SAFETY DATA SHEETS

This SDS packet was issued with item:

078914565

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

078914563 078914567

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078905435 078905436 078905437

Bayer HealthCare

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards and the Global Harmonization Standard

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

1. PRODUCT IDENTIFICATION

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME (AS LABELED): **ALENZA CHEWABLE TABLETS**
CHEMICAL NAME: Active Ingredients: Baicalins and Catechins Mixture
CHEMICAL CLASS: Active Ingredients: Plant Extract/Flavinoid and Vitamin Supplements
PRODUCT USE: Veterinary Pharmaceutical/Veterinary Supplement Medication

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME: **Bayer Animal Health**
ADDRESS: 12707 Shawnee Mission Parkway
Shawnee Mission, KS 66216
BUSINESS PHONE: 913-268-2000 [08:00 AM - 05:00 PM]
WEB ADDRESS: www.bayeranimalhealth.com
EMERGENCY PHONE: United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
International: 01-703-527-3887 (Chemtrec) [24-hours]
EMAIL: john.sheehan@bayer.com
DATE OF PREPARATION: June 26, 2012
DATE OF REVISION: February 8, 2013/Bayer

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The product is also classified per all applicable requirements of the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION LABELING AND CLASSIFICATION: This product has been classified under current GHS standards.
Classification: Acute Oral Toxicity Cat. 4, Skin Sensitization Cat. 1B, Aquatic Chronic Toxicity Cat. 3
Signal Word: Warning Hazard Statement Codes: H302, H317, H413
Precautionary Statement Codes: P261, P264, P270, P272, P280, P301 + P312, P330, P302 + P352, P333 + P313, P321, P501
Hazard Symbols/Pictograms: GHS07, GHS08

See Section 16 for classification information of this compound.

EMERGENCY OVERVIEW: Product Description: This product is a soft, chewable tablet with poultry odor. **Health Hazards:** This product presents minimal health hazards during handling by inhalation, skin or eye contact. Accidental ingestion may cause digestive upset. Chronic exposure may result in selenium toxicity or sensitization and allergic reaction to selenium compounds. **Flammability Hazards:** This compound is combustible and can ignite if highly heated or if exposed to direct flame. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds, including copper, magnesium, selenium, silicon, zinc, carbon and nitrogen oxides. **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** This product contains a compound that can cause chronic aquatic toxicity. **Emergency Considerations:** Emergency responders should wear appropriate protection for the situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/v	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENTS				
beta-Boswellic Acid	631-69-6	For Gum, CAS# 97952-72-2: 308-368-6	Proprietary	EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Alpha Lipoic Acid	1077-28-7	214-071-2		Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: None
d-alpha-Tocopherol	59-02-9	200-412-2		EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Ascorbic Acid	50-81-7	200-066-2		EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Copper Proteinate	NE	NE		EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Sodium Selenite	10102-18-8	233-267-9		Classification: Acute Oral Toxicity Cat. 2, Acute Inhalation Toxicity Cat. 3, Skin Sensitization Cat. 1, Aquatic Chronic Toxicity Cat. 2 Hazard Codes: H300, H331, H317, H411 Hazard Symbol/Pictogram: GHS06, GHS08
Zinc Proteinate	NE	NE		EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable

See Section 16 for full classification information of product and components.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/v	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
EXCIPIENTS				
Colloidal Silicon Dioxide	112945-52-5	231-545-5	Proprietary	EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Dicalcium Phosphate	7789-77-7	For Calcium Phosphate Dibasic: 231-826-1	Proprietary	EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Dried Poultry Liver	NE	NE	Proprietary	EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Maltodextrin	9050-36-6	232-940-4	Proprietary	EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	EU 67/548: Classification: Not Applicable EU/GHS 1272/2008: Classification: Not Applicable

See Section 16 for full classification information of product and components.

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

4. FIRST-AID MEASURES

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

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 dusts from product enter 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: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

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

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not available.

AUTOIGNITION TEMPERATURE: Not available.

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

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.

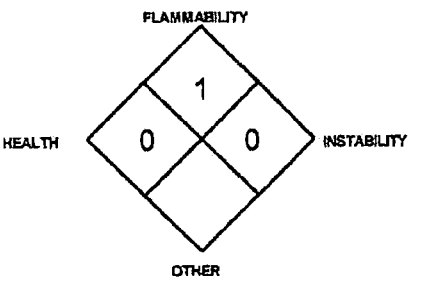
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: This product is combustible and can ignite if highly heated or if exposed to direct flame. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including copper, magnesium, selenium, silicon, zinc, carbon and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not applicable.

Explosion Sensitivity to Static Discharge: May be sensitive.

NFPA RATING



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

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 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.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: In the event of a spill, clear the area and protect people.

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g. a single container), wear double latex or nitrile disposable gloves and eye protection.

6. ACCIDENTAL RELEASE MEASURES (Continued)

PROTECTIVE EQUIPMENT (continued):

Large Spills: For large spills (e.g., a pallet of containers), protective apparel should be used with a respirator when there is any danger of airborne dusts being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Small Spills: Pick-up or sweep-up spilled tablets.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Sweep up spilled product carefully, avoiding the generation of airborne dusts. Wet down area for suppression of dusts.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

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

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

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

7. HANDLING and STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this material. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of particulates.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store this product in original container at controlled room temperature of 20-25°C (68-77°F). Inspect containers of this product for leaks or damage. Store away from incompatible materials (see Section 10, Stability and Reactivity).

SPECIFIC END USE(S): This product is an animal pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. In event of large spill, triple rinse area for complete decontamination.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: None normally needed. If dusts are produced during handling, use with adequate ventilation.

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m³	STEL mg/m³	TWA mg/m³	STEL mg/m³	TWA mg/m³	STEL mg/m³	IDLH mg/m³	mg/m³
beta-Boswellic Acid	631-69-6	NE	NE	NE	NE	NE	NE	NE	NE
Alpha Lipoic Acid	1077-28-7	NE	NE	NE	NE	NE	NE	NE	NE
d-alpha-Tocopherol	59-02-9	NE	NE	NE	NE	NE	NE	NE	NE
Ascorbic Acid	50-81-7	NE	NE	NE	NE	NE	NE	NE	NE
Colloidal Silicon Dioxide	112945-52-5	NE	NE	NE	NE	NE	NE	NE	NE
Copper Proteinate Exposure limits given are for copper dusts fume, as Cu	NE	Dust: 1 Fume: 0.2	NE	Dust: 1 Fume: 0.1	NE	Dust: 1 Fume: 0.1	NE	100 (as Cu)	Carcinogen: EPA-D
Dicalcium Phosphate	7789-77-7	NE	NE	NE	NE	NE	NE	NE	NE
Dried Poultry Liver	NE	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate Exposure limits are for Stearates	557-04-0	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Maltodextrin	9050-36-6	NE	NE	NE	NE	NE	NE	NE	NE
Microcrystalline Cellulose	9004-34-6	10	NE	15 (total dust), 5 (resp. fraction)	NE	10 (total dust), 5 (resp. fraction)	NE	NE	NE
Sodium Selenite Exposure limits given are for selenium & inorganic compounds, as Se	10102-18-8	0.2	NE	0.2	NE	0.2	NE	NE	DFG MAKs (Inorganic Compounds): TWA = 0.02 (inhalable fraction), skin PEAK = 8•MAK 15 min, average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C Carcinogen: Selenium compounds: EPA-D, IARC-3; Inorganic compounds: MAK-3B

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS (CONTINUED):

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m³	STEL mg/m³	TWA mg/m³	STEL mg/m³	TWA mg/m³	STEL mg/m³	IDLH mg/m³	mg/m³
Zinc Proteinate Exposure limits are for zinc and compounds	NE	NE	NE	NE	NE	NE	NE	NE	DFG MAKs: TWA = 0.1 (respirable fraction), 2 (inhalable fraction) PEAK = Inhalable: 2•MAK 15 min. average value, 1-hr interval, 4 per shift; Respirable: 4•MAK 15 min. average value, 1-hr interval, 4 per shift Carcinogen: EPA-II, EPA-D, EPA-I

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

PROTECTIVE EQUIPMENT: *The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132), *equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear). Please reference applicable regulations and standards for relevant details.*

RESPIRATORY PROTECTION: Not normally needed. Maintain airborne contaminant concentrations below exposure limits listed above if applicable. 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: Not normally needed. If dusts or particulates are present during manufacture or other similar industrial operations, wear splash goggles or safety glasses. If necessary, refer to appropriate regulations.

HAND PROTECTION: During manufacture or other similar industrial operations, wear latex or nitrile gloves. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. 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.

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Soft tablets
COLOR: Brownish.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
ODOR: Of chicken.
ODOR THRESHOLD: Not available.
BOILING POINT @ 760 mmHg: Not available.
MELTING POINT: Not available.
VAPOR PRESSURE (air = 1) @ 25°C: Not available.
SPECIFIC GRAVITY (water = 1): Not available.
EVAPORATION RATE (nBuAc = 1): Not applicable.
FLASH POINT: Not available.
SOLUBILITY IN WATER: Not available.
OTHER SOLUBILITIES: Not available.
COEFFICIENT WATER/OIL DISTRIBUTION: Not available.
HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The appearance may be a distinguishing characteristic of this compound in event of accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Normally stable.
DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include copper, magnesium, selenium, silicon, zinc, carbon and nitrogen oxides copper, magnesium, selenium, silicon, zinc, carbon and nitrogen oxides. *Hydrolysis:* None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Incompatible with oxidizing agents, alkalies.
POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF OVEREXPOSURE 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 generated by damaged tablets of this product may slightly irritate the nose, throat, and lungs.

CONTACT WITH SKIN or EYES: This product is not expected to cause significant irritation to skin; some irritation may occur to persons who have allergy to any ingredient. Dusts may irritation the eyes, causing redness, pain, and watering (mechanical irritation).

SKIN ABSORPTION: No specific information is available on possible skin absorption of components.

INGESTION: Ingestion of this compound is not anticipated to be a significant route of occupational overexposure. Ingestion may cause gastrointestinal upset. Ingestion of large amount may be harmful.

11. TOXICOLOGICAL INFORMATION (Continued)

INJECTION: Not a likely route of exposure.

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Ingestion may cause gastrointestinal upset or may be harmful. Dusts from product may cause skin, eyes and respiratory irritation.

Chronic: Repeated skin contact may cause dermatitis (dry, red skin). May cause skin sensitization.

TARGET ORGANS: Acute: Eyes, respiratory system (from dust). Chronic: Skin.

TOXICITY DATA: Currently, the following toxicological data are available for some of the active ingredients. Only select human data, irritation data, LD50 Oral-Rat or Mouse, LD50 Skin-Rabbit, Rat or Mouse, LC50 Inhalation-Rat or Mouse data are provided in this SDS. Toxicity data are available for excipient ingredients but are not provided in this SDS. Contact Bayer for more information.

d-ALPHA TOCOPHEROL (VITAMIN E):

TDLo (Oral-Human) 346.6 mg/kg: female 1-13 week(s) after conception: Reproductive: Effects on Newborn: growth statistics (e.g.%, reduced weight gain)

TDLo (Intravenous-Man) 257 µg/kg: Vascular: other changes

LD_{50} (Oral-Mouse) > 25 mL/kg

ASCORBIC ACID:

TDLo (Intravenous-Man) 2300 mg/kg/2 days: Blood: oxidant related (GPD deficient) anemia

TDLo (Intravenous-Woman) 900 mg/kg: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis)

TDLo (Oral-Human) 72.96 gm/kg/313 weeks-continuous: Tumorigenic: active as anti-cancer agent

TDLo (Oral-Human) 600 mg/kg/14 days-intermittent: Vascular: BP lowering not characterized in autonomic section; Endocrine: other changes

LD_{50} (Oral-Rat) 11,900 mg/kg: Sense Organs and Special Senses (Eye): lacrymation; Behavioral: somnolence (general depressed activity); Gastrointestinal: hypermotility, diarrhea

LD_{50} (Oral-Rat) 11.9 gm/kg: Behavioral: muscle contraction or spasticity; Lungs, Thorax, or Respiration: dyspnea; Nutritional and Gross Metabolic: body temperature decrease

LD_{50} (Oral-Mouse) 3387 mg/kg

LD_{50} (Oral-Mouse) 250 mg/kg: Nutritional and Gross Metabolic: other changes

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	See Section 8		See Section 8

For Routine Industrial Use and Handling Applications

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

SODIUM SELENITE:

TDLo (Oral-Man) 24 mg/kg: Gastrointestinal: changes in structure or function of salivary glands, hypermotility, diarrhea, nausea or vomiting

LD_{50} (Oral-Rat) 7 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: hypermotility, diarrhea

LD_{50} (Oral-Mouse) 7080 5476 µg/kg: g/kg

CARCINOGENIC POTENTIAL: Components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

COPPER PROTEINATE (as a copper compound): EPA-D (Not Classifiable as to Human Carcinogenicity)

MAGNESIUM STEARATE (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

SODIUM SELENITE (as a selenium compound): EPA-D (Not Classifiable as to Human Carcinogenicity); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B (Substances for which in vitro tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories)

ZINC PROTEINATE (as a zinc compound): EPA-D (Not Classifiable as to Human Carcinogenicity); EPA-II (Inadequate Information to Assess Carcinogenic Potential); EPA-I (Data are Inadequate for an Assessment of Human Carcinogenic Potential)

IRRITANCY OF PRODUCT: Dust from the product may cause eye irritation and may be irritating to the respiratory system. Prolonged skin contact may be irritating.

SENSITIZATION TO THE PRODUCT: Contains a selenium compound, which may cause skin sensitization and allergic reaction.

REPRODUCTIVE TOXICITY INFORMATION: No information is available on possible human mutagenic, embryotoxic, teratogenic or reproductive toxicity effects of this product or its components.

Mutagenicity: The following information is available for some components.

d-ALPHA TOCOPHEROL (VITAMIN E):

DNA Adduct (Intravenous-Rat) 27 nmol/kg

DNA Inhibition (Rat Liver) 100 µmol/L

ASCORBIC ACID:

DNA Damage (Human Fibroblast) 200 µmol/L

DNA Damage (Human Cells-Not Otherwise Specified) 200 µmol/L

DNA Damage (Human Cells-Not Otherwise Specified) 300 µmol/L/30 minutes

DNA Inhibition (Human HeLa cell) 2500 µmol/L

DNA Inhibition (Human-Not Otherwise Specified) 200 µmol/L

DNA Inhibition (Human Cells-Not Otherwise Specified) 200 mg/L

Mutation Test Systems-Not Otherwise Specified (Human Fibroblast) 200 µmol/L

Mutation Test Systems-Not Otherwise Specified (Human Cells-Not Otherwise Specified) 200 µmol/L

Mutation in Microorganisms (Bacteria-*Salmonella typhimurium*) 500 µg/plate

Mutation in Microorganisms (Microorganism-Not Otherwise Specified) 1000 ppm

Mutation in Microorganisms (Mold-*Neurospora crassa*) 2 mmol/L

ASCORBIC ACID (continued):

DNA Damage (Bacteria-*Bacillus subtilis*) 2 mg/disc

DNA Damage (Mammal-Species Unspecified Lymphocyte) 500 µmol/L

DNA Damage (Oral-Mouse) 1 mg/kg1 mg/kg

DNA Repair (Yeast-*Saccharomyces cerevisiae*) 100 mg/L

Gene Conversion and Mitotic Recombination (Yeast-*Saccharomyces cerevisiae*) 300 mg/L

Sex Chromosome Loss and Non-Disjunction (Yeast-*Saccharomyces cerevisiae*) 100 mg/L

Sperm Morphology (Parenteral-Silkworm) 25 µg

Micronucleus Test (Intraperitoneal-Mouse) 4500 mg/kg/3 days-continuous

Micronucleus Test (Hamster Ovary) 400 mg/L

Micronucleus Test (Oral-Mouse) 30 mg/kg

Mutation Test Systems-Not Otherwise Specified (Mouse-Liver) 500 µmol/L

Cytogenetic Analysis (Intraperitoneal-Mouse) 1600 mg/kg

Cytogenetic Analysis (Hamster Ovary) 300 mg/L

Sister Chromatid Exchange (Intraperitoneal-Mouse) 1600 mg/kg

Sister Chromatid Exchange (Hamster Ovary) 500 mg/L

SODIUM SELENITE:

DNA Damage (Human Fibroblast) 50 µmol/L

DNA Damage (Human Lymphocyte) 80 µmol/L

DNA Inhibition (Human Fibroblast) 80 µmol/L

DNA Inhibition (Human HeLa cell) 10 µmol/L

DNA Repair (Human Cells-Not Otherwise Specified) 0.01 umol/L/1 hour

Cytogenetic Analysis (Human Lymphocyte) 80 µmol/L

Cytogenetic Analysis (Human Fibroblast) 80 µmol/L

Unscheduled DNA Synthesis (Human Fibroblast) 80 umol/L/30 minutes

Mutation Test Systems-Not Otherwise Specified (Human Fibroblast) 80 µmol/L

Mutation Test Systems-Not Otherwise Specified (Human HeLa cell) 50 µmol/L

Sister Chromatid Exchange (Human Leukocyte) 7900 nmol/L/19 hours

Sister Chromatid Exchange (Human Leukocyte) 7900 nmol/L

Mutation in Microorganisms (Bacteria-*Salmonella typhimurium*) 1 µmol/plate

Mutation in Microorganisms (Yeast-*Saccharomyces cerevisiae*) 1 mmol/L

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Mutagenicity (continued):

SODIUM SELENITE (continued):
DNA Repair (Bacteria-*Salmonella typhimurium*) 10 µg/plate
Repair (Bacteria-*Bacillus subtilis*) 50 µmol/plate
Phage Inhibition Capacity (Bacteria-*Escherichia coli*) 25 µg/well
Gene Conversion And Mitotic Recombination (Yeast-*Saccharomyces cerevisiae*) 300 µmol/L

SODIUM SELENITE (continued):
Unscheduled DNA Synthesis (Rat Liver) 100 µmol/L
Unscheduled DNA Synthesis (Mouse Mammary Gland) 50 nmol/L
Cytogenetic Analysis (Rat Lymphocyte) 7500 nmol/L
Cytogenetic Analysis (Oral-Mouse) 7 mg/kg
Cytogenetic Analysis (Intraperitoneal-Mouse) 6650 µg/kg

SODIUM SELENITE (continued):
Cytogenetic Analysis (Intravenous-Rat) 10 mg/kg
Sperm Morphology (Oral-Rat) 4200 µg/kg/5 weeks-continuous
DNA Damage (Mouse Leukocyte) 20 µmol/L
Sister Chromatid Exchange (Intraperitoneal-Hamster) 6650 µg/kg
Sister Chromatid Exchange (Hamster Lung) 2 mg/L

Embryotoxicity/Teratogenicity/Reproductive Toxicity: No data available.

BIOLOGICAL EXPOSURE INDICES: Currently, there are no Biological Exposure Indices (BEIs) determined for components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: No information is available on mobility of this product.

PERSISTENCE AND BIODEGRADABILITY: No specific information on persistence or biodegradability is available for this product. It is expected to be mostly biodegradable and will not persist in the environment.

BIO-ACCUMULATION POTENTIAL: No information available. Bioaccumulation is not expected.

ECOTOXICITY: No information is available.

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.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This compound, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Incineration is recommended. Reusable equipment should be cleaned with soap and water. It is the responsibility of the generator to determine at the time of disposal whether the compound meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Incineration is recommended for the compound and disposable equipment. 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: 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 does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

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 components are not specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL U.S. 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 the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA HAZARD CATEGORIES (SECTION 311/312, 40 CFR 370-21): ACUTE: No; CHRONIC: No; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No

ADDITIONAL U.S. REGULATIONS (continued):

U.S. CERCLA REPORTABLE QUANTITY (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: Components of this product are the TSCA Inventory or are excepted as biological materials. Animal medicinal products are regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA.

OTHER U.S. FEDERAL REGULATIONS: Animal medical preparation are regulated under USDA and FDA regulations. Other requirements from the Center for Veterinary Medicine (CVM), and the Food Safety and Inspection Service (FSIS) may be applicable. In addition, this product may meet the definition of an animal feed additive, which then has requirements under U.S. animal Food Additive Petitions and Generally Recognized as Safe determinations.

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

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDSL STATUS: This product is regulated under the Veterinary Drug Directorate of Health Canada; it is exempt from the requirements of CEPA.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITY SUBSTANCES LISTS: Components are not on the CEPA substances lists.

OTHER CANADIAN REGULATIONS: This product, when used for treatment of food-product animals, may have requirements under Canadian Single Ingredient Feed Registration regulations. Food residue MRLs may be applicable.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act, including animal medicines.

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **CAUTION!** DUST FROM PRODUCT MAY CAUSE RESPIRATORY SYSTEM AND EYE SKIN IRRITATION. PROLONGED SKIN CONTACT MAY CAUSE IRRITATION. MAY CAUSE DIGESTIVE UPSET IF ACCIDENTALLY INGESTED. INGESTION MAY CAUSE SYSTEMIC SELENIUM TOXICITY OR SENSITIZATION. Do not take taste or swallow. Avoid contact with skin, eyes, and clothing. Keep container closed. Wear gloves, goggles, and suitable body protection. FIRST-AID: If swallowed, do not induce vomiting. Never give anything by mouth to an unconscious person. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. Remove contaminated clothing and shoes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If ingested, do not induce vomiting. Seek medical attention. IN CASE OF FIRE: Use water fog, dry chemical or CO_2, or alcohol foam. IN CASE OF SPILL: Sweep up or vacuum spilled product. Decontaminate area with soapy water and triple rinse area. Place in a suitable container. Refer to SDS for additional information.

GLOBAL HARMONIZATION LABELING AND CLASSIFICATION: This product has been classified under current GHS standards.

Classification: Acute Oral Toxicity Category 4, Skin Sensitization Category 1B, Aquatic Chronic Toxicity Category 3

Signal Word: Warning

Hazard Statement Codes: H302: Harmful if swallowed. H317: May cause an allergic skin reaction. H413: May cause long-lasting harmful effects to aquatic life.

Precautionary Statement Codes: P261: Avoid breathing dust. P264: Wash thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301 + P312: If swallowed, Call a POISON CENTER or doctor/physician if you feel unwell. P330: Rinse mouth. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P321: Specific treatment (remove from exposure and treat symptoms). P501: Dispose of contents/containers in accordance with all local, regional, national and international regulations.

Hazard Symbols/Pictograms: GHS07, GHS08

CLASSIFICATION FOR COMPONENTS:

Ropinirole Hydrochloride: Self-Classification

Classification: Acute Oral Toxicity Cat. 2, Acute Inhalation Toxicity Cat. 3, Skin Sensitization Cat. 1, Aquatic Chronic Toxicity Cat. 2

Signal Word: Danger

Hazard Statement Codes: H300: Fatal if swallowed. H331: Toxic if inhaled. H317: May cause an allergic skin reaction. H411: Toxic to aquatic life with long-lasting effects.

ALL OTHER COMPONENTS:

An official classification for these substances has not been published and is not applicable under GHS Standards.

REVISION DETAILS: New

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 compound.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721-1961 • (800) 441-3365

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DEFINITIONS OF TERMS

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

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

EXPOSURE LIMITS IN AIR:

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

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 of animals, or which produce mutagenic effects in somatic cells of mammals *in vivo* and have been shown to reach the germ cells in an active form. **3B:** Substances 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.

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 a 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_{50} Rat*: < 5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: < 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: < 20 mg/L.); 1 (Slight Hazard: Minor reversible injury may occur; slightly or mildly irritating. *Skin Irritation*: Slightly or mildly irritating. *Eye Irritation*: Slightly or mildly irritating. *Oral Toxicity LD_{50} Rat*: > 500-5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 1000-2000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 2-20 mg/L); 2 (Moderate Hazard: Temporary or transitory injury may occur. *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_{50} Rat*: > 50-500 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 200-1000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.5-2 mg/L.); 3 (Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may 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_{50} Rat*: > 1-50 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 20-200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05-0.6 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_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L).

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

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 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*: Packing 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*: Packing 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, 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_{50} for acute inhalation toxicity greater than 10,000 ppm.

DEFINITIONS OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD (continued): 1 (continued): Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD_{50} for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. 1 Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. 2 Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC_{50} for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. 3 (materials that, under emergency conditions, can cause serious or permanent injury): Gases and vapors whose LC_{50} for acute inhalation toxicity is greater than 1,000 ppm but less than or equal to 3,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials whose LD_{50} 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_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. 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_{50} for acute inhalation toxicity is less than or equal to 1,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD_{50} for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD_{50} for acute oral toxicity is less than or equal to 5 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 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 according 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 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.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 3 (continued): 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. 2 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. Autoignition 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_{50} - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; LC_{50} - 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^3 concentration expressed in weight of substance per volume of air; mg/kg quantity of material, by weight, administered to a test subject, based on their body weight in kg. 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. Subrankings (2A, 2B, etc.) are also used. Other Information: BEI - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

A mutagen is a chemical 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.

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_m = median threshold limit; Coefficient of Oil/Water Distribution is represented by log K_{ow} or log K_{oc} 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.