SAFETY DATA SHEETS

This SDS packet was issued with item:

078914558

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).

078520387

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. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME (AS LABELED):	**T8 KETO FLUSH**
CHEMICAL NAME:	Active Ingredient: Ketoconazole
CHEMICAL CLASS:	Active Ingredient: Imidazole Derivative
RELEVANT USE of the SUBSTANCE:	Veterinary Pharmaceutical/Veterinary Antifungal

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:	July 7, 2012
DATE OF REVISION:	February 19, 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: Reproductive Toxicity Cat. 1B, Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, Eye Irritation Cat. 2B, STOT (Inhalation-Respiratory Irritation) SE Cat. 3, STOT RE Cat. 2, Aquatic Acute Toxicity Cat. 1, Acute Chronic Toxicity Cat. 1

Signal Word: Warning

Hazard Statement Codes: H360F, H302, H315, H319, H335, H373, H400, H410

Precautionary Statement Codes: P201, P202, P260, P264, P270, P271, P272, P273, P280, P308 + P313, P301 + P312, P330, P302 + P352, P321, P332 + P313, P362 + P364, P305 + P351 + P338, P337 + P313, P304 + P340, P312, P391, P403 + P233 + P405, P501

Hazard Symbols/Pictograms: GHS07, GHS08, GHS09

See Section 16 for full text details on classification

EMERGENCY OVERVIEW: Product Description: This product is clear, colorless to yellow, odorless liquid. **Health Hazards:** The main health hazard in a workplace setting is expected to be irritation of skin or eyes and possible respiratory irritation if mists or sprays are inhaled. Accidental ingestion may be harmful. This product contains a compound that can cause damage to fertility. Refer to Section 11 (Toxicological Information) for information on additional possible hazards from exposure, based on information on human pharmaceutical products containing the active ingredient. **Flammability Hazards:** This solution is not flammable or combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** This product contains a compound that is highly toxic to aquatic organisms; all release to the environment should be avoided. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

3. COMPOSITION and INFORMATION ON INGREDIENTS

NOTE: This product contains trace amounts of Sodium Hydroxide and Hydrofluoric acid for pH adjustment only. No classification is given.

CHEMICAL NAME	CAS #	% w/w	GHS Classification Hazard Statement Codes
ACTIVE INGREDIENT			
Ketoconazole	65277-42-1	0.1%	Classification: Reproductive Toxicity Cat. 1B, Acute Oral Toxicity Cat. 1, STOT RE Cat. 2, Aquatic Acute Toxicity Cat. 1, Aquatic Chronic Toxicity Cat. 1 Hazard Codes: H360F, H301, H373, H400, H410 Hazard Symbol/Pictogram: GHS06, GHS08, GHS09
EXCIPIENTS			
Benzyl Alcohol	100-51-6	Proprietary	SELF CLASSIFICATION Classification: Acute Oral Toxicity Cat. 4, Acute Dermal Toxicity Cat. 4, Acute Inhalation Toxicity Cat. 4 Hazard Codes: H302 + H312 + H332 Hazard Symbol/Pictogram: GHS07
Carboxymethylcellulose Sodium	9004-32-4	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable
Microcrystalline Cellulose	9004-34-6	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable

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

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	% w/w	GHS Classification Hazard Statement Codes
EXCIPIENTS (continued)			
Propylene Glycol	57-55-6	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable
Tetrasodium Edetate	8013-51-2	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable
Tromethamine Base	77-86-1	Proprietary	SELF CLASSIFICATION Classification: Skin Irritation Cat. 2B, Eye Irritation Cat. 2, STOT (Inhalation-Respiratory Irritation) SE Cat. 3 Hazard Codes: H315, H319, H335 Hazard Symbol/Pictogram: GHS07
Tyloxapol, USP	25301-02-4	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable
Water	7732-18-5	Balance	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: 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. Take a copy this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

SKIN EXPOSURE: If this product contaminates the skin, begin decontamination with running water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

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

INHALATION: If this product is 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: Skin disorders may be aggravated by exposure 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 applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

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

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

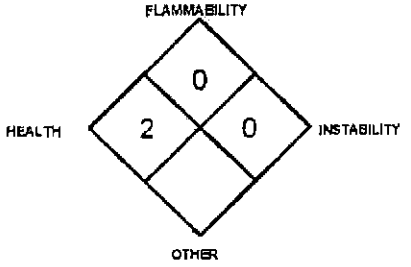
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL FIRE AND EXPLOSION HAZARDS: This product is not flammable. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



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

ADVICE TO 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: Uncontrolled releases should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used. In case of a spill, clear the affected area and protect people. Do not touch or walk through spilled material. Stop leak if you can do it without risk. Avoid allowing water runoff to contact spilled material. Call CHEMTREC (1-800-424-9300) for emergency assistance. Or if in Canada, call CANUTEC (613-996-6666). The atmosphere must have levels of the components of this product lower than those listed in Section 8, (Exposure Controls, Personal Protection), if applicable, and at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Spills may be slippery and present a slip hazard.

6. ACCIDENTAL RELEASE MEASURES (Continued)

PROTECTIVE EQUIPMENT:

Small Spills/Spills in Hoods: Personnel wearing gowns, double nitrile or latex gloves and eye protection should immediately clean spills of less than 5 mL outside a hood.

Large Spills: Use proper protective equipment, including double nitrile or latex gloves, full body gown, and full-face respirator equipped with an organic mist filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Cleanup of Small Spills: Liquids should be wiped with absorbent gauze pads; solids should be wiped with wet absorbent gauze.

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

Large Spills: Review Sections 2, 8, 11 & 12 before proceeding with cleanup. Restrict access to the spill areas. For spills of amounts larger than 5 mL limit spread by gently covering with absorbent sheets or other appropriate absorbent material. Be sure not to generate aerosols. Do not apply chemical in-activators as they may produce hazardous by-products.

All Spills: Clean the spill area (three times) using a bleach and detergent solution and then rinse with clean water. Place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered material and report spill per regulatory requirements.

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

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

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

7. HANDLING and STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this material should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this 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 aerosols. Spills may be slippery and pose slip hazard.

CONDITIONS FOR SAFE STORAGE: Minimize all exposures to this product. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal Protection). Open containers slowly on a stable surface in areas that have been designated for use of this product. Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Store away from incompatible materials (see Section 10, Stability and Reactivity). Material should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Empty containers may contain residual product; therefore, empty containers should be handled with care.

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 or autoclave as appropriate. In event of large spill, refer to procedure given in Section 6 (Accidental Release Measures). Dispose of all contaminated disposable items properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard animal medical product handling procedures. During decontamination, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS for the clean up of a large spill. Ensure eyewash stations are available and accessible in areas where this product is used. Wipe down work areas routinely to prevent accumulation of product.

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS: Note: Exposure limits for Sodium Hydroxide are not given as its use in the product is for pH balance and are not relevant to potential exposure.

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
Ketoconazole	25301-02-4	NE	NE	NE	NE	NE	NE	NE	NE
Benzyl Alcohol	100-51-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10
Celluloses (including CAS#s 9004-32-4, 9004-34-6)		10	NE	15 (total dust), 5 (respirable fraction)	NE	10 (total dust), 5 (respirable fraction)	NE	NE	NE
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10
Tetrasodium Edetate	8013-51-2	NE	NE	NE	NE	NE	NE	NE	NE
Tromethamine Base	77-86-1	NE	NE	NE	NE	NE	NE	NE	NE
Tyloxapol, USP	25301-02-4	NE	NE	NE	NE	NE	NE	NE	NE

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

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: 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: Wear safety glasses or goggles during administration of this product. If necessary, refer to appropriate regulations.

HAND PROTECTION: During use of this product, latex or nitrile gloves should be worn to avoid contact. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. If necessary, as described in 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: Liquid.
COLOR: Clear, colorless to yellow.
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
MOLECULAR FORMULA: For active: $C_{26}H_{28}Cl_2N_4O_4$
MOLECULAR WEIGHT: For active: 531.43
FREEZING POINT: ~0°C (~212°F)
BOILING POINT: ~100°C (~212°F)
RELATIVE VAPOR DENSITY (air = 1): Not available.
EVAPORATION RATE (n-BuAc = 1): Not available.
SPECIFIC GRAVITY (water = 1): Not available.
FLAMMABILITY: Not flammable or combustible.
VAPOR PRESSURE, mm Hg @ 20°C: Not available.
pH: 8.5
OXIDIZING PROPERTIES: Not an oxidizer.
EXPLOSIVE PROPERTIES: Not applicable.
SOLUBILITY IN WATER: Soluble
OTHER SOLUBILITY: Not available.
COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): Not available.
HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product may be an identification or warning property to identify it in event of an accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Not reactive. Stable under normal conditions.
DECOMPOSITION PRODUCTS: *Combustion:* Carbon and nitrogen oxides. *Hydrolysis*: None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong acids and other material incompatible with typical medical preparations and materials that are incompatible with water.
POSSIBILITY OF HAZARDOUS REACTIONS OR 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 EXPOSURE BY ROUTE OF EXPOSURE: The main routes of occupational exposure to this product are via contact with skin or eyes.

INHALATION: Inhalation of the product is not anticipated to be a likely form of exposure to this product. If inhaled, irritation of the nose and upper respiratory system may occur. Symptoms of such exposure may include irritation of respiratory system.

CONTACT WITH SKIN or EYES: Skin contact may cause moderate to severe irritation, depending on concentration and duration of exposure. Eye contact may cause moderate to severe irritation. Effects may include stinging, watering, and redness of the eyes.

SKIN ABSORPTION: No information is available on possible skin absorption. All skin contact should be avoided.

INGESTION: Ingestion of this product is not anticipated to be a significant route of occupational exposure. Ingestion of this product (i.e., through poor hygiene practices) may cause irritation of the gastrointestinal system. Chronic ingestion may cause nausea and vomiting, and acidification of urine. Accidental ingestion may cause allergic skin reaction. Higher exposure causes unconsciousness. Other effects may occur as described under 'Other Potential Health Effects'.

INJECTION: Accidental injection of this product, via laceration or puncture by a contaminated object may cause intense pain and irritation in addition to the wound.

OTHER POTENTIAL HEALTH EFFECTS: Human pharmaceutical preparations containing the active ingredient Ketoconazole have included dermatitis, discharge, dryness, erythema, irritation, burning sensation, pain, pruritus, and pustules, eye irritation, eye swelling, keratoconjunctivitis sicca, Impetigo, pyogenic granuloma, dizziness, headache, paresthesia, acne, nail discoloration and facial swelling.

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS (continued): In addition, hepatitis and, at high doses, lowered testosterone and ACTH induced corticosteroid serum levels have been seen with orally administered Ketoconazole; these effects have not been seen with topically administered Ketoconazole.

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Exposure to this product in the workplace may irritate contaminated skin, eyes, mucous membranes, and other contaminated tissue.

Chronic: Effects from chronic exposure may include those described under "Other Potential Health Effects".

TARGET ORGANS: Acute: Occupational Exposure: Skin. Chronic: Occupational Exposure: Skin.

TOXICITY DATA: The following data are available for the active ingredient of this product. Toxicity data are available for the excipient ingredients, but are not presented in this SDS. Contact Bayer for additional information.

KETOCONAZOLE:

LDLo (Oral-Man) 45 mg/kg/17 days-intermittent: Behavioral: coma; Liver: jaundice, other or unclassified

LDLo (Oral-Woman) 412 mg/kg/15 weeks-intermittent: Behavioral: coma; Liver: hepatitis (hepatocellular necrosis), diffuse, jaundice, other or unclassified

LDLo (Oral-Woman) 264 mg/kg/66 days-intermittent: Liver: other changes

TDLo (Oral-Human) 2.857 mg/kg: Immunological Including Allergic: anaphylaxis

TDLo (Oral-Human) 8.6 mg/kg: Endocrine: androgenic; Biochemical: Metabolism (Intermediary): other

TDLo (Oral-Human) 154.3 mg/kg/9 days-Intermittent: Endocrine: androgenic; Biochemical: Metabolism (Intermediary): other

TDLo (Oral-Human) 1539 mg/kg/90 days-intermittent: Endocrine: gynecomastia

TDLo (Oral-Woman) 60 mg/kg: Liver: other changes

TDLo (Oral-Woman) 20 mg/kg/2 days-intermittent: Vascular: BP lowering not characterized in autonomic section, regional or general arteriolar or venous dilation; Immunological Including Allergic: anaphylaxis

TDLo (Oral-Child) 450 mg/kg/90 days-intermittent: Endocrine: evidence of thyroid hypofunction; Nutritional and Gross Metabolic: other changes

TDLo (Oral-Man) 1029 mg/kg: male 60 day(s) pre-mating: Reproductive: Paternal Effects: other effects on male; Endocrine: androgenic

TDLo (Oral-Man) 49 mg/kg/17 days-intermittent: Liver: other changes

TDLo (Oral-Man) 5.7 mg/kg: Endocrine: androgenic, other changes

TDLo (Oral-Man) 240 mg/kg/3 weeks-intermittent: Endocrine: other changes; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Metabolism (Intermediary): other proteins

TDLo (Unreported-Man) 77,100 mg/kg/27 days-intermittent: Behavioral: headache; Liver: jaundice, other or unclassified; Kidney/Ureter/Bladder: other changes in urine composition

LD_{50} (Oral-Rat) 166 mg/kg

LD_{50} (Oral-Mouse) 618 mg/kg

LD_{50} (Oral-Dog) 178 mg/kg

LD_{50} (Oral-Guinea Pig) 178 mg/kg

LD_{50} (Intraperitoneal-Rat) 1474 mg/kg

LD_{50} (Intraperitoneal-Mouse) 2937 mg/kg

LD_{50} (Subcutaneous-Rat) > 2400 mg/kg

LD_{50} (Subcutaneous-Mouse) > 4 gm/kg

LD_{50} (Intravenous-Rat) 96 mg/kg

LD_{50} (Intravenous-Mouse) 32 mg/kg

LD_{50} (Intravenous-Dog) 23,300 µg/kg

LD_{50} (Intravenous-Guinea Pig) 23,300 µg/kg

TDLo (Oral-Rat) 24 mg/kg: Endocrine: androgenic; Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count)

TDLo (Oral-Rat) 227 mg/kg: Kidney/Ureter/Bladder: other changes

TDLo (Oral-Rat) 720 mg/kg/30 days-intermittent: Reproductive: Paternal Effects: testes, epididymis, sperm duct

KETOCONAZOLE (continued):

TDLo (Oral-Rat) 480 mg/kg/20 days-intermittent: Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Oral-Rat) 80 mg/kg/8 days-continuous: Endocrine: other changes; Related to Chronic Data: changes in uterine weight

TDLo (Oral-Rat) 750 mg/kg/30 days-intermittent: Reproductive: Paternal Effects: other effects on male

TDLo (Oral-Rat) 375 mg/kg/15 days-intermittent: Endocrine: changes in gonadotropins

TDLo (Oral-Rat) 1125 mg/kg/15 days-intermittent: Liver: changes in liver weight; Endocrine: changes in gonadotropins

TDLo (Oral-Rat) 1500 mg/kg/15 days-intermittent: Liver: changes in liver weight; Endocrine: changes in gonadotropins; Related to Chronic Data: changes in prostate weight

TDLo (Oral-Rat) 700 mg/kg/28 days-intermittent: Endocrine: estrogenic

TDLo (Oral-Rat) 2800 mg/kg/28 days-intermittent: Endocrine: changes in adrenal weight; Related to Chronic Data: changes in prostate weight

TDLo (Oral-Rat) 175 mg/kg/28 days-intermittent: Related to Chronic Data: changes in uterine weight

TDLo (Oral-Rat) 1400 mg/kg/28 days-intermittent: Endocrine: changes in adrenal weight; Related to Chronic Data: changes in ovarian weight

TDLo (Oral-Rat) 2800 mg/kg/28 days-intermittent: Cardiac: changes in heart weight; Endocrine: estrogenic; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Oral-Rat) 2800 mg/kg/28 days-intermittent: Liver: changes in liver weight; Kidney/Ureter/Bladder: changes in kidney weight; Endocrine: evidence of thyroid hypofunction

TDLo (Oral-Rat) 1135 mg/kg/5 days-intermittent: Liver: other changes; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

TDLo (Oral-Rat) 6480 mg/kg: male 9 week(s) pre-mating female 2 week(s) pre-mating: 7 day(s) after conception: Reproductive: Fertility: mating performance (e.g. # sperm positive females per # females mated; # copulations per # estrus cycles), female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)

TDLo (Oral-Rat) 600 mg/kg/3 days-continuous: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count)

TDLo (Oral-Rat) 600 mg/kg: male 3 day(s) pre-mating: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count); Fertility: male fertility index (e.g. # males impregnating females per # males exposed to fertile non-pregnant females)

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD (BLUE)	2*
FLAMMABILITY HAZARD (RED)	0
PHYSICAL HAZARD (YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

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

KETOCONAZOLE (continued):

TDLo (Oral-Rat) 3240 mg/kg: male 9 week(s) pre-mating female 2 week(s) pre-mating - 7 day(s) after conception: Reproductive: Fertility: pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea), litter size (e.g. # fetuses per litter; measured before birth)

TDLo (Oral-Ret) 980 mg/kg: female 7-17 day(e) after conception: Reproductive: Fertility: litter size (e.g. # fetuses per litter; measured before birth); Effects on Embryo or Fetus: fetal death; Specific Developmental Abnormalities: musculoskeletal system

TDLo (Oral-Rat) 1040 mg/kg: female 17-21 day(s) after conception lactating female 21 day(s) post-birth: Reproductive: Maternal Effects: parturition; Effects on Newborn: viability index (e.g. # alive at day 4 per # born alive)

TDLo (Oral-Rat) 300 mg/kg: male 1 day(s) pre-mating: Reproductive: Paternal Effects: other effects on male

TDLo (Oral-Rat) 520 mg/kg: female 6-18 day(s) after conception: Reproductive: Maternal Effects: other effects; Fertility: litter size (e.g. # fetuses per litter; measured before birth); Effects on Embryo or Fetus: fetal death

TDLo (Oral-Rat) 80 mg/kg: female 1-8 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)

TDLo (Oral-Rat) 175 mg/kg: male 28 day(s) pre-mating: Reproductive: Paternal Effects: prostate, seminal vesicle, Cowper's gland, accessory glands

TDLo (Oral-Rat) 2800 mg/kg: male 28 day(s) pre-mating: Reproductive: Paternal Effects: testes, epididymis, sperm duct, prostate, seminal vesicle, Cowper's gland, accessory glands

TDLo (Oral-Rat) 175 mg/kg: female 28 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina

TDLo (Oral-Rat) 1400 mg/kg: female 28 day(s) pre-mating: Reproductive: Maternal Effects: ovaries, fallopian tubes

TDLo (Oral-Rat) 2800 mg/kg: female 28 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina; Reproductive: Maternal Effects: menstrual cycle changes or disorders

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

KETOCONAZOLE (continued):

TDLo (Oral-Rat) 1760 mg/kg: female 1-21 day(s) after conception: Reproductive: Maternal Effects: other effects; Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: musculoskeletal system

TDLo (Oral-Mouse) 24,000 mg/kg/60 days-continuous: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count)

TDLo (Oral-Mouse) 1749 ng/kg/7 days-intermittent: Liver: other changes, changes in liver weight; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: hepatic microsomal mixed oxidase (dealkylation, hydroxylation, etc.)

TDLo (Oral-Mouse) 3125 ng/kg/21 days-intermittent: Liver: other changes

TDLo (Oral-Mouse) 300 mg/kg: male 1 day(s) pre-mating: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count)

TDLo (Oral-Rabbit) 40 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

KETOCONAZOLE (continued):

TDLo (Oral-Dog) 1200 mg/kg/30 days-intermittent: Liver: other changes, changes in liver weight

TDLo (Oral-Dog) 280 mg/kg/7 days-intermittent: Reproductive: Paternal Effects: testes, epididymis, sperm duct; Biochemical: Metabolism (Intermediary): other proteins

TDLo (Intraperitoneal-Rat) 100 mg/kg: Liver: hepatitis (hepatocellular necrosis), zonal; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

TDLo (Intraperitoneal-Rat) 600 mg/kg/4 days-intermittent: Liver: changes in liver weight; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intraperitoneal-Rat) 2250 mg/kg/15 days-intermittent: Liver: changes in liver weight; Endocrine: androgenic; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intraperitoneal-Rat) 500 mg/kg/5 days-intermittent: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects; Related to Chronic Data: changes in testicular weight

KETOCONAZOLE (continued):

TDLo (Intraperitoneal-Mouse) 900 mg/kg/6 weeks-intermittent: Tumorigenic: active as anti-cancer agent; Nutritional and Gross Metabolic: other changes

TDLo (Subcutaneous-Rat) 350 mg/kg/14 days-intermittent: Endocrine: androgenic

TDLo (Subcutaneous-Rat) 700 mg/kg/14 days-intermittent: Reproductive: Paternal Effects: prostate, seminal vesicle, Cowper's gland, accessory glands; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intraduodenal-Rat) 50 mg/kg: Liver: other changes; Biochemical: Metabolism (Intermediary): lipids including transport

TDLo (Unreported-Rat) 40 mg/kg: Liver: other changes; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

TDLo (Unreported-Rat) 144 mg/kg/12 days-continuous: Reproductive: Maternal Effects: parturition; Endocrine: other changes

DNA Inhibition (Human Lymphocyte) 10 mg/L

DNA Inhibition (Human Cells-Not Otherwise Specified) 1 µmol/L

DNA Damage (Human Liver) 1 mmol/L/48 hours

CARCINOGENIC POTENTIAL OF COMPONENTS: The carcinogenic potential of Ketoconazole, when in human-use gel formulations, has been evaluated in a 2-year dermal carcinogenicity study in CD-1 mice. Ketoconazole gel applied topically at doses up to 80 mg Ketoconazole/kg/day (76 times the human dose) exhibited no evidence of dermal or systemic tumorigenic effects attributable to Ketoconazole or the gel vehicle. A long-term feeding study in Swiss Albino mice and in Wistar rats showed no evidence of oncogenic activity. Ketoconazole gel at a dosage up to 5 mg/kg/dose is not photocarcinogenic when topically applied to hairless mice five days per week for a period of 40 weeks.

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: This product may irritate the respiratory system, mucous membranes, skin, and eyes, depending on the duration and concentration of exposure.

SENSITIZATION TO THE PRODUCT: Contact dermatitis has been reported following topical application of imidazole-derivative azole antifungals. Cross-sensitization appears to occur among the imidazole derivatives; however, cross-sensitivity appears to be unpredictable. The fact that patients with contact sensitivity to one imidazole-derivative azole antifungal may be sensitive to other similar drugs should be considered.

REPRODUCTIVE TOXICITY INFORMATION: When used in human-use gel products, Ketoconazole is rated Pregnancy Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks). The following information is available for the active component of this product.

Mutagenicity: Ketoconazole produced no evidence of mutagenicity in the dominant lethal mutation test in male and female mice at single oral doses up to 80 mg/kg. When tested in the Ames assay, Ketoconazole was found to be non-mutagenic to *Salmonella typhimurium* in the presence and absence of metabolic activation. Ketoconazole, in combination with another drug, gave equivocal results in the mouse micronucleus test.

Embryotoxicity/Teratogenicity: Ketoconazole was tested for its effects on offspring in the rat at oral doses of 10, 20, 40, 80, and 160 mg/kg. Ketoconazole was teratogenic (syndactylia and oligodactylia) at 80 mg/kg/day and embryotoxic at 160 mg/kg/day (76 and 152 times the human dose, respectively). However, these effects may be related to maternal toxicity, which was also seen at these dose levels. Oral doses of 10, 20, 40, 80, and 160 mg/kg were studied in pre- and postnatal development studies in rats. Doses of 40 mg/kg (38 times the human dose) and above were associated with maternal toxicity, an increase in the length of gestation, and an increase in the number of stillborn fetuses. These doses of Ketoconazole were also toxic to the offspring, resulting in a decrease in fetal/pup weights and viability.

Reproductive Toxicity: At oral doses of 75 to 80 mg/kg/day (71 to 76 times the human dose) Ketoconazole impaired the reproductive performance in female (decreased pregnancy and implantation rates) and male (increased abnormal sperm and decreased sperm motility) rats.

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY IN SOIL: This product has not been tested for mobility in soil. Due to liquid form, it is expected to be mobile.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that some biodegradation will occur to this product; however, no specific information is known.

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

12. ECOLOGICAL INFORMATION (Continued)

ECOTOXICITY: This product may be harmful or fatal to contaminated plant and animal-life (especially if large quantities are released). This product has not been tested for aquatic toxicity; however, the active ingredient is an anti-fungal compound which is highly toxic to aquatic organisms.

OTHER ADVERSE EFFECTS: The components of this product are not known to have 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 product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. 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 product 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 product 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 to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

UN Identification Number:	UN 3082
Proper Shipping Name:	Environmentally hazardous substance, liquid, n.o.s. (Ketoconazole)
Hazard Class Number and Description:	9 (Miscellaneous Hazardous Material)
Packing Group:	PG III
Dot Label(s) Required:	Class 9 (Miscellaneous Hazardous Material)

North American Emergency Response Guidebook Number (2004): 171

Marine Pollutant: This product meets the definition of a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product meets the criteria as Dangerous Goods, per regulations of Transport Canada.

UN Identification Number:	UN 3082
Proper Shipping Name:	Environmentally hazardous substance, liquid, n.o.s. (Ketoconazole)
Hazard Class Number and Description:	9 (Miscellaneous Hazardous Material)
Packing Group:	PG III
Hazard Shipping Label(s) Required:	Class 9 (Miscellaneous Hazardous Material)
Special Provisions:	16
Explosive Limit & Limited Quantity Index:	5
ERAP Index:	None
Passenger Carrying Ship Index:	None
Passenger Carrying Road Or Rail Vehicle Index:	None

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product meets the criteria as Dangerous Goods, per rules of IATA.

UN Identification Number:	UN 3082
Proper Shipping Name:	Environmentally hazardous substance, liquid, n.o.s. (Ketoconazole)
Hazard Class or Division:	9 (Miscellaneous Hazardous Material)
Hazard Label(s) Required:	Class 9 (Miscellaneous Hazardous Material)
Packing Group:	III
Excepted Quantities:	E1
Passenger and Cargo Aircraft Packing Instruction:	964
Passenger and Cargo Aircraft Maximum Net Quantity Per Pkg:	450 L
Passenger and Cargo Aircraft Limited Quantity Packing Instruction:	Y964
Passenger and Cargo Aircraft Limited Quantity Maximum Net Quantity Per Pkg:	30 kg G
Cargo Aircraft Only Packing Instruction:	954
Cargo Aircraft Only Maximum Net Quantity Per Pkg:	450 L
Special Provisions:	A97, A158
ERG Code:	9L

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.

15. REGULATORY INFORMATION (Continued)

ADDITIONAL U.S. REGULATIONS (continued):

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: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No

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

U.S. TSCA INVENTORY STATUS: 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): **WARNING!** MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. MAY BE HARMFUL BY INGESTION. CONTAINS COMPOUND THAT MAY CAUSE DAMAGE TO FETUS AND FERTILITY. CONTAINS COMPOUND THAT IS HIGHLY TOXIC TO AQUATIC ORGANISMS. 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. Seek medical attention. IN CASE OF FIRE: Use water fog, dry chemical or CO_2, or alcohol foam. IN CASE OF SPILL: Absorb spilled product with polypads or other appropriate absorbent. Decontaminate area with soapy water. Place in a suitable container. Refer to SDS for additional information.

GLOBAL HARMONIZATION LABELING AND CLASSIFICATION:

Classification: Reproductive Toxicity Category 1B, Acute Oral Toxicity Category 4, Skin Irritation Category 2, Eye Irritation Category 2B, Specific Target Organ Toxicity (Inhalation-Respiratory Irritation) Single Exposure Category 3, Aquatic Acute Toxicity Category 1, Acute Chronic Toxicity Category 1

Signal Word: Danger

Hazard Statements: H360F: May damage fertility. H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation. H373: May cause damage to organs through prolonged or repeated exposure. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.

Precautionary Statements:

Prevention: P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breath mists, sprays, fume. P264: Wash thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response: P308 + P313: IF exposed or concerned: Get medical advice/attention. 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. P332 + P313: If skin irritation occurs, get medical attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention. P304 + P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing. P312: Call a POISON CENTER or doctor if you feel unwell. P321: Specific treatment (remove from exposure and treat symptoms). P391: Collect spillage.

Storage: P403 + P233 + P405: Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal: P501: Dispose of contents/containers in accordance with all local, regional, national and international regulations.

Hazard Symbols/Pictograms: GHS07, GHS08, GHS09

16. OTHER INFORMATION (Continued)

GLOBAL HARMONIZATION LABELING AND CLASSIFICATION (continued):

CLASSIFICATION FOR COMPONENTS:

FULL TEXT GLOBAL HARMONIZATION:

KETOCONAZOLE:

Classification: Reproductive Toxicity Category 1B, Acute Oral Toxicity Category 1, Specific Target Organ Toxicity Repeated Exposure Category 2, Aquatic Acute Toxicity Category 1, Aquatic Chronic Toxicity Category 1

Hazard Statements: H360F: May damage fertility. H301: Toxic if swallowed. H373: May cause damage to organs through prolonged or repeated exposure. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.

BENZYL ALCOHOL:

Classification: Acute Oral Toxicity Category 4, Acute Dermal Toxicity Category 4, Acute Inhalation Toxicity Category 4

Hazard Statement s: H302 + H312 + H332: Harmful if swallowed, in contact with skin or if inhaled.

TROMETHAMINE BASE:

Classification: Skin Irritation Category 2B, Eye Irritation Category 2, Specific Target Organ Toxicity (Inhalation-Respiratory Irritation) Single Exposure Category 3

Hazard Statement s: H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation.

ALL OTHER COMPONENTS:

An official classification for these substances has not been published.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

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.

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

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed.

DFG MAK Pregnancy Risk Group Classification (continued): 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.

EXPOSURE LIMITS IN AIR (continued):

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*: > 0.05-0.5 mg/L.); 4 (Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure. *Skin Irritation*: Not appropriate. Do not rate as a "4", based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a "4", based on eye irritation alone. *Oral Toxicity LD_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L).

FLAMMABILITY HAZARD: 0 (Minimal Hazard-Materials that will not burn in air when exposure to a temperature of 815.5°C [1500°F] for a period of 5 minutes.); 1 (Slight Hazard-Materials that must be pre-heated before ignition can occur. Material 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;

DEFINITIONS OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 2 (continued): 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 whose LC_{50} for acute inhalation toxicity is greater than 10,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 200 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 2000 mg/kg. Materials whose LD_{50} for acute oral toxicity is greater than 2000 mg/kg. Materials that are essentially non-irritating to the respiratory tract, eyes and skin. 1 (materials that, under emergency conditions, can cause significant irritation): Gases and vapors whose LC_{50} for acute inhalation toxicity is greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 10 mg/L but less than or equal to 200 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials whose LD_{50} for acute oral toxicity is greater than 500 mg/kg but less than or equal to 2000 mg/kg. Materials that cause slight to moderate irritation to the respiratory tract, eyes and skin. 2 (materials that, under emergency conditions, can cause temporary incapacitation or residual injury): Gases and vapors whose LC_{50} for acute inhalation toxicity is greater than 3,000 ppm but less than or equal to 5,000 ppm.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD (continued): 2 (continued): Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 2 mg/L but less than or equal to 10 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 200 mg/kg but less than or equal to 1000 mg/kg. Materials whose LD_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 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 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. 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. 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 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. 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.

DEFINITIONS OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD (continued): 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_{ow}** 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.

REGULATORY INFORMATION (continued):

U.S. and CANADA (continued):

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.