SAFETY DATA SHEETS

This SDS packet was issued with item:
078475075

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

078683419

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, REACH, European Union CLP EC 1272/2008 and the Global Harmonization Standard

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

1. SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

TRADE NAME/MATERIAL NAME: Ketoconazole Cream 2.0%

DESCRIPTION:	Ketoconazole Cream 2.0%
NDC #:	0168-0099-15; 0168-0099-30; 0168-0099-60
CHEMICAL NAME (for active ingredient):	*cis*-1-Acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1*H*-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine
CHEMICAL FAMILY (for active ingredient):	Substituted Piperazine
HOW SUPPLIED:	2.0% Ketoconazole Cream
FORMULA (for active ingredient):	$C_{26}H_{28}Cl_2N_4O_4$
RELEVANT USE of the SUBSTANCE:	Pharmaceutical for Human Use
USES ADVISED AGAINST	Other than Relevant Use
SUPPLIER/MANUFACTURER'S NAME:	**FOUGERA PHARMACEUTICALS INC.**
ADDRESS:	60 Baylis Road Melville, NY 11747
BUSINESS PHONE/GENERAL SDS INFORMATION:	1-631-454-7677
EMERGENCY PHONE (U.S./Canada/Puerto Rico):	CHEMTEL: (U.S, Canada, Int'l) 1(813) 676-1670 (24 hrs)

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW: ***Product Description:*** This product is a white, smooth, odorless cream. ***Health Hazards:*** In the workplace, exposure via eye contact may cause irritation. Prolonged skin contact may cause redness or skin discomfort. Ingestion may be harmful. Inhalation is unlikely due to viscosity. In therapeutic use, the most common adverse effects reported include local skin reactions such as severe irritation, itching and stinging at the site of application or surrounding areas. Rare reports of contact dermatitis have been associated with Ketoconazole Cream, but may due to one of its excipients, namely Sodium Sulfite. Painful allergic skin reaction has also been reported. Human information indicates possible adverse effects on fertility in men. May cause harm to the fetus during pregnancy, based on animal data. These effects may be possible as a result of workplace exposure. See Section 11 (Toxicological Information) for information on other potential health hazards known from therapeutic use. ***Flammability Hazards:*** This product is combustible and may ignite if exposed to direct flame or if highly heated for a prolonged period. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds, including carbon, sodium, sulfur and nitrogen oxides, formaldehyde, hydrogen chloride. ***Reactivity Hazards:*** This product is not reactive. ***Environmental Hazards:*** This product has not been tested for environmental effects. ***Emergency Considerations:*** Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
ACTIVE INGREDIENT				
Ketoconazole *cis*-1-Acetyl-4-[4-[[2-(2,4-dichlorophenyl)-2-(1*H*-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine	65277-42-1	Not Listed	0.05%	SELF-CLASSIFICATION EU 67/548 Classification: Reproductive Toxicity Cat. 2, Dangerous for the Environment Risk Phrase Codes: R60, R25, R48/22, R50/53 Hazard Symbol: T, N GHS & EU 1272/2008 Classification: Reproductive Toxicity Cat. 1B, Acute Oral Toxicity Cat. 3, STOT (Ingestion-Liver) 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

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

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
EXCIPIENTS:				
Cetyl Alcohol	36653-82-4	253-149-0	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Not Applicable Risk Phrases: Not Applicable Symbols: Applicable GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5, Acute Dermal Toxicity Cat. 5 Hazard Statement Codes: H303 + H313 Hazard Symbols/Pictograms: Not Applicable
Isopropyl Myristate	110-27-0	203-751-4	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Irritant Risk Phrases: R38 Symbols: Xi GHS and EU 1272/2008 Classification: Skin Irritation Cat. 2 Hazard Statement Codes: H315 Hazard Symbols/Pictograms: GHS07
Polysorbate 60	9005-67-8	NLP: 500-020-4	Proprietary	EU 67/548 Classification Not Applicable EU/GHS 1272/2008 Classification Not Applicable
Polysorbate 80	9005-65-6	NLP: 500-019-9	Proprietary	EU 67/548 Classification Not Applicable EU/GHS 1272/2008 Classification Not Applicable
Propylene Glycol	57-55-6	200-338-0	Proprietary	EU 67/548 Classification Not Applicable EU/GHS 1272/2008 Classification Not Applicable
Sodium Sulfite Anhydrous	7757-83-7	231-821-4	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Carcinogenic Cat. 3, Harmful Risk Phrases: R40, R22 Symbols: Xn GHS and EU 1272/2008 Classification: Carcinogenic Cat. 2, Acute Oral Toxicity Cat. 4 Hazard Statement Codes: H351, H302 Hazard Symbols/Pictograms: GHS07, GHS08
Sorbitan Monostearate	123-94-4	204-664-4	Proprietary	EU 67/548 Classification Not Applicable EU/GHS 1272/2008 Classification Not Applicable
Stearyl Alcohol	112-92-5	204-017-6	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Not Applicable Risk Phrases: Not Applicable Symbols: Applicable GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbols/Pictograms: Not Applicable
Water and other trace components of less than 1% concentration			Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 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

PROTECTION OF FIRST AID RESPONDERS: rescuers should wear adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, if necessary. Remove victim(s) to fresh air, as quickly as possible. Take copy of product label and SDS to physician or other health professional with victim(s).

Skin Exposure: If adverse skin effects occur, discontinue use. Seek medical attention.

Eye Exposure: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Inhalation: If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

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.

4 FIRST-AID MEASURES (Continued)

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions, renal conditions, blood disorders, cardiac arrhythmia, liver conditions and allergy to azoles or triazoles may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to this material, or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. No specific antidote is available for this product. Treatment should be symptomatic and supportive.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not applicable.

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

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

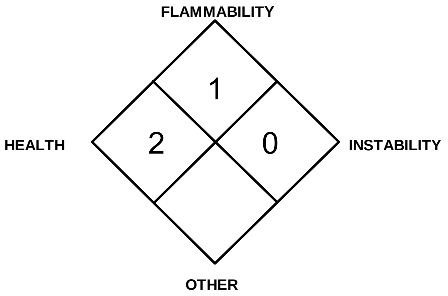
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE PRODUCT: This product is combustible. If heated to high temperatures for a prolonged period it may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic gases (e.g., carbon, sodium, sulfur and nitrogen oxides, formaldehyde, hydrogen chloride).

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

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12” x 12”) of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product. Spills may be slippery.

PROTECTIVE EQUIPMENT:

Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

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

METHODS FOR CLEAN-UP AND CONTAINMENT:

Cleanup of Small Spills: The product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Large Spills: Review Sections 2, 8, 11 and 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 spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements.

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, 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 USE

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 product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.

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

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F) [USP Controlled Room Temperature]. Protect from freezing. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat. Wipe equipment down with damp sponge or polypad. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water. Collect all rinsates and dispose of according to applicable waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

***Ventilation and Engineering Controls**:* Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Workplace Exposure Limits/Control Parameters:

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	ppm
Ketoconazole	65277-42-1	NE	NE	NE	NE	NE	NE	NE	NE
Cetyl Alcohol	36653-82-4	NE	NE	NE	NE	NE	NE	NE	NE
Isopropyl Myristate	110-27-0	NE	NE	NE	NE	NE	NE	NE	NE
Polysorbate 60	9005-67-8	NE	NE	NE	NE	NE	NE	NE	NE
Polysorbate 80	9005-65-6	NE	NE	NE	NE	NE	NE	NE	NE
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10
Sodium Sulfite Anhydrous	7757-83-7	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Sorbitan Monostearate (Exposure limits are for Stearates)	123-94-4	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Stearyl Alcohol	112-92-5	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established

International Occupational Exposure Limits: The following additional international exposure limits are available for some components.

CETYL ALCOHOL:
Austria: MAK 200 mg/m^3 (20 ppm), JAN 2006
PROPYLENE GLYCOL:
Australia: TWA = 10 mg/m^3 (particulates), JUL 2008
Australia: TWA = 150 ppm (474 mg/m^3) (total), JUL 2008
New Zealand: TWA = 10 mg/m^3 (particulates only), JAN 2002
PROPYLENE GLYCOL (continued):
Russia: STEL = 7 mg/m^3, JUN 2003
United Kingdom: TWA = 10 mg/m^3 (particulate), 2005
United Kingdom: TWA = 150 ppm (474 mg/m^3) (total vapor), 2005
STEARYL ALCOHOL:
Austria: MAK 224 mg/m^3 (20 ppm), JAN 2006

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), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PROTECTIVE EQUIPMENT (continued):

Respiratory Protection: Not typically needed under normal circumstances of handling and use. Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

Skin Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Creamy liquid.

MOLECULAR WEIGHT: Mixture.

ODOR: Odorless.

BOILING POINT: Not established.

EVAPORATION RATE (nBuAc = 1): Not established.

VAPOR PRESSURE (air = 1): Not established.

SOLUBILITY IN WATER: Soluble.

COLOR: White to off-white.

MOLECULAR FORMULA: Mixture.

ODOR THRESHOLD: Not applicable.

FREEZING/MELTING POINT: Not established.

pH: 6.5-8.5

SPECIFIC GRAVITY @ 50°C (water = 1): Approx. 0.9

OTHER SOLUBILITIES: Not known.

COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

HOW TO DETECT THIS SUBSTANCE (warning properties): There appearance may be a property to identify the product in event of accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon, sodium, sulfur and nitrogen oxides, formaldehyde, hydrogen chloride). ***Hydrolysis:*** None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, strong oxidizers, water reactive materials, and other chemicals that could affect its performance should be avoided.

POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat and contact with incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

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

Inhalation: Inhalation of the product is unlikely due to viscosity of product. If aerosols are somehow generated and inhaled, irritation of the nose and upper respiratory system may occur. Symptoms of such exposure may include sneezing, coughing, and nasal congestion.

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness and other symptoms described under 'Other Health Effects'. Symptoms of eye contact may include redness, pain, and watering.

Skin Absorption: This product is designed to be absorbed into the skin.

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 be harmful or irritate the mouth, throat, and other tissues of the gastrointestinal system.

Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection.

OTHER HEALTH EFFECTS-Therapeutic Use: In therapeutic use, the most common adverse effects reported include local skin reactions such as severe irritation, itching and stinging at the site of application or surrounding areas. Rare reports of contact dermatitis have been associated with Ketoconazole Cream, but may due to one of its excipients, namely Sodium Sulfite or Propylene Glycol. Painful allergic skin reaction has also been reported. Human information indicates possible adverse effects on fertility in men. May cause harm to the fetus during pregnancy, based on animal data.

11. TOXICOLOGICAL INFORMATION (Continued)

IRRITANCY OF PRODUCT: Prolonged contact may irritate contaminated tissue.

SENSITIZATION OF PRODUCT: Rare reports of skin sensitization and contact dermatitis have been reported from therapeutic use of this product.

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

Acute: This product may cause irritation via inhalation or eye contact. Ingestion may be harmful.

Chronic: Repeated skin contact may cause dermatitis (dry, red skin). Chronic exposure may cause symptoms as described under 'Other Potential Health Effects'.

TARGET ORGANS:

Acute: *Occupational Exposure:* Skin. *Therapeutic Doses:* Skin.

Chronic: *Occupational Exposure:* Skin. *Therapeutic Doses:* Skin.

TOXICITY DATA: Only toxicity data available for the active component of this product are presented in this SDS. Additional data are available for the excipient components of this product, but are not presented in this SDS; Contact Fougera for more 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

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
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

KETOCONAZOLE (continued):
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
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 INFORMATION: The following information is available for the active ingredient.

A long-term feeding study in Swiss Albino mice and in Wistar rats showed no evidence of oncogenic activity. This material is not listed by agencies tracking the carcinogenic potential of chemical compounds.

Excipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

SODIUM MONOSTEARATE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)
SODIUM SULFITE, ANHYDROUS: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

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.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of Ketoconazole in pregnant women; however, Ketoconazole may cause fetal harm when administered to a pregnant woman. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. This product is rated by the FDA for therapeutic risk as Pregnancy Risk 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).

Mutagenicity: The dominant lethal mutation test in male and female mice revealed that single oral doses of Ketoconazole as high as 80 mg/kg produced no mutation in any stage of germ cell development. The Ames Salmonella microsomal activator assay was also negative. A long term feeding study in Swiss Albino mice and in Wistar rats showed no evidence of oncogenic activity.

Embryotoxicity/Teratogenicity: Ketoconazole has also been found to be embryotoxic in the rat when given in the diet at doses higher than 80 mg/kg during the first trimester of gestation. Ketoconazole has been shown to be teratogenic (syndactylia and oligodactylia) in the rat when given in the diet at 80 mg/kg/day (10 times the maximum recommended human dose). However, these effects may be related to maternal toxicity, evidence of which also was seen at this and higher dose levels. It is likely that both the malformations and the embryotoxicity resulting from the administration of oral Ketoconazole during gestation are a reflection of the particular sensitivity of the female rat to this drug. For example, the oral LD50 of Ketoconazole given by gavage to the female rat is 166 mg/kg whereas in the male rat the oral LD50 is 287 mg/kg.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (CONTINUED):

Reproductive Toxicity: Human oligospermia has been reported in investigational studies with the drug at dosages above those currently approved. Oligospermia has not been reported at dosages up to 400 mg daily, however sperm counts have been obtained infrequently in patients treated with these dosages. Ketoconazole may be found in breast milk; however, it is not known whether Ketoconazole Cream, 2% administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

Non-Teratogenic Effects: Dystocia (difficult labor) was noted in rats administered oral Ketoconazole during the third trimester of gestation. This occurred when Ketoconazole was administered at doses higher than 10 mg/kg (higher than 1.25 times the maximum human dose).

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for soil absorption or mobility. The following information is available for the components of this product:

ISOPROPYL MYRISTATE: Using a structure estimation method based on molecular connectivity indices, the Koc can be estimated to be about 15,000. According to a classification scheme, this estimated Koc value suggests that this compound is expected to be immobile in soil.

PROPYLENE GLYCOL: The Koc is estimated as 8, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that this compound is expected to have very high mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. The following information is available for the components of this product:

ISOPROPYL MYRISTATE: If released to air, a vapor pressure of 9.35X10-5 mm Hg at 25°C indicates this compound will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase material will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 20 hours. Particulate-phase material will be removed from the atmosphere by both wet and dry deposition. If released to soil, this compound is expected to have no mobility based upon an estimated Koc of 15,000. Volatilization from moist soil surfaces is expected to be an important fate process based upon an estimated Henry's Law constant of 0.009 atm-cu m/mole. However, adsorption to soil is expected to attenuate volatilization. This compound is expected to rapidly biodegrade in aerobic soils as suggested by the rapid biodegradation of structurally similar long-chain fatty acid esters. If released into water, this material is expected to adsorb to suspended solids and sediment in the water column based upon the estimated Koc. This compound is expected to rapidly biodegrade in aerobic waters as suggested by the rapid biodegradation of structurally similar long-chain fatty acid esters. Volatilization from water surfaces is expected to be an important fate process based upon this compound's estimated Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 5 hours and 6.5 days, respectively. However, volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column. The volatilization half-life from a model pond is estimated to be about 60 hours ignoring adsorption; when considering maximum adsorption the volatilization half-life increases to 130 days. An estimated base-catalyzed second-order hydrolysis rate constant of 0.021 L/mole-sec corresponds to half-lives of 10.2 years and 1 year at pH values of 7 and 8, respectively.

PROPYLENE GLYCOL: Based on a classification scheme, an estimated Koc value of 8, determined from a log Kow of -0.92 and a regression-derived equation, indicates that this material is expected to have very high mobility in soil. Volatilization of this compound from moist soil surfaces is not expected to be an important fate process given an estimated Henry's Law constant of 1.3X10-8 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/liter. This compound is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Laboratory experiments using agricultural soils from South Carolina conducted at 22°C and a fortification of 1,000 ppm this compound, yielded 73-78% mineralization during a 51 day incubation period, suggesting that biodegradation will be an important fate process in soils. Based on a classification scheme, an estimated Koc value of 8, determined from a log Kow of -0.92 and a regression-derived equation, indicates that this compound is not expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is not expected based upon an estimated Henry's Law constant of 1.3X10-8 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/L. Numerous screening studies using wastewater or sewage inoculum as seed, suggests that this material will be degraded readily under aqueous environments. According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, Propylene Glycol, which has a vapor pressure of 0.13 mmHg at 25°C, is expected to exist solely as a vapor in the ambient atmosphere. Vapor-phase material is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 32 hours, calculated from its rate constant of 1.2X10-11 cu cm/molecule-sec at 25°C

BIOACCUMULATION: This product has not been tested for bioconcentration. The following information is available for the components of this product:

ISOPROPYL MYRISTATE: An estimated BCF of 1200 was calculated using an estimated log Kow of 7.17 and a regression-derived equation. According to a classification scheme, the estimated BCF suggests the potential for bioconcentration in aquatic organisms is very high.

PROPYLENE GLYCOL: An estimated BCF of 3 was calculated, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

ECOTOXICITY: No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities. The following are aquatic toxicity data currently available for some components of this product.

PROPYLENE GLYCOL:
EC_{50} (*Photobacterium phosphoreum*, bacteria) 30 minutes = 26,800 mg/L
EC_{50} (*Daphnia magna*, crustacean) 48 hours = 34,400 mg/L
EC_{50} (*Daphnia magna*, crustacean) 24 hours = > 10,000 mg/L
EC_{50} (*Nitocra spinipes*, crustacean) 96 hours = > 10,000 mg/L
LC_{50} (*Carassius auratus*) 24 hours = > 5,000 mg/L

PROPYLENE GLYCOL (continued):
LC_{50} (*Lebistes reticulatus*, guppy) 48 hours > 10,000 mg/L
LC_{50} (*Salmo gairdneri*) 24 hours = 50,000 mg/L
LC_{50} (*Pimephales promelas*) 96 hr = 54,900 mg/L
LC_{50} (Artemia salina) 24 hours = >10,000 mg/L
LC_{100} (*Pimephales promelas*) 96 hr = 65,610 mg/L

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

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

OTHER ADVERSE EFFECTS: No component of this product is known to have ozone depletion potential.

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

13. DISPOSAL CONSIDERATIONS (Continued)

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

PREPARING WASTES FOR DISPOSAL: This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this product should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

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

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component is listed on the California Proposition 65 lists.

Other U.S. Federal Regulations: Not applicable.

CANADIAN REGULATIONS:

Canadian DSL/NDSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: The components of this product are not on the CEPA Priorities Substances Lists.

Other Canadian Regulations: Not 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.

EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: Formulated, finished medicinal products for human use are subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **WARNING!** INGESTION MAY BE HARMFUL. PROLONGED SKIN CONTACT MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE RESPIRATORY SYSTEM AND EYE IRRITATION. LIMITED EVIDENCE OF HARM TO FETUS DURING PREGNANCY, BASED ON ANIMAL DATA. MAY BE COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES.

16. OTHER INFORMATION

ANSI LABELING (continued): Do not use therapeutically without prescription. Do not 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. If alert, give victim up to three glasses of water. 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: Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place in a suitable container. Refer to SDS for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

Full Text CLP 1272/2008/Global Harmonization:

Ketoconazole: The following is a Self-Classification.

Classification: Reproductive Toxicity Category 1B, Acute Oral Toxicity Category 3, Specific Target Organ Toxicity (Ingestion-Liver) Repeated Exposure Category 2, Aquatic Acute Toxicity Category 1, Aquatic Chronic Toxicity Category 1

Hazard Statement Codes: H360Fd: May damage fertility. Suspected of damaging the unborn child. H301: Toxic if swallowed. H373: May cause damage to liver through prolonged or repeated exposure by ingestion. H410: Very toxic to aquatic life with long-lasting effects.

Cetyl Alcohol: This is a self-classification.

Classification: Acute Oral Toxicity Category 5, Acute Dermal Toxicity Category 5

Hazard Statements: H303 + H313: May be harmful if swallowed or in contact with skin.

Isopropyl Myristate: This is a self-classification.

Classification: Skin Irritation Category 2

Hazard Statement Codes: H315: Causes skin irritation.

Sodium Sulfite Anhydrous: This is a self-classification.

Classification: Carcinogenic Category 2, Acute Oral Toxicity Category 4

Hazard Statements: H351: Suspected of causing cancer. H302: Harmful if swallowed.

Stearyl Alcohol: This is a self-classification.

Classification: Acute Oral Toxicity Category 5

Hazard Statements: H303: May be harmful if swallowed.

All Other Components: No classification has been published or is applicable.

Full Text EU 67/548/EEC:

Ketoconazole: The following is a Self-Classification.

Classification: Reproductive Toxicity Category 2, Toxic, Dangerous for the Environment

Hazard Statements: R60: May impair fertility. R63: Possible risk of harm to the unborn child. R25: Toxic if swallowed. R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Isopropyl Myristate: This is a self-classification.

Classification: Irritant

Hazard Statements: R38: Irritating to skin.

All Other Components: No classification has been published or is applicable.

REVISION DETAILS: June 2014: Up-date of entire SDS to include European CLP and the Global Harmonization Standard.

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 • 800/441-3365 • 808/969-4846

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DEFINITION 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.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed humans. **2:** Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed mammals.

EXPOSURE LIMITS IN AIR (continued):

DFG MAK Germ Cell Mutagen Categories (continued): 3A: Substances that have been shown to induce genetic damage in germ cells of human of animals, or which produce mutagenic effects in somatic cells of mammals *in vivo* and have been shown to reach the germ cells in an active form. **3B:** Substances that are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell *in vivo*; in exceptional cases, substances for which there are no *in vivo* data, but that are clearly mutagenic in vitro and structurally related to known in vivo mutagens.

DEFINITION OF TERMS (Continued)

EXPOSURE LIMITS IN AIR (continued)

DFG MAK Germ Cell Mutagen Categories (continued): 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: 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, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

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

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

WEEL: Workplace Environmental Exposure Limits from the AIHA.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

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

HEALTH HAZARD: **0** Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation*: Essentially non-irritating. Mechanical irritation may occur. PII or Draize = 0. *Eye Irritation*: Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. *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; may irritate the stomach if swallowed; may defat the skin and exacerbate existing dermatitis. *Skin Irritation*: Slightly or mildly irritating. PII or Draize > 0 < 5. *Eye Irritation*: Slightly to mildly irritating, but reversible within 7 days. Draize > 0 ≤ 25. *Oral Toxicity* 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; prolonged exposure may affect the CNS. *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize ≥ 5, with no destruction of dermal tissue. *Eye Irritation*: Moderately to severely irritating; reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. *Oral Toxicity* 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 cause destruction of dermal tissue, skin burns, and dermal necrosis. PII or Draize > 5–8, with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity* 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; extremely toxic; irreversible injury may result from brief contact. *Skin Irritation*: Not appropriate. Do not rate as a 4, based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a 4, based on eye irritation alone. *Oral Toxicity* 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 requires considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. This usually includes the following: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C (200°F) (i.e. OSHA Class IIIB); and Most ordinary combustible materials (e.g. wood, paper, etc.).

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

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

PHYSICAL HAZARD: **0** *Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No 0 rating. *Unstable Reactives*: Substances that will not polymerize, decompose, condense, or self-react). **1** *Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. *Explosives*: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives*: Substances that may decompose condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. Substances that readily undergo hazardous polymerization in the absence of inhibitors. **2** *Water Reactivity*: Materials that may react violently with water. *Organic Peroxides*: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives*: Division 1.4 explosives. Explosive substances where the explosive effects are 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 oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. **3** *Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.3 explosives. Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I oxidizers. Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. Liquids: any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. **4** *Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability 4. *Oxidizers*: No 4 rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

DEFINITION OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC$_{50}$ for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC$_{50}$ for acute inhalation toxicity greater than 200 mg/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. **3** Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC$_{50}$ for acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater 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. Dusts and mists with an LC$_{50}$ for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD$_{50}$ for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an LD$_{50}$ for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. **4** Materials that, under emergency conditions, can be lethal. Gases with an LC$_{50}$ for acute inhalation toxicity less than or equal to 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LC$_{50}$ for acute inhalation toxicity, if its LC$_{50}$ is less than or equal to 1000 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.

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 of NFPA 704. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendations on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85% by weight. Liquids that have no fire point when tested by ASTM D 92, *Standard Test Method for Flash and Fire Points by Cleveland Open Cup*, up to the boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal, and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD (continued): **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily. Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air, Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

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

FLAMMABILITY LIMITS IN AIR:

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

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. LD$_{50}$: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC$_{50}$: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. mg/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. TDLo: Lowest dose to cause a symptom. TCLo: Lowest concentration to cause a symptom. TDo, LDLo, and LDo, or TC, TCo, LCLo, and LCo: Lowest dose (or concentration) to cause lethal or toxic effects.

Cancer Information: IARC: International Agency for Research on Cancer. NTP: National Toxicology Program. RTECS: Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** BEI: ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An embryo toxin is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

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

REGULATORY INFORMATION:

U.S.:

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

CANADA:

WHMIS: Canadian Workplace Hazardous Materials Information System. TC: Transport Canada. DSL/NDSL: Canadian Domestic/Non-Domestic Substances List.

REVISION HISTORY

Date	**Changes**
November 16, 2015	Change emergency phone number to CHEMTEL.
June 15, 2014	Up-date to include current GHS & to add EU compliance.