

STERIS LABORATORIES INC. MATERIAL SAFETY DATA SHEET

FILE COPY

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS, and European Standards

1. PRODUCT IDENTIFICATION

TRADE/MATERIAL NAME: PROMETHAZINE HYDROCHLORIDE INJECTION, USP

DESCRIPTION: Aqueous Promethazine Hydrochloride Solution

OTHER DESIGNATIONS: NDC # (s): 0402-0259; 0402-1107; 0591-3157; 0591-3158

CHEMICAL NAME: 10H-phenothiazine-10-ethanamine, N,N,α-trimethyl-mono-hydrochloride

CHEMICAL FAMILY: Antihistamine

HOW SUPPLIED: 1 mL Ampoules

FORMULA: C₁₇H₂₁ClN₂S

PRODUCT USE:	Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER'S NAME:	STERIS LABORATORIES INC.
ADDRESS:	620 North 51 st Avenue Phoenix, Arizona 85043
BUSINESS PHONE:	1-602-278-1400

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	EXPOSURE LIMITS IN AIR					
				ACGIH-TLV		OSHA-PEL		NIOSH IDLH ppm	OTHER ppm
				TWA ppm	STEL ppm	TWA ppm	STEL ppm		
Phenol	108-95-2		0.5%	5 (skin)	NE	5 (skin)	NE	250	NIOSH RELs: TWA = 5 STEL = 15.6 15 minutes (ceiling) DFG MAK: Skin Carcinogen: EPA-D, IARC-3, MAK-3B, TLV-AA
Promethazine Hydrochloride	58-33-3	200-376-2	2.5-5.0%	NE	NE	NE	NE	NE	NE
Sterile Water	7732-18-5	231-791-2	Balance	NE	NE	NE	NE	NE	NE
Other components which are each present in less than 1 percent concentration (or 0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens).				None of the other components contribute significant additional hazards at the concentrations present in this product. All pertinent hazard information has been provided in this document, per the requirements of the Federal Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards; Canadian Workplace Hazardous Materials Identification System Standards (CPR 4); and the applicable Council Directives of the European Community.					

NE = Not Established C = Ceiling Limit mppcf = Millions of Particles Per Cubic Foot See Section 16 for Definitions of Terms Used.
NOTE: All WHMIS and EC required information is included. It is located in appropriate sections based on the ANSI Z400.1-1993 format.

PROMETHAZINE HYDROCHLORIDE INJECTION, USP MSDS

EFFECTIVE DATE: SEPTEMBER 23, 2002

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Promethazine Hydrochloride Injection, USP is a clear, colorless, odorless, aqueous solution. **Health Hazards:** The primary health hazard associated with emergency response to this material is the potential for slight irritation of contaminated skin or eyes. **Flammability Hazards:** This product is not flammable. In the event of a fire, this product may decompose and emit carbon monoxide, carbon dioxide, nitrogen oxides and chloride and sulfur compounds. **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** Large quantities released to the aquatic and terrestrial environment may have an adverse effect. **Emergency Considerations:** Emergency responders should wear appropriate protection for situation to which they respond.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. This product is designed for intravenous or deep intramuscular injections. The following paragraphs describe the symptoms of exposure, via route of entry, for relatively high doses of this product.

INHALATION: Inhalation of mist or sprays of this solution may be slightly irritating to the mucous membranes and upper respiratory tract. Exposure symptoms may include coughing, sneezing, and effects described in "Other Potential Health Effects".

CONTACT WITH SKIN or EYES: Eye contact with this product may cause transient irritation. Prolonged, repeated skin contact with product may cause persistent irritation. Symptoms are generally alleviated when overexposure ends.

SKIN ABSORPTION: Skin absorption may be a potential route of exposure for this product; symptoms of exposure may include those described under "Other Potential Health Effects".

INGESTION: Ingestion is not a likely route of occupational exposure for this product. Should this product be swallowed in very high doses, symptoms of such exposure may include nausea, vomiting, and diarrhea. Other effects of ingestion exposure may also include those described under "Other Potential Health Effects".

INJECTION: Injection of this material (via puncture or laceration by a contaminated object) may cause a stinging or burning sensation, reddening and local swelling. If injection of therapeutic doses occurs, symptoms described under "Other Potential Health Effects" may develop.

OTHER POTENTIAL HEALTH EFFECTS: Symptoms which may be experienced by individuals overexposed to this product include the following: sedation, blurred vision, dizziness, disorientation, blood pressure effects, blood effects, nausea and vomiting. Long-term exposure to the Phenol component of this product has resulted in reports of contact with symptoms such as vomiting, difficulty swallowing, diarrhea, loss of appetite, headache, fainting, dizziness, mental disturbances and dark coloration of the urine. Skin discoloration and eruptions were also observed. The disease was sometimes fatal and extensive damage to the liver and kidneys was observed. In an unsubstantiated study, employees exposed to an average of 5.4 ppm phenol for 13.15 years (mean) were compared to employees with no phenol exposure. Several statistically significant changes in blood chemistry were observed. Repeated or prolonged skin contact with Phenol can lead to a characteristic darkening of skin and urine (ochronosis).

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

ACUTE: Slight irritation of contaminated skin and eyes is the primary health effect anticipated for occupational exposures to this product. Additional symptoms which may be experienced by individuals overexposed to this product include the following: sedation, blurred vision, dizziness, disorientation, blood pressure effects, blood effects, nausea and vomiting.

CHRONIC: Repeated or prolonged skin contact with products that contain Phenol may lead to a characteristic darkening of skin and urine (ochronosis). See Section 11 (Toxicological Information) for additional information.

TARGET ORGANS: **ACUTE:** Skin, eyes (occupational exposures). Central nervous system and blood (therapeutic doses). **CHRONIC:** Skin (occupational exposures).



HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	1
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FLAMMABILITY HAZARD	(RED)	0
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PHYSICAL HAZARD	(YELLOW)	0
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PROTECTIVE EQUIPMENT	x
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EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

See Section 16 for Definition of Ratings

4 FIRST-AID MEASURES

Persons who are exposed to this product should seek medical attention if any adverse health effects occur. In the event medical attention is sought, the physician or health care professional should receive a copy of this product's label and this MSDS. The following information is provided for immediate care of persons overexposed to this product.

SKIN EXPOSURE: If spilled on skin, begin decontamination with copious amounts of running water. Minimum flushing is for 15 minutes if the exposure has resulted in an adverse effect. The contaminated individual must seek medical attention if any adverse effect occurs.

EYE EXPOSURE: If the product contaminates the eyes, open eyes under gently running water. Use sufficient force to open eyelids and then "roll" while flushing eyes. Minimum flushing is for 15 minutes if the exposure has resulted in an adverse effect. The contaminated individual must seek medical attention if any adverse effect occurs.

INHALATION: If mists or sprays of this product are inhaled, remove the contaminated individual to fresh air. Seek medical attention if adverse effect occurs.

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.

INJECTION: In the event of accidental injection, wash contaminated area with soap and water. Physicians should refer to Section 11 (Toxicological Information) for specific recommendations. The Medical Surveillance requirements of the OSHA Bloodborne Pathogen standard (29 CFR 1910.1030) may be applicable.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Disorders involving the Target Organs of this compound (see Section 3, Hazard Information) can be aggravated by overexposures to this product.

RECOMMENDATIONS TO PHYSICIANS: This product should only be used by persons experienced in management of patients receiving the type of therapy intended for this product. **INJECTION EXPOSURE:** In the event of accidental injection, wash contaminated area with soap and water. The Medical Surveillance requirements of the OSHA Bloodborne Pathogen standard (29 CFR 1910.1030) may be applicable. **EXPOSURE BY OTHER ROUTES:** Treat symptoms and eliminate exposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable; non-flammable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS (in air by volume, %):

Lower (LEL): Not applicable.

Upper (UEL): Not applicable.

FIRE EXTINGUISHING MATERIALS: Non-flammable. Use extinguishing media appropriate for surrounding fire.

Water Spray: OK Carbon Dioxide: OK

Foam: OK Dry Chemical: OK

Halon: OK Other: Any "ABC" Class

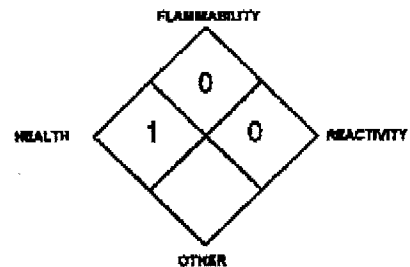
UNUSUAL FIRE AND EXPLOSION HAZARDS: At extremely high temperatures this product will decompose to produce irritating vapors and toxic gases (e.g., carbon monoxide, carbon dioxide, nitrogen oxides and chloride and sulfur compounds).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. Fire-fighting equipment which is contaminated should be cleaned with soapy water before returning to service.

NFPA RATING



**See Section 16 for
Definition of Ratings**

6. ACCIDENTAL RELEASE MEASURES

LEAK RESPONSE: For small releases of this compound (1 vial), wear double latex or butyl rubber gloves and safety glasses. Clean-up solution with a damp sponge, polypad, or other appropriate material for small spills and place in a bag and hold for waste disposal. Avoid producing sprays or mists of this product during clean-up. In case of a large spill, clear the affected area and protect people. Large or uncontrolled releases should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used, including double butyl rubber 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 in event of a large spill. Decontaminate the area of the spill thoroughly using detergent and water. Place

State, and local regulations or with regulations of the EC and its member states or Canada and its Provinces.

7. HANDLING and USE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers which contain this compound. Follow SPECIFIC USE INSTRUCTIONS supplied with compound.

STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. Contaminated waste must be properly handled. Work areas must be regularly decontaminated. Ensure containers of this product are properly labeled. Keep container tightly closed. Store this product away from incompatible materials. Store this product in original container at a controlled room temperature, 15-30°C (59-86°F).

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

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All containers of this product and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

NOTE: Consistent with the U.S. OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030), observe Universal Precautions while using this product. Place used or product-contaminated hypodermic needles and syringes in a rigid "Sharps" container. Do not recap or clip used or product-contaminated hypodermic needles.

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 MSDS for the clean-up of a spill.

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently there are international exposure limits for the components of this product, as follows:

PHENOL:

ARAB Republic of Egypt: TWA = 5 ppm (19 mg/m³), Skin, JAN 1993
 Australia: TWA = 5 ppm (19 mg/m³), Skin, JAN 1993
 Austria: MAK = 5 ppm (19 mg/m³), Skin, JAN 1999
 Denmark: TWA = 5 ppm (19 mg/m³), Skin, JAN 1993
 Denmark: TWA = 1 ppm (4 mg/m³), Skin, JAN 1999
 Finland: TWA = 5 ppm (19 mg/m³), STEL = 10 ppm (38 mg/m³), Skin, JAN 1999
 France: VME = 5 ppm (19 mg/m³), Skin, JAN 1999
 Germany: MAK = 5 ppm (19 mg/m³), Skin, JAN 1999
 Hungary: TWA = 4 mg/m³, STEL = 8 mg/m³, Skin, JAN 1993
 Japan: OEL = 5 ppm (19 mg/m³), Skin, JAN 1999
 The Netherlands: MAC-TGG = 5 ppm (19 mg/m³), Skin, JAN 1999
 The Philippines: TWA = 6 ppm (10 mg/m³), Skin, JAN 1993

PHENOL (continued):

Poland: MAC (TWA) = 10 mg/m³, MAC(STEL) = 20 mg/m³, JAN 1999
 Russia: TWA = 5 ppm, STEL = 0.3 mg/m³, Skin, JAN 1993
 Sweden: NGV = 1 ppm (4 mg/m³), KTV = 2 ppm (8 mg/m³), Skin, JAN 1999
 Switzerland: MAK-W = 5 ppm (19 mg/m³), KZG-W = 10 ppm (38 mg/m³), Skin, JAN 1999
 Thailand: TWA = 5 ppm (19 mg/m³), JAN 1993
 Turkey: TWA = 5 ppm (19 mg/m³), Skin, JAN 1993
 United Kingdom: TWA = 5 ppm (20 mg/m³), STEL = 10 ppm, Skin, SEP 2000
 In Argentina, Bulgaria, Colombia, Jordan, Korea, New Zealand, Singapore, Vietnam check ACGIH TLV

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product. Airborne contaminant concentrations must be maintained below guidelines listed in Section 2 (Composition and Information on Ingredients). If respiratory protection is needed, use only protection authorized in the U.S. Federal OSHA Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, and EC member states. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998). If use of this product results in exposure to mists or sprays, consideration of the use of the following NIOSH respiratory protection equipment should be considered.

PHENOL

CONCENTRATION

Up to 50 ppm:

Up to 125 ppm:

Up to 250 ppm:

RESPIRATORY PROTECTION

Any Chemical Cartridge Respirator with organic vapor cartridge(s) in combination with a dust and mist filter, or any Supplied-Air Respirator (SAR).

Any SAR operated in a continuous-flow mode, or any Powered, Air-Purifying Respirator (PAPR) with organic vapor cartridge(s) in combination with a dust and mist filter.

Any Chemical Cartridge Respirator with a full facepiece and organic vapor cartridge(s) in combination with a high-efficiency particulate filter, or any Air-Purifying, Full-Facepiece Respirator (gas mask) with a chin-style, front- or back-mounted organic vapor canister having a high-efficiency particulate filter, or any PAPR with a tight-fitting facepiece and organic vapor cartridge(s) in combination with a high-efficiency particulate filter, or any Self-Contained Breathing Apparatus (SCBA) with a full facepiece, or any SAR with a full facepiece.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

RESPIRATORY PROTECTION (continued):

PHENOL

CONCENTRATION

Emergency or Planned Entry into Unknown Concentrations or IDLH Conditions: Any SCBA that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode, or any SAR that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary SCBA operated in pressure-demand or other positive-pressure mode.

Escape:

Any Air-Purifying, Full-Facepiece Respirator (gas mask) with a chin-style, front- or back-mounted organic vapor canister having a high-efficiency particulate filter, or any appropriate escape-type, SCBA.

EYE PROTECTION: For situations in which excessive splashes or sprays may be generated, wear chemical splash goggles, or regular splash goggles. If necessary, refer to U.S. OSHA 29 CFR 1910.133, the European Standard EN166 and appropriate Standards of Canada for further information.

HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. If necessary, refer to U.S. OSHA 29 CFR 1910.138, and appropriate Standards of the EC and Canada for further information.

BODY PROTECTION: For situations in which excessive splashes or sprays may be generated, use a full body gown which is closed at the front and has long sleeves. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: $\approx 100^{\circ}\text{C}$ (212 $^{\circ}\text{F}$)

EVAPORATION RATE (nBuAc = 1): Similar to water.

VAPOR PRESSURE (air = 1): Not applicable.

ODOR THRESHOLD: Not applicable. Odorless.

SPECIFIC GRAVITY (water = 1): ≈ 1.0

COEFFICIENT WATER/OIL DISTRIBUTION: Not determined.

APPEARANCE AND COLOR: This product is a clear, colorless, aqueous solution.

HOW TO DETECT THIS SUBSTANCE (warning properties): There are no distinguishing characteristics.

FREEZING/MELTING POINT: $\approx 0^{\circ}\text{C}$ (32 $^{\circ}\text{F}$)

SOLUBILITY IN WATER: Soluble.

MOLECULAR WEIGHT: Not applicable.

pH: 4.0-5.5

10. STABILITY and REACTIVITY

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

DECOMPOSITION PRODUCTS: When heated to decomposition temperatures, this product will emit carbon dioxide, carbon monoxide, nitrogen oxides, and sulfur and nitrogen compounds.

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

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Heat may cause this product to decompose, destroying the compound and producing irritating vapors and toxic gases. Avoid contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: The following toxicological data are for Promethazine Hydrochloride and other components present in greater than 1% concentration:

PROMETHAZINE HYDROCHLORIDE:

LD₅₀ (Subcutaneous-Dog) 250 mg/kg

TDLo (Oral-Human) 3500 $\mu\text{g}/\text{kg}$ / days:

Behavioral: sleep, convulsions or effect on seizure threshold, rigidity (including catalepsy)

TDLo (Oral-Child) 20 mg/kg: Behavioral: excitement, changes in motor activity (specific assay), stiffness

LD₅₀ (Oral-Mouse) 255 mg/kg: Behavioral: convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration: other changes

LD₅₀ (Intraperitoneal-Rat) 170 mg/kg

LD₅₀ (Intraperitoneal-Mouse) 180 mg/kg

LD₅₀ (Intraperitoneal-Guinea Pig) 35 mg/kg

LD₅₀ (Subcutaneous-Rat) 400 mg/kg

LD₅₀ (Subcutaneous-Mouse) 240 mg/kg

PROMETHAZINE HYDROCHLORIDE (continued):

LD₅₀ (Intravenous-Rat) 15 mg/kg

LD₅₀ (Intravenous-Mouse) 50 mg/kg

LD₅₀ (Intravenous-Guinea Pig) 42,500 $\mu\text{g}/\text{kg}$

TDLo (Oral-Rat) 665 mg/kg/16 days-intermittent: Related to Chronic Data: death

TDLo (Oral-Rat) 2164 mg/kg/13 weeks-intermittent: Sense Organs and Special Senses (Olfaction): effect, not otherwise specified; Liver: changes in liver weight

TDLo (Oral-Rat) 60 mg/kg: female 5-16 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)

(continued):
 TDLo (Oral-Rat) 900 mg/kg/16 days-intermittent: Liver: changes in liver weight: Related to Chronic Data: death
 TDLo (Oral-Mouse) 2925 mg/kg/13 weeks-intermittent: Liver: changes in liver weight;

TDLo (Oral-Rat) 240 mg/kg: female 5-16 day(s) after conception: Reproductive: Fertility: other measures of fertility
 TDLo (Intraperitoneal-Rabbit) 25 mg/kg/5 days-intermittent: Blood: changes in serum composition (e.g. TP, bilirubin,

Metabolic: weight loss or decreased weight gain; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases

SUSPECTED CANCER AGENT: Components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

PHENOL: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); EPA-D (Not Classifiable as to Human Carcinogenicity); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B (Substances Which Cause Concern That They Could Be Carcinogenic for Man, But Cannot Be Assessed Conclusively Because of Lack of Data-Substances for which *in vitro* tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories)

The remaining components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, CAL/OSHA, IARC, and therefore is not considered to be, nor suspected to be a cancer-causing agent by these agencies.

IRRITANCY OF PRODUCT: This product may be slightly irritating to contaminated tissue.

SENSITIZATION OF PRODUCT: No component of this product is known to be a human skin or respiratory sensitizer.

REPRODUCTIVE TOXICITY INFORMATION: Promethazine Hydrochloride is currently not rated as to safety for use during pregnancy. Listed below is information concerning the effect of this solution on the human and animal reproductive systems.

Mutagenicity: This product is not reported to be mutagenic in therapeutic doses. There are human mutation data for the Phenol component of this product, however, no conclusions can be drawn from one report of increased chromosomal aberrations in a small number of employees exposed to Phenol, formaldehyde and styrene. Positive results have been obtained in tests using cultured human cells. A small number of studies using live animals do not provide sufficient evidence of mutagenicity. Positive and negative results have been obtain in tests using cultured animal cells and bacteria.

Embryotoxicity: This product is not reported to produce embryotoxic effects in humans.

Teratogenicity: This product is not reported to cause teratogenic effects in humans.

Reproductive Toxicity: This product is not reported to cause reproductive toxicity effects in humans. Animal reproductive toxicity data are available for Promethazine Hydrochloride; these data were obtained during test studies of rats who where administered this substance orally. One animal study involving the Phenol component has shown fetotoxicity (reduced weight gain) in the offspring of rats exposed to doses which did not produce harmful effects in the mothers.

*A **mutagen** is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generation 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.*

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have been determined for the Phenol component of this product, as follows:

CHEMICAL DETERMINANT	SAMPLING TIME	BEI
Phenol • Total Phenol in urine	• End of shift	• 250 mg/g creatinine

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: This product is expected to biodegrade in the environment. The following environmental information is available for the Phenol component of this product.

PHENOL:

Terrestrial Fate: Based on a recommended classification scheme, experimentally determined Koc values for Phenol indicate that it would be highly mobile in soil and may leach. Phenol's vapor pressure, 0.330 mm Hg at 25°C and low adsorptivity to soil indicate that volatilization from dry soil and other surfaces may occur. Phenol will be primarily removed from soil as a result of biodegradation. Despite its high mobility in soil, biodegradation is sufficiently rapid that most groundwater is generally free of Phenol. The half-lives of Phenol in soil is usually < 5 days, even in subsurface soil and aquifer material, although for acid soils and some surface soils the half-life may be of the order of 20-25 days and in the case of a till subsoil, 116 days. Radio-labeled Phenol was rapidly released from soil in a environmental standard system; after 1 day, half of the label was found in the air phase as a result of mineralization. Degradation will be slower under anaerobic conditions than under aerobic conditions and acclimation times will also be longer. Phenol may also be removed from soil as a result of surface-catalyzed reaction or oxidative processes that are not well understood. Phenol is sensitive to indirect photolysis and these reactions may be expected to occur on the soil surface.

Aquatic Fate: Because the pKa of Phenol is 9.994, it will be partially dissociated at higher pHs and therefore, its transport and reactivity may be pH dependent. Based on a recommended classification scheme, experimentally determined Koc values for Phenol indicate that it would not adsorb to sediment and particulate matter in the water column. Phenol would not volatilize from water based on its Henry's Law

12. ECOLOGICAL INFORMATION (Continued)

constant of 3.33×10^{-7} atm-cu m/mole. Its estimated volatilization half-life in a model river is 107 days. Removal will be primarily a result of biodegradation with complete degradation occurring in a few days. Degradation is slower in salt water; the degradation half-life in an estuarine river was 9 days). Phenol may undergo indirect photolysis in natural waters due to reaction with transients generated by the absorption of sunlight by, for example, dissolved natural organic matter and flavins. Photolysis rates range widely and depend on the intensity of sunlight, concentration and nature of humic materials and photo-sensitizers present in the water and pH; phenolate ions are more readily oxidized than undissociated Phenol and therefore rates will increase with pH. According to a recommended classification scheme, the low reported BCF values for Phenol and its rapid elimination suggest that bioaccumulation of Phenol is not an important fate process.

Atmospheric Fate: According to a model of gas/particle partitioning of semivolatile organic compounds in the atmosphere, Phenol, which has a vapor pressure of 0.350 mm Hg at 25°C will exist in the vapor phase in the ambient atmosphere. Vapor-phase Phenol is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals during the day and nitrate radicals at night; the half-lives for these reactions in air is estimated as 14.6 hours and 12 minutes, respectively. Phenol has a low Henry's Law constant which explains why it is so effectively scavenged from the air by rain. Its presence in rainwater has been confirmed by several investigators(4-6). Its concentration in rain has been shown to decrease markedly as the rain event progresses.

Bioconcentration: The BCFs reported in aquatic organisms include: goldfish, (*Carassius auratus*), 1.9; fish (unspecified), 17; fish (unspecified), 1.7; water flea (*Daphnia magna*), 277; golden orfe, 20, algae (*Chlorella fusca*), 200; freshwater phytoplankter (*Scenedesmus quadricauda*), 3.5. Phenol was rapidly eliminated from goldfish(8) and therefore would be unlikely to bioaccumulate. When U-14C-Phenol was interperitonally administered to goldfish, the concentration decreased to one tenth the initial concentration in 2 hours. A BCF of 7.6 was estimated for Phenol, using the log Kow of 1.46 and a recommended regression-derived equation. According to a recommended classification scheme, the estimated and reported BCF values and the rapid elimination of Phenol suggests that bioaccumulation of Phenol is unlikely.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No specific information is currently available on the effect of this product on plants or animals in the terrestrial environment. This product may be harmful to contaminated plant and animal life.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of this product on plants or animals in the aquatic environment. This product may be harmful to aquatic plant and animal life in contaminated bodies of water, especially if released in large quantities. The following information is available for components of this product.

PHENOL:

Toxic (*Chlorella pyrenoidosa* algae) = 233; 1,060 mg/L
 IC₁₀ (*Scenedesmus subspicatus* green algae) inhibition of fluorescence = 7.8 mg/L
 IC₁₀ (*Scenedesmus subspicatus* green algae) growth inhibition = 28 mg/L
 LC₀ (*Scenedesmus* algae) = 40 mg/L
 EC₀ (*Pseudomonas putida* bacteria) 16 hours = 64 mg/L
 EC₀ (*Microcystis aeruginosa* algae) 8 days = 4.8 mg/L
 EC₀ (*Scenedesmus quadricauda* algae) 7 days = 7.5 mg/L
 EC₃₇ (*Chlorella* sp. algae) 10 days = 300 ppm
 EC₄₁ (*Protococcus* sp algae) 10 days = 300 ppm
 EC₄₉ (*Dunaliella eucloa* algae) 10 days = 100 ppm
 EC₁₀₀ (*Phaeodactylum tricornutum* algae) 10 days = 100 ppm
 EC₁₀₀ (*Monochrysis lutheri* algae) 10 days = 100 ppm
Entosiphon sulcatum protozoan) 72 hours = 33 mg/L
 EC₀ (*Uronema parduizi* Chatton-Lwoff protozoan) 144 mg/L
 Perturbation Level (*Paramecium caudatum* protozoan) = 10 mg/L
 Perturbation Level (*Vorticella campanula* protozoan) = 3 mg/L
 LC (rainbow trout) 3 hours = 5 mg/L
 LC (perch) 1 hour = 9 mg/L
 LC₀ (*Daphnia* crustacean) 16 mg/L
 LC₀ (creek chub) 10 mg/L
 LC₅₀ (*Daphnia magna* crustacean) 24-48 hours = 100 mg/L
 LC₅₀ (*Daphnia magna*, young crustacean) 24 hours = 7 mg/L
 LC₅₀ (*Daphnia magna*, young crustacean) 48 hours = 17 mg/L
 LC₅₀ (*Daphnia magna*, adult crustacean) 24hours = 21 mg/L

PHENOL (continued):

LC₅₀ (*Daphnia magna*, adult crustacean) 48 hours = 61 mg/L
 LC₅₀ (brine shrimp) 24 hours = 56 mg/L
 LC₅₀ (brine shrimp) 48 hours = 157 mg/L
 LC₅₀ (*M. latipinna*) 24 hours = 22 mg/L
 LC₅₀ (*M. latipinna*) 48 hours = 63 mg/L
 LC₅₀ (*Arctopsyche grandis*) 24hours = 61mg/L
 LC₅₀ (*Arctopsyche grandis*) 48 hours = 56 mg/L
 LC₅₀ (*Arctopsyche grandis*) 96 hours = 0.001 mg/L
 LC₅₀ (mosquito fish) 24-hours = 23 mg/L
 LC₅₀ (mosquito fish) 48 hours = 22 mg/L
 LC₅₀ (mosquito fish) 96 hours = 56 mg/L
 LC₅₀ (bluegill) 24 hours = 19 mg/L
 LC₅₀ (bluegill) 48 hours = 19 mg/L
 LC₅₀ (bluegill) 96 hours = 5.7 mg/L
 LC₅₀ (fathead) soft water 24 hours = 41 mg/L
 LC₅₀ (fathead) soft water 48 hours = 41 mg/L
 LC₅₀ (fathead) soft water 96 hours = 34 mg/L
 LC₅₀ (fathead) hard water 24 hours = 39 mg/L
 LC₅₀ (fathead) hard water 48 hours = 39 mg/L
 LC₅₀ (fathead) hard water 296 hours = 32 mg/L
 LC₅₀ (bluegill) soft water 24 hours = 28 mg/L
 LC₅₀ (bluegill) soft water 48 hours = 24 mg/L
 LC₅₀ (bluegill) soft water 96 hours = 24 mg/L
 LC₅₀ (goldfish) 24 hours = 50 mg/L
 LC₅₀ (goldfish) 48 hours = 49 mg/L
 LC₅₀ (goldfish) 96 hours = 44 mg/L
 LC₅₀ (guppy) 24 hours = 50 mg/L
 LC₅₀ (guppy) 48 hours = 50 mg/L
 LC₅₀ (guppy) 96 hours = 39 mg/L
 LC₅₀ (crucian carp) 24 hours = 25 mg/L
 LC₅₀ (roach) 24 hours = 15 mg/L
 LC₅₀ (tench) 24 hours = 17 mg/L
 LC₅₀ (trout embryos) 24 hours = 5 mg/L
 LC₅₀ (*Carassius auratus*) 48 hours = 44 mg/L
 LC₅₀ (bluegill sunfish) 24 hours = 23 mg/L
 LC₅₀ (goldfish) 24 hours = 46 mg/L
 LC₅₀ (*Brachydanio rerio*) 24 hours = 36 mg/L

PHENOL (continued):

LC₅₀ (*Brachydanio rerio*) 48 hours = 38 mg/L
 LC₅₀ (*Brachydanio rerio*) 96 hours = 36 mg/L
 LC₅₀ (fathead minnow) 24 hours = 8.2 mg/L
 LC₅₀ (fathead minnow) 96 hours = 5 mg/L
 LC₅₀ (*Poecilia reticulata* guppy) 24 hours = 30 ppm
 LC₅₀ (*Poecilia reticulata* guppy) 14 days = 0.23 mg/L
 LC_{50,S} (goldfish) 60-200 mg/L
 LC_{50,S} (golden shiner) 24 hours = 35-129 mg/L
 LC_{50,S} (bluegill) 24 hours = 19-160 mg/L
 LC_{50,S} (*Crassostrea virginica* mollusc) 48 hours = 58 ppm
 LC_{50,S} (*Mercenaria mercenaria* mollusc) 48 hours = 52 ppm
 LC_{50,S} (*Mercenaria mercenaria* mollusc) 12 days = 55 ppm
 LC_{50,S} (golden shiner) 24 hours = 35-129 mg/L
 LC_{50,S} (fathead minnow) 1 hour = > 50 mg/L
 LC_{50,S} (fathead minnow) 24 hours = > 50 mg/L
 LC_{50,S} (fathead minnow) 48 hours = > 33 mg/L
 LC_{50,S} (fathead minnow) 96 hours = > 32 mg/L
 LC_{50,S} (*Ophicephalus punctatus*) 48 hours = 46 mg/L
 LC_{50,F} (trout) 24 hours = 12 mg/L
 LC_{50,F} (trout) 48 hours = 12 mg/L
 LC_{50,F} (trout) 96 hours = 12 mg/L
 LC_{50,F} (fathead minnow) 48 hours = 41 mg/L at 15°C
 LC_{50,F} (fathead minnow) 96 hours = 36 mg/L at 15°C
 LC_{50,F} (fathead minnow) 48 hours = 28 mg/L 25°C
 LC_{50,F} (fathead minnow) 96 hours = 28 mg/L 25°C
 LC₁₀₀ (creek chub) 20 mg/L
 LC₁₀₀ (*Tetrahymena pyriformis*) 24 hours = 600 mg/L

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EC, its member states, Canada and its Provinces. 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. Incineration is recommended for the product and disposable equipment. Reusable equipment should be cleaned with soap and water.

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

14. TRANSPORTATION INFORMATION

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME: Not Regulated
HAZARD CLASS NUMBER and DESCRIPTION: Not Applicable
UN IDENTIFICATION NUMBER: Not Applicable
PACKING GROUP: Not Applicable
DOT LABEL(S) REQUIRED: Not Applicable
NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2000): Not Applicable
MARINE POLLUTANT: No component of this product is classified by the U.S. DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

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

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

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act, and are listed as follows:

CHEMICAL NAME	SARA 302 (40 CFR 355, Appendix A)	SARA 304 (40 CFR Table 302.4)	SARA 313 (40 CFR 372.65)
Phenol	Yes	Yes	Yes

U.S. SARA THRESHOLD PLANNING QUANTITY: Phenol = 10,000 lb (4540 kg)

U.S. SARA EXTREMELY HAZARDOUS REPORTABLE QUANTITY: Phenol = 500 lb (227 kg); Phenol is an extremely hazardous substance (EHS) subject to reporting requirements when stored in amounts in excess of its threshold planning quantity (TPQ) of 500/10,000 lbs.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Phenol = 1000 lb (454 kg)

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration regulations and is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component of this product is on the California Proposition 65 lists.

U.S. STATE REGULATORY INFORMATION: The components of this product are covered under the following specific State regulations, as follows:

Alaska - Designated Toxic and Hazardous Substances: Phenol.	Michigan Critical Register List: No.	Pennsylvania - Hazardous Substance List: Phenol.
California - Permissible Exposure Limits for Chemical Contaminants: Phenol.	Minnesota - List of Hazardous Substances: Phenol.	Rhode Island - Hazardous Substance List: Phenol.
Florida - Substance List: Phenol.	Missouri - Employer Information/Toxic Substance List: Phenol.	Texas - Hazardous Substance List: Phenol.
Illinois - Toxic Substance List: Phenol.	New Jersey - Right to Know Hazardous Substance List: Phenol.	West Virginia - Hazardous Substance List: Phenol.
Kansas - Section 302/313 List: Phenol.	North Dakota - List of Hazardous Chemicals, Reportable Quantities: Phenol.	Wisconsin - Toxic and Hazardous Substances: Phenol.
Massachusetts - Substance List: Phenol.		

OTHER U.S. FEDERAL REGULATIONS: Based on this product's use, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) may be applicable. Federal law prohibits dispensing without prescription.

PROMETHAZINE HYDROCHLORIDE INJECTION, USP MSDS

EFFECTIVE DATE: SEPTEMBER 23, 2002

15. REGULATORY INFORMATION (Continued)

UNITED STATES REGULATIONS (continued):

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE EYE OR SKIN IRRITATION. MAY BE HARMFUL IF INJECTED, SWALLOWED, OR IF THERE IS PROLONGED SKIN CONTACT. Do not taste or swallow. Do not accidentally get on skin, in eyes, or on clothes. Avoid prolonged or repeated skin contact. Avoid breathing mists or sprays. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. If necessary, wear gloves, goggles, and appropriate body protection. Store containers at room temperature, tightly closed, away from direct light. **FIRST-AID:** In case of contact, immediately flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If ingested, induce vomiting. Get medical attention if necessary. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or "alcohol" foam. **IN CASE OF SPILL:** Absorb spill with polypads and place in suitable container. Consult Material Safety Data Sheet for additional information.

CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product is regulated by the Food and Drug Administration of Health Canada; it is exempt from the requirements of CEPA.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: This material is not on the CEPA Priorities Substances Lists.

CANADIAN WHMIS SYMBOL: Class D2B (Materials Causing Other Toxic Effects)



EUROPEAN COMMUNITY REGULATIONS:

EC LABELING/CLASSIFICATION: This product does not meet the definition of any hazard class as defined by the European Community Council Directive 67/548/EEC. Additionally, this Directive is not applicable to medicinal products (per Article 1, 88/379/EEC).

EC HAZARD CLASSIFICATION: Not applicable.

EC RISK PHRASES: Not applicable.

EC SAFETY PHRASES: Not applicable.

EUROPEAN ECONOMIC COMMUNITY ANNEX II HAZARD SYMBOL: Not applicable.

NOTE: This product's components are classified by the EC, as follows:

Promethazine Hydrochloride: EC EINECS/ELINCS NUMBER: 232-681-7

EC CLASSIFICATION: An official classification for this substance has not been published in Commission Directives 93/72/EEC, 94/69 EC, or and 96/54/EC.

PHENOL:

EC EINECS/ELINCS NUMBER: 203-632-7

HAZARD CLASSIFICATION: [T]: Toxic; [C]: Corrosive.

RISK PHRASES: [R: 24/25]: Toxic in contact with skin and if swallowed. [R: 34]: Causes burns.

AT CONCENTRATIONS GREATER THAN OR EQUAL TO 10%:

HAZARD CLASSIFICATION: [C] Corrosive.

RISK PHRASES: [R: 35]: Causes severe burns

AT CONCENTRATIONS EQUAL TO OR MORE THAN 5%:

HAZARD CLASSIFICATION: [T] Toxic.

RISK PHRASES: [R: 24/25]: Toxic in contact with skin and if swallowed. [R: 34]: Causes burns.

AT CONCENTRATIONS EQUAL TO OR MORE THAN 1% AND LESS THAN 5%:

HAZARD CLASSIFICATION: [Xn] Harmful.

RISK PHRASES: [R: 21/22]: Harmful in contact with skin and if swallowed. [R: 36/38]: Irritating to eyes and skin.

SAFETY PHRASES: [S: 2½]: Keep locked-up and out of reach of children. (*This safety phrase can be omitted from the label when the substance or preparation is sold for industrial use only.*) [S: 28]: After contact with skin, wash immediately with plenty of (to be specified by manufacturer). [S: 45]: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

16. OTHER INFORMATION

This Material Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Steris Laboratories, Inc. knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

PREPARED BY:

CHEMICAL SAFETY ASSOCIATES, Inc.
PO Box 3519, La Mesa, CA 91944-3519

PROMETHAZINE HYDROCHLORIDE INJECTION, USP MSDS

EFFECTIVE DATE: SEPTEMBER 23, 2002

DEFINITION OF TERMS

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

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

EXPOSURE LIMITS IN AIR:

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

LOQ: Limit of Quantitation.

MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.

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

NIC: Notice of Intended Change.

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

NIOSH RELs: NIOSH's Recommended Exposure Limits.

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

SKIN: Used when 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.

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.

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 LD₅₀ Rat:* < 5000 mg/kg. *Dermal Toxicity LD₅₀ Rat or Rabbit:* < 2000 mg/kg. *Inhalation Toxicity 4-hrs LC₅₀ Rat:* < 20 mg/L.; **1 (Slight Hazard):** Minor reversible injury may occur, slightly or mildly irritating. *Skin Irritation:* Slightly or mildly irritating. *Eye Irritation:* Slightly or mildly irritating. *Oral Toxicity LD₅₀ Rat:* > 500-5000 mg/kg. *Dermal Toxicity LD₅₀ Rat or Rabbit:* > 1000-2000 mg/kg. *Inhalation Toxicity LC₅₀ 4-hrs Rat:* > 2-20 mg/L.; **2 (Moderate Hazard):** Temporary or transitory injury may occur. *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 LD₅₀ Rat:* > 50-500 mg/kg. *Dermal Toxicity LD₅₀ Rat or Rabbit:* > 200-1000 mg/kg. *Inhalation Toxicity LC₅₀ 4-hrs Rat:* > 0.5-2 mg/L.; **3 (Serious Hazard):** Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation:* Severely irritating and/or corrosive; may 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 LD₅₀ Rat:* > 1-50 mg/kg.

Dermal Toxicity LD₅₀ Rat or Rabbit: > 20-200 mg/kg. *Inhalation Toxicity LC₅₀ 4-hrs Rat:* > 0.05-0.5 mg/L.;

4 (Severe Hazard): Life-threatening; major or permanent damage may result from single or repeated 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 LD₅₀ Rat:* ≤ 1 mg/kg. *Dermal Toxicity LD₅₀ Rat or Rabbit:* ≤ 20 mg/kg. *Inhalation Toxicity LC₅₀ 4-hrs Rat:* ≤ 0.05 mg/L.

FLAMMABILITY HAZARD:

0 (Minimal Hazard)-Materials that will not burn in air when exposure to a temperature of 815.5°C (1500°F) for a period of 5 minutes.; **1 (Slight Hazard)-Materials that must be pre-heated before ignition can occur. Material 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 III-B, 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 coarse dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp; Solids and semisolids that readily give off flammable vapors.);** **3 (Serious Hazard)- Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 38 C (100 F) and below 37.8°C [100°F] [e.g. OSHA Class IB and IC]; Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air [e.g., dusts of combustible solids, mists or droplets of flammable liquids]; Materials that burn extremely rapidly, usually by reason of self-contained oxygen [e.g. dry nitrocellulose and many organic peroxides];** **4 (Severe Hazard)-Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and which will burn readily, including: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C [100°F] [e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below [e.g. pyrophoric].**

PHYSICAL HAZARD:

0 (Water Reactivity): Materials that do not react with water. **Organic Peroxides:** Materials that are normally stable, even under fire conditions and will not react with water. **Explosives:** Substances that are Non-Explosive. **Unstable Compressed Gases:** No Rating. **Pyrophorics:** No Rating. **Oxidizers:** No "0" rating allowed. **Unstable Reactives:** Substances that will not polymerize, decompose, condense or self-react.;

1 (Water Reactivity): Materials that change or decompose upon exposure to moisture. **Organic Peroxides:** Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy. **Explosives:** Division 1.5 & 1.6 substances that are very insensitive explosives or that do not have a mass explosion hazard. **Compressed Gases:** Pressure below OSHA definition. **Pyrophorics:** No Rating. **Oxidizers:** Packaging Group III; **Solids:** any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. **Liquids:** any material that exhibits a mean pressure

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. **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 \geq 514.7 psi absolute at 21.1°C (70°F) [500 psig]. **Pyrophorics:** No Rating. **Oxidizers:** Packing Group I **Solids:** any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. **Liquids:** Any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)cellulose mixture. **Unstable Reactives:** Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a moderate potential to cause significant heat generation or explosion.); 4 (**Water Reactivity:** Materials that react explosively with water without requiring heat or confinement. **Organic Peroxides:** Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. **Explosives:** Division 1.1 & 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. **Compressed Gases:** No Rating. **Pyrophorics:** Add to the definition of Flammability "4". **Oxidizers:** No "4" rating. **Unstable Reactives:** Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.). PPE Rating B: Hand and eye protection is required for routine chemical use. PPE Rating C: Hand, eye, and body protection may be required for routine chemical use.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: 0 (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); 1 (materials that on exposure under fire conditions could cause irritation or minor residual injury); 2 (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); 3 (materials that can on short exposure could cause serious temporary or residual injury); 4 (materials that under very short exposure could cause death or major residual injury).

FLAMMABILITY HAZARD AND REACTIVITY HAZARD: Refer to definitions for "Hazardous Materials Identification System".

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: **LD₅₀ -** Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC₅₀ -** 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 **LD₀₁**, or **TC**, **TC₀₁**, **LCLo**, and **LC₀₁**, 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.

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. **TL₅₀ =** 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:**

This section explains the impact of various laws and regulations on the material. EPA is the U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits. NIOSH is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (OSHA). WHMIS is the Canadian Workplace Hazardous Materials Information System. DOT and TC are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act (SARA); the Canadian Domestic/Non-Domestic Substances List (DSL/NDL); the U.S. Toxic Substance

the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund); and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label. OSHA - U.S. Occupational Safety and Health Administration. EUROPEAN: EC is the European Community (formerly known as the EEC, European Economic Community). EINECS: This is the European Inventory of Existing Chemical Substances. The ARD is the European Agreement Concerning the International Carriage of Dangerous Goods by Road and the RID are the International Regulations Concerning the Carriage of Dangerous Goods by Rail.