.

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELS		NIOSH	OTHER
		TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	IDLH mg/m ³	mg/m ³
Elspar® is composed of a variety of materials as described below. The exposure limits for "Particulates, Not Otherwise Classified" (PNOC) could be potentially applicable for occupational exposures to this product. See note above.		NE	NE	50 mppcf or 15 (Total Dust) 15 mppcf or 5 (Respirable Fraction)	NE	NE	NE	NE	DFG MAKs: TWA = 4 (inhalable fraction), 1.5 (Resp. Fraction)
L-Asparaginase	9015-68-3	NE	NE	NE	NE	NE	NE	NE	NE
Mannitol	87-78-5	NE	NE	NE	NE	NE	NE	NE	NE

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

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use with a Biological Safety Cabinet, or glove box. If respiratory protection is needed, such as in a spill or other situation where the material may be airborne, use only protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134) and 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: Prevent all eye contact with the use of safety glasses or chemical splash goggles. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or the Canadian CSA Standard Z94.3-02, *Industrial Eye and Face Protectors*.

HAND PROTECTION: Double glove, using butyl or nitrile-type rubber gloves or other appropriate gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. 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 they are torn or punctured. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate Standards Canada for further information.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

BODY PROTECTION: During patient administration, use of lightweight cotton gown or other medical attire is recommended to prevent all skin contact. For operations involving open material, additional protective clothing such as sleeve covers, shoe covers and body suits may be necessary. Additional protective clothing would be necessary for spill cleanup or other operations involving open material, such as sleeve covers, shoe covers and body suits.

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

9. PHYSICAL and CHEMICAL PROPERTIES

APPEARANCE, ODOR AND COLOR: Odorless, white powder.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance may be a manner to identify spills as a white powder. Reconstituted product will look like water and will not be easily identifiable.

MOLECULAR WEIGHT (active ingredient): 31731.9

pH: Not established.

VAPOR PRESSURE (air = 1): Not applicable for product.

BOILING POINT: Not established.

SPECIFIC GRAVITY (water = 1): Not established.

FREEZING/MELTING POINT: Not established.

EVAPORATION RATE (nBuAc = 1): Not established.

ODOR THRESHOLD: Not applicable.

COEFFICIENT WATER/OIL DISTRIBUTION: Not established. **SOLUBILITY IN WATER:** Soluble.

10. STABILITY and REACTIVITY

DECOMPOSITION CONDITIONS/STABILITY: This product is stable when properly stored (see Section 7, Handling and Storage).

DECOMPOSITION PRODUCTS: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, and sulfur oxides).

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 temperatures above 8°C (46°F) and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

GENERAL TOXICITY INFORMATION: Asparaginase is an anti-neoplastic agent. It removes an exogenous source of L-Asparagine for malignant cells that depend on this essential amino acid for survival. The compound has been shown to cause decreased embryo/fetal survival and birth defects in laboratory animals (rabbits) when given intravenously at doses of 50-100 I.U./kg (0.2-0.4 mg/kg). It has been reported to have immunosuppressive activity in animal experiments. In repeat-dose intravenous studies, Asparaginase produced changes in serum proteins and G.I. distress in dogs and liver changes in monkeys (LOAEL = 100 I.U./kg/day or 0.4 mg/kg/day). A single I.V. dose of 1000 I.U./kg (4 mg/kg/day) caused parathyroid necrosis and death in rabbits, a species unusually sensitive to ELSPAR®. Pancreatic necrosis was observed at higher dosages. A small increase in pulmonary adenomas was reported in newborn Swiss mice injected with 2500 I.U./kg/day (11 mg/kg/day) for 4 days. It was negative in the Ames microbial mutagenesis test.

In clinical use of the final product ELSPAR®, acute hypersensitivity reactions are possible. Those adverse reactions following intravenous administration include skin rashes, urticaria, arthralgia, respiratory distress, and acute anaphylaxis have been reported. Rare serious reactions include hemorrhage due to low fibrinogen, pancreatitis, liver dysfunction, bone marrow suppression and central nervous system effects.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue.

SENSITIZATION POTENTIAL OF PRODUCT: Persons who are hypersensitive to this product or to other *Escherichia coli*-derived L-Asparaginases may have an allergic reaction to this drug.

TOXICITY DATA: The following are toxicity data for the active component of this product. The data given are Human, LD₅₀ (oral-rat), and LD₅₀ (oral-mouse) data. Other data are available but are not presented in this MSDS. Contact Lundbeck Inc. for additional information.

L-ASPARAGINASE:

TDL₀ (Intramuscular-Child) 8145 µg/kg/1 week: Gastrointestinal: changes in structure or function of endocrine pancreas

LD₅₀ (Oral-Rat) 7500 µg/kg

LD₅₀ (Oral-Mouse) 5000 µg/kg

CARCINOGEN POTENTIAL OF COMPONENTS: The intraperitoneal injection of 2500 I.U./kg/day of asparaginase for 4 days in newborn Swiss mice resulted in a small increase in pulmonary adenomas; lymphatic leukemia was not increased. The remaining components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of this product and its components on the human reproductive system. This product is rated as Pregnancy Category C-RISK CANNOT BE RULED OUT, Human evidence is lacking, but animal evidence is positive.

Mutagenicity: No mutagenic effects have been reported in humans. L-Asparaginase at concentrations of 152-909 I.U./plate was not mutagenic in the Ames microbial mutagen test with or without metabolic activation.

Embryotoxicity: No embryotoxic effects have been reported in humans. In mice and rats ELSPAR has been shown to cause resorptions when given in doses of more than 1000 I.U./kg (the recommended human dose). The intravenous administration of 50 or 100 I.U./kg (one-twentieth or one-tenth of the human dose) to pregnant rabbits on Day 8 and 9 of gestation resulted in dose dependent embryotoxicity.

Teratogenicity: In mice and rats ELSPAR has been shown to cause gross abnormalities and skeletal abnormalities when given in doses of more than 1000 I.U./kg (the recommended human dose). The intravenous administration of 50 or 100 I.U./kg (one-twentieth or one-tenth of the human dose) to pregnant rabbits on Day 8 and 9 of gestation resulted in dose dependent gross abnormalities.

Reproductive Toxicity: No reproductive effects have been reported in humans. In mice and rats ELSPAR has been shown to retard the weight gain of mothers and fetuses when given in doses of more than 1000 I.U./kg (the recommended human dose).

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, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility in soil.

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

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

ECOTOXICITY: This product has not been tested for aquatic or plant toxicity; it may be harmful to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

OTHER ADVERSE EFFECTS: This product does not contain any component with known 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.

U.S. EPA WASTE NUMBER: Not applicable.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS: This product is NOT classified as a hazardous material 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.

OFFICIAL MEXICAN STANDARD; REGULATION FOR THE TRANSPORT OF DANGEROUS GOODS AND RESIDUES: This product is not classified as Dangerous Goods, per transport regulations of Mexico.

15. REGULATORY INFORMATION

ADDITIONAL 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.

15. REGULATORY INFORMATION (Continued)

ADDITIONAL UNITED STATES REGULATIONS (continued):

SARA 302 EXTREMELY HAZARDOUS THRESHOLD PLANNING QUANTITY (TPQ): Not applicable.

SARA 304 EXTREMELY HAZARDOUS REPORTABLE QUANTITY (RQ): Not applicable.

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.

OTHER U.S. FEDERAL REGULATIONS: Manufacturers, packers, and distributors of drug and drug products for human use are responsible for complying with the labeling, certification, and usage requirements as prescribed by the Federal Food, Drug, and Cosmetic Act, as amended (sections 201-902, 52 Stat. 1040 et seq., as amended; 21 U.S.C. 321-392).

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

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDL INVENTORY STATUS: The components of this product are listed on the DSL Inventory or a exempt.

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

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Not applicable.

16. OTHER INFORMATION

Disclaimer: The information and recommendations contained herein are based upon tests believed to be reliable. However, Lundbeck Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Lundbeck Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

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DATE OF PRINTING:

DEFINITION OF TERMS

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

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

EXPOSURE LIMITS IN AIR:

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

DFG MAKs: Federal Republic of Germany Maximum Concentration Values in the workplace. Exposure limits are given as TWA (Time-Weighted Average) or PEAK (short-term exposure) values.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed humans. 2: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed mammals. 3A: Substances that have been shown to induce genetic damage in germ cells of human 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 that are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell *in vivo*; in exceptional cases, substances for which there are no *in vivo* data, but that are clearly mutagenic *in vitro* and structurally related to known *in vivo* mutagens. 4: Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g. purely aneugenic substances] if research results make this seem sensible.) 5: Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

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

EXPOSURE LIMITS IN AIR (continued):

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.

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

NIC: Notice of Intended Change.

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

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL" is placed next to the PEL that was vacated by Court Order.

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

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

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

TWA: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD: 0 Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation:* Essentially non-irritating. Mechanical irritation may occur. PII or Draize = 0. *Eye Irritation:* Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HEALTH HAZARD (continued): 1 (continued) Oral Toxicity LD₅₀ Rat: > 5000 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit: > 2000 mg/kg. Inhalation Toxicity 4-hrs LC₅₀ Rat: > 20 mg/L. 1 Slight Hazard: Minor reversible injury may occur; may irritate the stomach if swallowed; may defat the skin and exacerbate existing dermatitis. Skin Irritation: Slightly or mildly irritating. PII or Draize > 0 < 5. Eye Irritation: Slightly to mildly irritating, but reversible within 7 days. Draize > 0 ≤ 25. Oral Toxicity LD₅₀ Rat: > 500–5000 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit: > 1000–2000 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat: > 2–20 mg/L. 2 Moderate Hazard: Temporary or transitory injury may occur; prolonged exposure may affect the CNS. Skin Irritation: Moderately irritating; primary irritant; sensitizer. PII or Draize ≥ 5, with no destruction of dermal tissue. Eye Irritation: Moderately to severely irritating; reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. Oral Toxicity LD₅₀ Rat: > 50–500 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit: > 200–1000 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat: > 0.5–2 mg/L. 3 Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. Skin Irritation: Severely irritating and/or corrosive; may cause destruction of dermal tissue, skin burns, and dermal necrosis. PII or Draize > 5–8, with destruction of tissue. Eye Irritation: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. Oral Toxicity LD₅₀ Rat: > 1–50 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit: > 20–200 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat: > 0.05–0.5 mg/L. 4 Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposures; extremely toxic; irreversible injury may result from brief contact. Skin Irritation: Not appropriate. Do not rate as a 4, based on skin irritation alone. Eye Irritation: Not appropriate. Do not rate as a 4, based on eye irritation alone. Oral Toxicity LD₅₀ Rat: ≤ 1 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit: ≤ 20 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat: ≤ 0.05 mg/L.

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

PHYSICAL HAZARD: 0 Water Reactivity: Materials that do not react with water. Organic Peroxides: Materials that are normally stable, even under fire conditions and will not react with water. Explosives: Substances that are Non-Explosive. Compressed Gases: No Rating. Pyrophorics: No Rating. Oxidizers: No 0 rating. Unstable Reactives: Substances that will not polymerize, decompose, condense, or self-react. 1 Water Reactivity: Materials that change or decompose upon exposure to moisture. Organic Peroxides: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. Explosives: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. Compressed Gases: Pressure below OSHA definition. Pyrophorics: No Rating. Oxidizers: Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD (continued): 1 (continued) Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. Unstable Reactives: Substances that may decompose, condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. 2 Water Reactivity: Materials that may react violently with water. Organic Peroxides: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. Explosives: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. Compressed Gases: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. Pyrophorics: No Rating. Oxidizers: Packaging Group II oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. Reactives: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. 3 Water Reactivity: Materials that may form explosive reactions with water. Organic Peroxides: Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. Explosives: Division 1.3 explosives. Explosive substances 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 oxidizers. Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. Liquids: any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. Unstable Reactives: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. 4 Water Reactivity: Materials that react explosively with water without requiring heat or confinement. Organic Peroxides: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. Explosives: Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. Compressed Gases: No Rating. Pyrophorics: Add to the definition of Flammability 4. Oxidizers: No 0 rating. Unstable Reactives: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: 0 Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC₅₀ for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 200 mg/L. Materials with an LD₅₀ for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD₅₀ 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 LC₅₀ for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD₅₀ 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 LD₅₀ 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 LC₅₀ 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 LC₅₀ for acute inhalation toxicity, if its LC₅₀ 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 LC₅₀ for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD₅₀ 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 LD₅₀ for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg.

DEFINITION OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS

(continued):

HEALTH HAZARD (continued): 3 Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC₅₀ for acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD₅₀ for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an LD₅₀ for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. 4 Materials that, under emergency conditions, can be lethal. Gases with an LC₅₀ for acute inhalation toxicity less than or equal to 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 1000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD₅₀ for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD₅₀ for acute oral toxicity is less than or equal to 5 mg/kg.

FLAMMABILITY HAZARD: 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 of NFPA 704. 1 Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur. Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the *UN Recommendations on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85% by weight. Liquids that have no fire point when tested by ASTM D 92, *Standard Test Method for Flash and Fire Points by Cleveland Open Cup*, up to the boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 2 Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal, and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 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 (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 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% 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% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS

(continued):

INSTABILITY HAZARD: 0 Materials that in themselves are normally stable, even under fire conditions. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. 1 Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. 2 Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100 W/mL. 3 Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. 4 Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

FLAMMABILITY LIMITS IN AIR:

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

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. **LD₅₀:** Lethal Dose (solids & liquids) that kills 50% of the exposed animals. **LC₅₀:** Lethal Concentration (gases) that kills 50% of the exposed animals. **ppm:** Concentration expressed in parts of material per million parts of air or water. **mg/m³:** Concentration expressed in weight of substance per volume of air. **mg/kg:** Quantity of material, by weight, administered to a test subject, based on their body weight in kg. **TDLo:** Lowest dose to cause a symptom. **TCLo:** Lowest concentration to cause a symptom. **TD₀₁, LDLo, and LDo,** or **TC₀₁, LCLo, and LCo:** Lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** **IARC:** International Agency for Research on Cancer. **NTP:** National Toxicology Program. **RTECS:** Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI:** ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

ECOLOGICAL INFORMATION:

EC: Effect concentration in water. **BCF:** Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. **TLm:** Median threshold limit. **log K_{ow}** or **log K_{oc}:** Coefficient of Oil/Water Distribution is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

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