SAFETY DATA SHEETS

This SDS packet was issued with item:

078914548

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

078914550 078914551

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).

078881069 078881077 078881085

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

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME (AS LABELED): **RELIEF SHAMPOO**
CHEMICAL NAMES: Active Ingredient: Pramoxine HCl: Morpholine: 4-[3-(4-butoxyphenoxy) propyl]-, hydrochloride
CHEMICAL CLASSES: Active Ingredient: Pramoxine HCl: Morpholine
PRODUCT USE: Veterinary Pharmaceutical/Veterinary Shampoo

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: December 29, 2012
DATE OF REVISION: February 19, 2013/Bayer

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 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: Classified in accordance with the Global Harmonization Standard. The following classification is self-classification for the pure material when not in a formulated human pharmaceutical product.

Classification: Reproductive Toxicity Cat. 2, Eye Damage Cat. 1, Acute Oral Toxicity Cat. 4, Skin Sensitization Cat. 1, Skin Irritation Cat. 2, Eye Irritation Cat. 2A, Aquatic Acute Toxicity Cat. 1, Aquatic Chronic Toxicity Cat. 1
Signal Word: Danger
Hazard Statement Codes: H361d, H318, H302, H315, H317, H410
Precautionary Statement Codes: P201, P202, P261, P264, P270, P272, P273, P280, P308 + P313, P305 + P351 + P338 + P310, P301 + P312, P330, P302 + P352, P333 + P313, P362 + P364, P321, P391, P405, P501
Hazard Symbol/Pictogram: GHS05, GHS07, GHS08, GHS09

See Section 16 for full text details on classification

EMERGENCY OVERVIEW: Product Description: This product is an opaque greenish viscous liquid with floral odor. **Health Hazards:** Ingestion of the product may be harmful. Direct eye contact may cause damage to cornea. Vapors may cause eye irritation. Contains possible skin sensitizers. Contact with abraded skin or breaks in skin may cause anaphylactic reactions in susceptible individuals. Prolonged or chronic skin contact may cause contact dermatitis. Inhalation of mists or sprays may cause moderate to severe irritation to the respiratory system. Contains compound that is a suspect reproductive toxin, based on animal data. See Section 11 (Toxicological Information) for information on other potential health hazards. **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, sulfur and nitrogen oxides, hydrogen chloride, phenol, formaldehyde, formic acid, glyoxal, and dioxalane). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** Although this product has not been tested for environmental harm, it contains compounds that pose an acute and chronic aquatic toxicity hazard. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% w/w	LABEL ELEMENTS GHS Classification Hazard Statement Codes
ACTIVE INGREDIENT			
Pramoxine HCl Morpholine: 4-[3-(4-butoxyphenoxy) propyl]-, hydrochloride	637-58-1	Proprietary	SELF CLASSIFICATION Classification: Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, Eye Irritation Cat. 2B, STOT (Inhalation-Respiratory Irritation) SE Cat. 3 Hazard Codes: H302, H315 + H320, H335 Hazard Symbol/Pictogram: GHS07
EXCIPIENTS			
Ammonium Lauryl Sulfate	2235-54-3	Proprietary	SELF CLASSIFICATION Classification: Eye Damage Cat. 1, Skin Irritation Cat. 2 Hazard Codes: H318, H315 Hazard Symbol/Pictogram: GHS05

See Section 16 for full classification information of this product.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	% w/w	LABEL ELEMENTS GHS Classification Hazard Statement Codes
EXCIPIENTS			
Cetrimonium Chloride	112-02-7	Proprietary	SELF CLASSIFICATION Classification: Eye Damage Cat. 1, Skin Irritation Cat. 2, Acute Aquatic Toxicity Cat. 1 Hazard Codes: H318, H315, H400 Hazard Symbol/Pictogram: GHS05, GHS09
Citric Acid	77-92-9	Proprietary	SELF CLASSIFICATION Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: Not Applicable
Cocamidolpropyl Betaine	86893-19-9	Proprietary	SELF CLASSIFICATION Classification: Eye Damage Cat. 1, Skin Irritation Cat. 2 Hazard Codes: H318, H315 Hazard Symbol/Pictogram: GHS05, GHS07
Colloidal Oatmeal	134134-86-4	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable
FD&C Blue #1	3844-45-9	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable
FD&C Yellow #5	1934-21-0	Proprietary	SELF CLASSIFICATION Classification: Skin Sensitization Cat. 1B Hazard Codes: H317 Hazard Symbol/Pictogram: GHS08
Floral Fragrance	Mixture	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable
Methyl Paraben	99-76-3	Proprietary	SELF CLASSIFICATION Classification: Skin Sensitization Cat. 2 Hazard Codes: H317 Hazard Symbol/Pictogram: GHS08
2-Phenoxyethanol	122-99-6	Proprietary	Classification: Acute Oral Toxicity Cat. 4, Eye Irritation Cat. 2A Hazard Codes: H302, H319 Hazard Symbol/Pictogram: GHS07
Quaternium-15	51229-78-8	Proprietary	Classification: Flammable Solid Cat. 2, Reproductive Toxicity Cat. 2, Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, Eye Irritation Cat. 2A, Skin Sensitization Cat. 1, Aquatic Chronic Toxicity Cat. 2 Hazard Codes: H228, H361d, H302, H315, H319, H317, H411 Hazard Symbol/Pictogram: GHS02, GHS07, GHS08, GHS09
Safflower Oil	8001-23-8	Proprietary	Hazard Classification: Not Applicable Hazard and Precautionary Statement Codes: Not Applicable
Sodium Chloride	7647-14-5	Proprietary	SELF CLASSIFICATION Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: Not Applicable
Sodium Laureth Sulfate	3088-31-1	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

NOTE: This product may contain small amounts of sodium hydroxide for pH adjustment. This compound does not contribute and further hazard to this product and so is not addressed in this SDS. See Section 16 for full classification information of this product.

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 of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

SKIN EXPOSURE: If contact with this product results in adverse effect, flush affected area with 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 occurs after flushing.

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

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, give victim up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to ingredients, dermatitis and other 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.

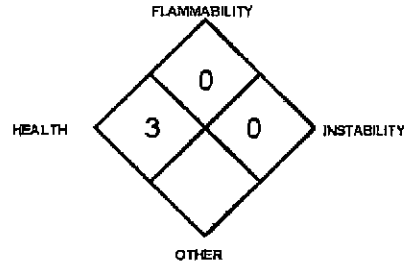
5. FIRE-FIGHTING MEASURES

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 HAZARDS ARISING FROM THE PRODUCT: This product is not flammable. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, sulfur and nitrogen oxides, hydrogen chloride, phenol, formaldehyde, formic acid, glyoxal, and dioxalane).

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

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

NFPA RATING



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

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 able to be incinerated. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product.
PROTECTIVE EQUIPMENT:

Small Spills/Spills in Hoods: Personnel wearing nitrile or other appropriate gloves, labcoat and eye protection should immediately clean spills of less than 5 mL.
Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, protective clothing (i.e., Tyvek coveralls), 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 spilled 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.
Spills in Hoods: Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the HEPA filter of a hood is contaminated, label the unit "Do not use-contaminated" and have trained personnel wearing appropriate protective equipment change and dispose of the filter properly as soon as possible.
Large Spills: Restrict access to the spill areas. For spills of 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 STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this material should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat or drink while handling this material. After handling this material, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Minimize all exposures to this material. Avoid generation of aerosols. Areas in which this material is used should be wiped down, so that this material does not accumulate.
CONDITIONS FOR SAFE STORAGE: Containers of this material must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F). Store away from incompatible materials (see Section 10, Stability and Reactivity). 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 material; therefore, empty containers should be handled with care and disposed of properly.

7. HANDLING and STORAGE (Continued)

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

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat or other protective clothing. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water.

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 is not necessarily applicable as this compound is added for pH balancing and once reacted with other ingredients, no free Sodium Hydroxide remains. No exposure limits for this compound are given in this SDS.

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
Pramoxine HCl	637-58-1	NE	NE	NE	NE	NE	NE	NE	Teva OEL Range $\mu g/m^3$ ≥ 10 - < 100 (established 05Mar2012)
Ammonium Lauryl Sulfate	2235-54-3	NE	NE	NE	NE	NE	NE	NE	NE
Cetrimonium Chloride	112-02-7	NE	NE	NE	NE	NE	NE	NE	NE
Citric Acid	77-92-9	NE	NE	NE	NE	NE	NE	NE	NE
Cocamidolpropyl Betaine	61790-40-0	NE	NE	NE	NE	NE	NE	NE	NE
Colloidal Oatmeal	Not Applicable	NE	NE	NE	NE	NE	NE	NE	NE
FD&C Blue #1	3844-45-9	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
FD&C Yellow #5	1934-21-0	NE	NE	NE	NE	NE	NE	NE	NE
Methyl Paraben	99-76-3	NE	NE	NE	NE	NE	NE	NE	NE
2-Phenoxyethanol	122-99-6	NE	NE	NE	NE	NE	NE	NE	DFG MAKs: TWA = 110 (skin) PEAK = 2•MAK 15 min. average value, 1-hr interval, 4 per shift Danger of Sensitization of the Skin DFG MAK Pregnancy Risk Classification: C
Quaternium-15	51229-78-8	NE	NE	NE	NE	NE	NE	NE	NE
Safflower Oil Exposures given are for vegetable oil mist	8001-23-8	NE	15 (total dust), 5 resp. fract.)	NE	10 (total dust), 5 resp. fract.)	NE	NE	NE	NE
Sodium Chloride	7647-14-5	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Laureth Sulfate	3088-31-1	NE	NE	NE	NE	NE	NE	NE	NE

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

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

RESPIRATORY PROTECTION: 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 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 neoprene rubber gloves. Use triple 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: Viscous liquid.
ODOR: Characteristic.
MOLECULAR FORMULA: Mixture.
COLOR: Opaque greenish.
ODOR THRESHOLD: Not applicable.
FREEZING POINT: Not available.

9. PHYSICAL and CHEMICAL PROPERTIES

RELATIVE VAPOR DENSITY (air = 1): Not available.
EVAPORATION RATE (n-BuAc = 1): Not available.
SPECIFIC GRAVITY (water = 1): Not available.
BOILING POINT: Not available.
VAPOR PRESSURE, mm Hg @ 20°C: Not available.
pH: Not available.
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 viscosity and color of this product may be an identification or warning property to identify it in event of an accidental release.

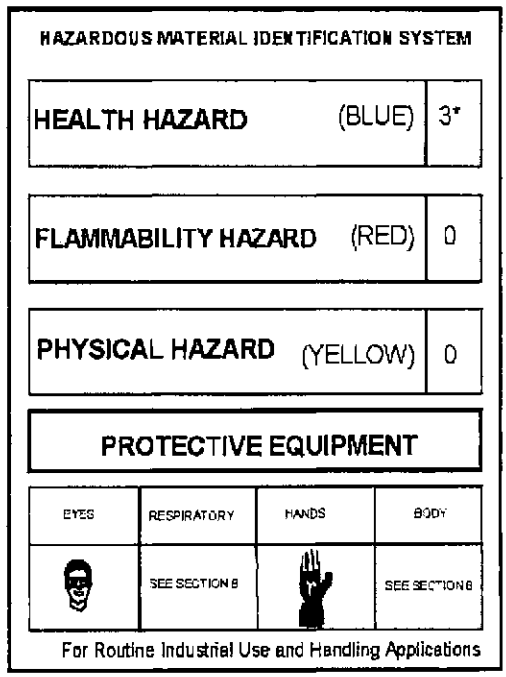
10. STABILITY and REACTIVITY

REACTIVITY/CHEMICAL STABILITY: Not reactive. Stable under normal conditions.
DECOMPOSITION PRODUCTS: *Combustion*: Carbon, sulfur and nitrogen oxides, hydrogen chloride, phenol, formaldehyde, formic acid, glyoxal, and dioxalane. *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 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 due to viscosity. 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. Irritation is greater when skin is abraded. Prolonged skin contact may cause contact dermatitis and severe irritation. Eye contact may cause severe irritation or damage to eyes, depending on concentration and duration of exposure.
SKIN ABSORPTION: The active ingredient and other ingredients may be absorbed via intact skin. While no specific information is available on harmful effect by this route of exposure, 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 with vomiting and nausea.
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. Accidental injection may cause respiratory distress syndrome, which can be fatal.
OTHER HEALTH EFFECTS: Due to the 2-Phenoxyethanol component, exposure may result in headache, tremors, and central nervous system depression. Chronic effects from 2-Phenoxyethanol can include effects on the liver, kidney and thyroid and blood effects.



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

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Eye contact can cause damage to cornea. This product may cause irritation via inhalation or skin or eye contact. Ingestion may be harmful. Contact with broken skin may cause anaphylactic reactions.
Chronic: Repeated skin contact may cause dermatitis (dry, red skin), as well as contact dermatitis.

TARGET ORGANS: Acute: Occupational Exposure and Therapeutic Use: Skin, eyes, respiratory system. Chronic: Occupational Exposure: Skin. Therapeutic Use: Skin.
TOXICITY DATA: The following data are available for some of the active ingredients of this product. Toxicity data are available for the excipient ingredients, but are not presented in this SDS. Contact Bayer for additional information.

PRAMOXINE HYDROCHLORIDE:
LD_{50} (Oral-Mouse) 1050 mg/kg
LD_{50} (Intravenous-Mouse) 79500 µg/kg
LD_{50} (Intravenous-Rabbit) 39 mg/kg
LD_{50} (Intraperitoneal-Mouse) 460 mg/kg

PRAMOXINE HYDROCHLORIDE (continued):
LD_{50} (Intravenous-Guinea-Pig) 109 mg/kg: Behavioral: convulsions or effect on seizure threshold; Cardiac: cardiac output; Lungs, Thorax, or Respiration: other changes

PRAMOXINE HYDROCHLORIDE (continued):
LD_{50} (Subcutaneous-Mouse) 1470 mg/kg: Behavioral: convulsions or effect on seizure threshold; Cardiac: cardiac output; Lungs, Thorax, or Respiration: other changes

11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC POTENTIAL OF COMPONENTS: Long-term studies in animals have not been done with the Pramoxine Hydrochloride component. The excipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

FD&C BLUE # 1: 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.

IRRITANCY OF PRODUCT: This product may cause severe irritation or cause damage to the eyes. Irritation of the respiratory system, mucous membranes, skin may occur, depending on the duration and concentration of exposure. Prolonged skin contact may cause severe irritation.

SENSITIZATION TO THE PRODUCT: This product may cause skin sensitization and contact dermatitis.

REPRODUCTIVE TOXICITY INFORMATION: No information is available on possible human or animal reproductive toxicity of Pramoxine Hydrochloride. Equivocal data are available for the 2-Phenoxyethanol component for possible harm to fetus during pregnancy, but are not presented in this SDSs.

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. The following information is available for some components.

CETRIMONIUM CHLORIDE: Using a structure estimation method based on molecular connectivity indices, the Koc for this compound can be estimated to be 2.2X10+5. According to a classification scheme, this estimated Koc value suggests that material is expected to immobile in soil.

2-PHENOXYETHANOL: Based upon a water solubility of 26,940 mg/L at 25°C, the Koc for this compound can be estimated to be 16 from a regression-derived equation. Based upon a measured log Kow of 1.16, the Koc for this material can be estimated to be 102 from a regression-derived equation. These BCF values suggest that this material has a high to very high soil mobility.

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. The following information is available for some components.

CETRIMONIUM CHLORIDE: If released to air, an estimated vapor pressure of 2.8X10-10 mm Hg at 25°C indicates this compound will exist solely in the particulate phase in the ambient atmosphere. Particulate-phase material will be removed from the atmosphere by wet and dry deposition. If released to soil, this compound is expected to have no mobility based upon an estimated Koc of 2.2X10+5. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 2.9X10-10 atm-cu m/mole. This compound will not volatilize from dry soil surfaces based upon its estimated vapor pressure. If released into water, this material is expected to adsorb to suspended solids and sediment in water based upon the estimated Koc. 10-20 ppm this compound was degraded with a half-life of 3.1 days in freshwater at 20°C and pH 6.9. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant.

2-PHENOXYETHANOL: If released to air, this compound will degrade relatively rapidly by reaction with photochemically produced hydroxyl radicals (estimated half-life of 11.6 hr). Physical removal from air via wet deposition is possible since it is relatively soluble in water. If released to soil or water, this compound is expected to degrade through biodegradation. Leaching in soil is possible. This material will evaporate slowly from terrestrial surfaces.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential. The following information is available for some components.

CETRIMONIUM CHLORIDE: An estimated BCF of 71 was calculated for this compound, using an estimated log Kow of 3.23 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is moderate.

2-PHENOXYETHANOL: Based upon a water solubility of 26,940 mg/L at 25°C, the BCF for this compound can be estimated to be 2 from a regression-derived equation. Based upon a measured log Kow of 1.16, the BCF for this material can be estimated to be 4.5 from a regression-derived equation. These BCF values suggest that this compound will not bioconcentrate significantly in aquatic organisms.

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. This product may be harmful or fatal to contaminated aquatic plant and animal life. The following aquatic toxicity data are available for some components. Only select data are provided; contact Teva for further information.

CITRIC ACID:

EC_0 (*Pseudomonas putida* bacteria) 16 hours = > 10,000 mg/L
EC_0 (*Microcystis aeruginosa* algae) 8 days - 80 mg/L
EC_0 (*Scenedesmus quadricauda* green algae) 7 days = 640 mg/L
EC_0 (*Entosiphon sulcatum* protozoa) 72 hours = 485 mg/L
EC_0 (*Uronema parduczi* Chetton-Lwoff protozoa) = 622 mg/L
LC_{50} (*Carcinus maenas* Green or European shore crab) 48 hour = 160 mg/L
LD_{100} (*Daphnia magna* giant water flea) = 120 mg/l long-time exposure in soft water
LD_{100} (goldfish) 694 mg/L, long-time exposure in hard water
Toxic (*Daphnia* water flea) = 100 mg/L
Toxic (goldfish) 4 hours = 894 ppm fresh water
TLm (shore crab) 48 hours = 160 ppm salt water

FD&C BLUE #1:

EC_{50} (*Daphnia magna* Water Flea, age < 24 hr) 48 hours = > 97,000 µg/L
LC_{50} (*Lepomis macrochirus* Bluegill) 96 hours = > 96,000 µg/L
LC_{50} (*Oncorhynchus gorbuscha* Pink Salmon) 96 hours = 239,000-619,000 µg/L
LC_{50} (*Oncorhynchus keta* Chum Salmon) 96 hours = 427,000 µg/L
LC_{50} (*Oncorhynchus kisutch* Coho Salmon) 96 hours = 332,000-1,144,000 µg/L
LC_{50} (*Oncorhynchus mykiss* Rainbow Trout) 96 hours = 412,000-1,370,000 µg/L
LC_{50} (*Oncorhynchus nerka* Sockeye Salmon) 96 hours = 180,000 µg/L

2-PHENOXYETHANOL:

EC_{50} (*Pimephales promelas* fathead minnow) 96 hours = 344 mg/L
LC_{50} (*Pimephales promelas* fathead minnow) 96 hours = 344 mg/L

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.

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.

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

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This material 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. (Cetrimonium Chloride, Quaternium-15)
Hazard Class Number and Description:	9 (Miscellaneous Hazardous Material)
Packing Group:	III
DOT Label(s) Required:	Class 9 (Miscellaneous Hazardous Material)
Emergency Response Guidebook Number, 2012:	171

Marine Pollutant: This product meets the criteria to be a Marine Pollutant (49 CFR 172.101, Appendix B).

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

UN Identification Number:	UN 3082
Proper Shipping Name:	Environmentally hazardous substance, liquid, n.o.s. (Cetrimonium Chloride, Quaternium-15)
Hazard Class Number and Description:	9 (Miscellaneous Hazardous Material)
Packing Group:	III
Hazard Label(s) Required:	Class 9 (Miscellaneous Hazardous Material)
Special Provisions:	16
Explosive Limit and Limited Quantity Index:	5
ERAP Index:	None
Passenger Carrying Ship Index:	None
Passenger Carrying Road or Rail Vehicle Index:	None

Marine Pollutant: This product meets the criteria to be a Marine Pollutant.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This material 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. (Cetrimonium Chloride, Quaternium-15)
Hazard Class Number and Description:	9 (Miscellaneous Hazardous Material)
Packing Group:	III
Hazard Label(s) Required:	Class 9 (Miscellaneous Hazardous Material)
Excepted Quantities:	E1
Passenger and Cargo Aircraft Packing Instruction:	954
Passenger and Cargo Aircraft Maximum Net Quantity per Pkg:	450 L
Passenger and Cargo Aircraft Limited Quantity Packing Instruction:	Y954
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

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This material is classified as Dangerous Goods by the International Maritime Organization.

UN Identification Number:	UN 3082
Proper Shipping Name:	Environmentally hazardous substance, liquid, n.o.s. (Cetrimonium Chloride, Quaternium-15)
Hazard Class Number and Description:	9 (Miscellaneous Hazardous Material)
Packing Group:	III
Label(S) Required:	Class 9 (Miscellaneous Hazardous Material)
Special Provisions:	179, 274, 335, 909
Excepted Quantities:	E1
Limited Quantities:	5 L
Packing:	Instructions: P001, LP01; Provisions: PP1
8IBCs:	Instructions: IBC03; Provisions: None
Tanks:	Instructions: T4; Provisions: TP2, TP29
EmS:	F-A, S-F
Stowage and Segregation:	Category A.

Marine Pollutant: This product meets the criteria of a marine pollutant.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: See the information under the individual jurisdiction listings for IBC information.

14. TRANSPORTATION INFORMATION (Continued)

ENVIRONMENTAL HAZARDS: This product meets the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN).

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

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

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA HAZARD CATEGORIES (SECTION 311/312, 40 CFR 370-21): ACUTE: 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 preparations 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. The active components may be regulated under FIFRA as pesticides and may cause this product to have requirements und FIFRA.

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: 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, including animal medicines.

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **DANGER!** DIRECT EYE CONTACT MAY CAUSE DAMAGE TO THE CORNEA. PROLONGED SKIN CONTACT MAY CAUSE SEVERE IRRITATION. MAY BE HARMFUL BY INGESTION. MAY CAUSE SKIN SENSITIZATION AND ALLERGIC REACTION. Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Keep container closed. Use gloves, safety glasses, and appropriate respiratory and body protection. **FIRST-AID:** If exposed, seek immediate medical attention. 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. **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 spill debris in a suitable container. Refer to SDS for additional information.

GLOBAL HARMONIZATION LABELING AND CLASSIFICATION:

Classification: Reproductive Toxicity Category 2, Eye Damage Category 1, Acute Oral Toxicity Category 4, Skin Sensitization Category 1, Skin Irritation Category 2, Eye Irritation Category 2A, Aquatic Acute Toxicity Category 1, Aquatic Chronic Toxicity Category 1

Signal Word: Danger

Hazard Statements: H361d: Suspected of damaging the unborn child. H318: Causes serious eye damage. H302: Harmful if swallowed. H315: Causes skin irritation. H317: May cause an allergic skin reaction. 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. P261: Avoid breathing mists, sprays, fume. P264: Wash thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P272: Contaminated work clothing should not be allowed out of the workplace. 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. P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. P301 + P312: If swallowed, Call a POISON CENTER or doctor if you feel unwell. P330: Rinse mouth. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P321: Specific treatment (remove from exposure and treat symptoms). P391: Collect spillage.

Storage: P405: Store locked up.

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

Hazard Symbols/Pictograms: GHS05, GHS07, GHS08, GHS09

16. OTHER INFORMATION (Continued)

GLOBAL HARMONIZATION LABELING AND CLASSIFICATION (continued):

CLASSIFICATION FOR COMPONENTS:

FULL TEXT GLOBAL HARMONIZATION:

Pramoxine Hydrochloride: This is a self-classification.

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

Hazard Statements: H302: Harmful if swallowed. H315 + H320: Causes skin and eye irritation. H335: May cause respiratory irritation.

Ammonium Laureth Sulfate: This is a self-classification.

Classification: Eye Damage Cat. 1, Skin Irritation Cat. 2

Hazard Statements: H318: Causes serious eye damage. H315: Causes skin irritation.

Cetrimonium Chloride: This is a self-classification.

Classification: Eye Damage Cat. 1, Skin Irritation Cat. 2, Acute Aquatic Toxicity Cat. 1

Hazard Statements: H318: Causes serious eye damage. H315: Causes skin irritation. H400: Very toxic to aquatic life.

Citric Acid, Sodium Chloride: This is a self-classification.

Classification: Acute Oral Toxicity Category 5

Hazard Statements: H303: May be harmful if swallowed.

Cocamidopropyl Betaine: This is a self-classification.

Classification: Eye Damage Category 1, Skin Irritation Cat. 2

Hazard Statements: H318: Causes serious eye damage. H315: Causes skin irritation.

FD&C Yellow # 5 and Methyl Paraben: The following is a Self-Classification.

Classification: Skin Sensitization Category 1B

Hazard Statement Codes: H317: May cause an allergic skin reaction.

2-Phenoxyethanol: This is a published classification.

Classification: Acute Oral Toxicity Category 4, Eye Irritation Cat. 2A

Hazard Statements: H302: Harmful if swallowed. H319: Causes serious eye irritation.

All Other Components:

An official classification for these substances has not been published in the CLP 1272: 2008.

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.

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DEFINITIONS OF TERMS

For information on medical terms used in this SDS consult an on-line database such as Medline Plus: http://www.nlm.nih.gov/medlineplus/druginformation.html.
A large number of abbreviations and acronyms appear on a SDS. Some of these, which are commonly used, include the following:

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

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

IDLH-Immediately Dangerous to Life and Health: This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

LOQ: Limit of Quantification.

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: NOSH's Recommended Exposure Limits.

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

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

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

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

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

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

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

HEALTH HAZARD: 0 (Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation*: Essentially non-irritating. PII or Draize = "0". *Eye Irritation*: Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. Draize = "0". *Oral Toxicity LD_{50} Rat*: < 5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: < 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: < 20 mg/L.); 1 (Slight Hazard: Minor reversible injury may occur; slightly or mildly irritating. *Skin Irritation*: Slightly or mildly irritating. *Eye Irritation*: Slightly or mildly irritating. *Oral Toxicity LD_{50} Rat*: > 500-5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 1000-2000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 2-20 mg/L); 2 (Moderate Hazard: Temporary or transitory injury may occur. *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize > 0, < 5. *Eye Irritation*: Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. Draize > 0, ≤ 25. *Oral Toxicity LD_{50} Rat*: > 50-500 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 200-1000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.5-2 mg/L.); 3 (Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may destroy dermal tissue, cause skin burns, dermal necrosis. PII or Draize > 5-8 with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD_{50} Rat*: > 1-50 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 20-200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05-0.5 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).

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD: 0 (Minimal Hazard-Materials that will not burn in air when exposure to a temperature of 815.5°C [1500°F] for a period of 5 minutes.); 1 (Slight Hazard-Materials that must be pre-heated before ignition can occur. Material require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur, including: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C [200°F] (e.g. OSHA Class IIIB, or; Most ordinary combustible materials [e.g. wood, paper, etc.]; 2 (Moderate Hazard-Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres in air, including: Liquids having a flash-point at or above 37.8°C [100°F]; Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp; Solids and semisolids that readily give off flammable vapors.); 3 (Serious Hazard- Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.6°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 effects 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.).

DEFINITIONS 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 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. 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 815°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.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

FLAMMABILITY 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 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

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

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (**NFPA**). Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD_{50}** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC_{50}** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m³** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. 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 permenent changes to genetic material (DNA) such that the changes will propagate through generational lines. An embryotoxin is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance which interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

EC is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. **TL_m** = median threshold limit; Coefficient of Oil/Water Distribution is represented by **log K_{ow}** or **log K_{oc}** and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

ACGIH: American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). **WHMIS** is the Canadian Workplace Hazerdous Materials Information System.

DOT and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act (**SARA**); the Canadian Domestic/Non-Domestic Substances List (**DSL/NDSL**); the U.S. Toxic Substance Control Act (**TSCA**); Marine Pollutent status according to the **DOT**; the Comprehensive Environmental Response, Coinpensation, 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.