SAFETY DATA SHEETS

This SDS packet was issued with item:

078937399

N/A

GensiaSicor™ PHARMACEUTICALS

MATERIAL SAFETY DATA SHEET

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

1. PRODUCT IDENTIFICATION

PRODUCT NAME (AS LABELED): **SULFAMETHOXAZOLE and TRIMETHOPRIM (SMX-TMP) Injection, USP**

SUPPLIER/MANUFACTURER'S NAME: **GensiaSicor Pharmaceuticals, Inc.**
ADDRESS: 17 Hughes
Irvine, CA 92618

CHEMTREC EMERGENCY NO.: 1-800-424-9300 (United States)**
1-202-483-7616 (International Collect)

BUSINESS PHONE: 1-800-729-9991
FAX: 1-949-855-8210

Common Names: SMX-TMP
Chemical Name: 4-Amino-N-(5-methyl-3-isoxazolyl) benzenesulfonamide) &
5-[(3,4,5-trimethoxyphenyl)methyl]-2,4-pyrimidinediamine
Chemical Formula: $C_{10}H_{11}N_3O_3S$ and $C_{14}H_{18}N_4O_3$
Chemical Family: Antibacterial
How Supplied: 80 mg SMX/16 mg TMP per mL in 5 mL, 10 mL, and 30 mL vials

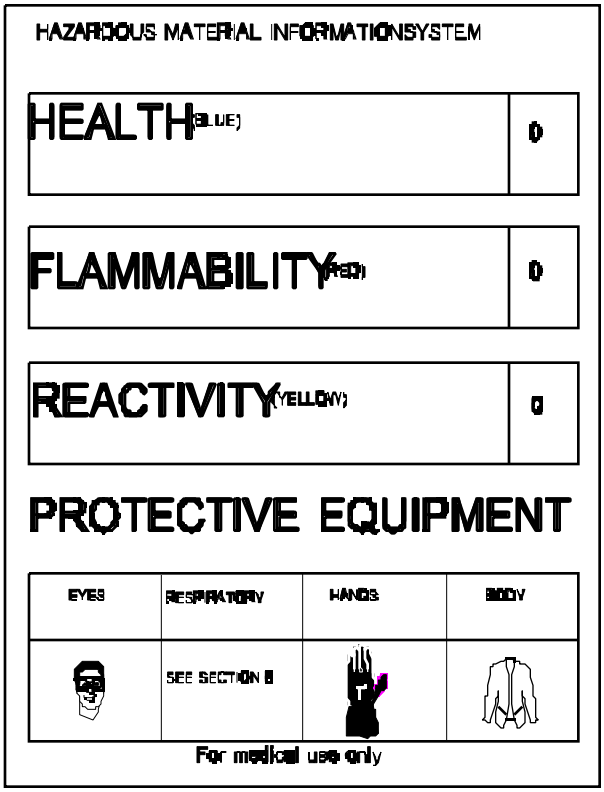
2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% by weight	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA			OTHER
			TLV	STEL	PEL	STEL	IDLH	
SULFAMETHOXAZOLE	723-46-6	8	NE	NE	NE	NE	NE	NE
TRIMETHOPRIM	738-70-5	2	NE	NE	NE	NE	NE	NE
PROPYLENE GLYCOL	57-55-6	40	NE	NE	NE	NE	NE	NE
ETHYL ALCOHOL	64-17-5	10	1000 ppm	NE	1000 ppm	NE	NE	NIOSH REL: 1000 ppm
BENZYL ALCOHOL	100-51-6	1	NE	NE	NE	NE	NE	NE
DIETHANOLAMINE	111-42-2	<1	NE	15 mg/m^3	NE	NE	NE	NIOSH REL: 3 mg/m^3
SODIUM METABISULFITE	7681-57-4	< 1	5 mg/m^3	NE	5 mg/m^3	NE	NE	NIOSH REL: 5 mg/m^3
WATER FOR INJECTION	7732-18-5	>37	NE	NE	NE	NE	NE	NE

* NE = Not Established. **Chemtrec number: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this chemical.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This clear, colorless solution may irritate the skin and eyes. Injection or ingestion in large quantities may be harmful. Thermal decomposition of this product may result in the release of toxic nitrogen and carbon oxides.



SYMPTOMS OF OVER EXPOSURE BY ROUTE OF EXPOSURE: This material may be harmful if swallowed, inhaled, or injected into skin. This solution can cause skin and eye irritation. The solution can be irritating to mucous membranes and the respiratory tract. This product contains sodium metabisulfite and the symptoms of hypersensitivity or sulfite allergy may include rash, fever, respiratory difficulty, or asthma-like symptoms.

INHALATION: No information on inhalation is available. Symptoms similar to those of injection might occur.

CONTACT WITH SKIN or EYES: Contact of the product with the skin or eyes may cause local irritation.

SKIN ABSORPTION: There is currently no evidence that skin absorption is a significant route of entry for this product.

INGESTION: Studies indicate that this product IS moderately toxic by ingestion. Symptoms similar to those of injection may occur.

INJECTION: Injection of this product can lead to decreased urine volume, complete cessation of urine production, dermatitis, rash, and systemic metabolic changes.

HEALTH EFFECTS OR RISKS FROM EXPOSURE (An explanation in **lay terms)**.

ACUTE: Over exposure may affect the kidney and the body_s ability to produce urine. Rash or other metabolic symptoms may occur. Allergy-like reactions may develop.

CHRONIC: Limited animal studies suggest this product may be carcinogenic, but no human data are available. No fetotoxic effects have been reported.

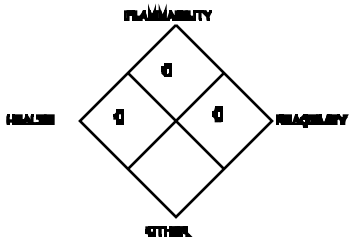
PART II *What should I do if a hazardous situation occurs?*

4. FIRST-AID MEASURES

If spilled on skin, immediately wash the affected area with soap and water and rinse with running water for at least 15 minutes. Remove exposed or contaminated clothing, taking care not to contaminate eyes. If the product is splashed in eyes, open victim's eyes while under gentle running water. Use sufficient force to open eye lids. Have victim "roll" eyes. Minimum flushing should be 15 minutes. If product is inhaled, remove victim to fresh air and use artificial respiration to support vital functions. Remove or cover gross contamination to avoid exposure to rescuers. Victim and rescuers should obtain medical attention, if appropriate.

If product is swallowed, rinse victim_s mouth and CALL a PHYSICIAN OR a POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If accidently injected, obtain medical advice or call a POISON CONTROL CENTER immediately. If professional advice is not available, DO NOT induce vomiting. Victim(s) of contamination with this product and all rescuers should be taken for medical attention, if appropriate. Take copy of label and MSDS to physician or health professional with victim.

5. FIRE-FIGHTING MEASURES



NFPA RANKING

FLASH POINT, C (method): Not applicable.
AUTOIGNITION TEMPERATURE, C: Not applicable.
FLAMMABLE LIMITS (in air by volume, %): Lower: Not applicable.
Upper: Not applicable.

FIRE EXTINGUISHING MATERIALS: The size and nature of this product is such that it will not contribute to the intensity of a fire. Fire fighting should be aimed at surrounding materials.

Water Spray: OK Carbon Dioxide: OK
Foam: OK Dry Chemical: OK Halon: OK

SPECIAL FIRE FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural fire fighters must wear self-contained breathing apparatus and full protective equipment.

UNUSUAL FIRE and EXPLOSION HAZARDS: When heated to decomposition, this product may emit toxic fumes containing oxides of nitrogen.

6. ACCIDENTAL RELEASE MEASURES

SPILL and LEAK RESPONSE: For small releases of this product (i.e. one vial, 30 mL) wear latex or nitrile gloves and safety glasses. Absorb spilled liquid with polypads or other appropriate materials. Avoid splashing or spraying liquid. Rinse area thoroughly with soap and water.

Large or uncontrolled releases (i.e. 1000 mL) should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used. In case of a spill, clear the affected area, protect people, and respond with trained personnel. Absorb spilled liquid with polypads or other appropriate materials. Avoid splashing or spraying liquid. Rinse area thoroughly with soap and water. Place all spill residue in a double plastic bag.

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

7. HANDLING and STORAGE

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

STORAGE and HANDLING PRACTICES: Store product in original container at 15 - 30^{o}C.

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION and ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures.
RESPIRATORY PROTECTION: None required under routine conditions of use.
EYE PROTECTION: Safety glasses.
HAND PROTECTION: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands after removing gloves.
BODY PROTECTION: Routine medical clothing, such as lab coat, gown, or smock, should be worn when preparing or handling this product.
Product Preparation Instructions for Medical Personnel: Follow standard procedures for handling biological materials.

9. PHYSICAL and CHEMICAL PROPERTIES

VAPOR DENSITY: Not applicable. EVAPORATION RATE (n-BuAc=1): Similar to water.
SPECIFIC GRAVITY: 1 @ 20°C MELTING POINT or RANGE: 0_ C
SOLUBILITY IN WATER: Highly. BOILING POINT: 100°C.
VAPOR PRESSURE, mm Hg @ 25°C: 20 mm Hg pH 9.5 - 10.5
APPEARANCE and COLOR: This product is a clear, pale yellow viscous solution.
HOW TO DETECT THIS SUBSTANCE (warning properties): The pale yellow color and syrup-like consistency identifies this product.

10. STABILITY and REACTIVITY

STABILITY: Stable when stored under ambient conditions up to the shelf-life of the product. The recommended storage temperature is 15 - 30 °C.
CONDITIONS TO AVOID: Heat may cause product to decompose, destroying the product or producing toxic fumes.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Acids, caustics. Avoid extreme pH conditions.
HAZARDOUS POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Heat and contact with incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA:
TDLo oral woman 346 mg/kg
TDLo intravenous man 80 mg/kg
LDLo oral human 274 mg/kg
LD_{50} oral rat 5350 mg/kg
LD_{50} intraperitoneal rat 1840 mg/kg
LD_{50} oral mouse 3740 mg/kg
LD_{50} intraperitoneal mouse 2010 mg/kg

SUSPECTED CANCER AGENT: This products ingredient's are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, CAL/OSHA.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Gastrointestinal problems.

RECOMMENDATIONS TO PHYSICIANS: Refer to adverse reaction information provided with the product.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL STABILITY: Based on the size of the product packaging and shipping method, environmental impact is not expected.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: Studies indicate that this product should not cause significant impact on plants or animals.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available regarding the potential affect of this material on aquatic life.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by the handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority.

EPA WASTE NUMBER: Not applicable.

14. TRANSPORTATION INFORMATION

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

PROPER SHIPPING NAME:	Not applicable.
HAZARD CLASS NUMBER and DESCRIPTION:	Not applicable.
UN IDENTIFICATION NUMBER:	Not applicable.
PACKING GROUP:	Not applicable.
DOT LABEL(S) REQUIRED:	Not applicable.
EMERGENCY RESPONSE GUIDE NUMBER:	Not applicable.
RQ:	Not applicable.

15. REGULATORY INFORMATION

SARA REPORTING REQUIREMENTS: Diethanolamine is subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act.

TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory.

MARINE POLLUTANT: This product contains no component listed as a Marine Pollutant under 49 CFR 172.101, Appendix B.

CALIFORNIA PROPOSITION 65: This product IS NOT on the California Proposition 65 lists.

CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

15. REGULATORY INFORMATION (cont.)

STATE REGULATORY INFORMATION: Sulfamethoxazole and trimethoprim are covered under the following specific State regulations (NONE indicates no special regulations were noted.)

Alabama	None	**New Hampshire**	None
Alaska	None	**New Jersey**	None
California	None	**New York**	None
Connecticut	None	**North Dakota**	None
Delaware	None	**Oklahoma**	None
Florida	None	**Oregon**	None
Illinois	None	**Pennsylvania**	None
Kansas	None	**Rhode Island**	None
Maine	None	**Tennessee**	None
Maryland	None	**Texas**	None
Massachusetts	None	**Vermont**	None
Michigan	None	**Washington**	None
Minnesota	None	**Wisconsin**	None
Missouri	None	**West Virginia**	None
Montana	None		

LABELING (Precautionary Statements): **DANGER!** May cause kidney or metabolic disturbances when used for medical treatment. Use must be under the supervision of a physician. Occupational exposure to this substance (i.e. splashing the product on skin or eyes) may result in irritation of affected area.

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16. OTHER INFORMATION

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc.
9163 Chesapeake Drive,
San Diego, CA 92123-1002
619/565-0302

DATE OF PREPARATION: November 30, 1999

SAFETY DATA SHEET

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

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

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME:	**SULFAMETHOXAZOLE and TRIMETHOPRIM INJECTION**
CHEMICAL NAME: Active Ingredients:	Sulfamethoxazole: 1-(5-methyl-3-isoxazolyl)sulfanilamide Trimethoprim: 2,4-diamino-5-(3,4,5-trimethoxybenzyl) pyrimidine
CHEMICAL CLASS: Active Ingredients:	Sulfamethoxazole: Sulfonamide Trimethoprim: Catechol Antibiotic
THERAPEUTIC CLASS:	Antibacterial
HOW SUPPLIED:	Sulfamethoxazole 800 mg/10 mL (80 mg/mL) & Trimethoprim 160 mg/10 mL (16 mg/mL) in 10 mL Multiple Dose Vials; Sulfamethoxazole 400 mg/5 mL (80 mg/mL) & Trimethoprim 80 mg/5 mL (16 mg/mL) in 5 mL Single Dose Vials
RELEVANT USE of the SUBSTANCE:	Human Pharmaceutical
USES ADVISED AGAINST:	Other than Relevant Use

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME:	**TEVA**
ADDRESS:	1090 Horsham Road North Wales, PA 19454
BUSINESS PHONE:	215-591-3000 [08:00 AM --> 05:00 PM]
EUROPEAN CONTACT:	**TEVA/TAPI**
ADDRESS:	Sicor sri-Via Terrazzano 77-20017 Cho (MI), Italy
BUSINESS PHONE:	+39 02 93197 306 [08:00 AM --> 05:00 PM]
EMERGENCY PHONE:	United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
EMAIL:	TevaSDSRequest@tevapharm.com
DATE OF PREPARATION:	October 10, 2012
DATE OF REVISION:	April 28, 2015

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 EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

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

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

EMERGENCY OVERVIEW: Product Description: This product is a pale yellow, clear, aqueous solution. **Health Hazards:** In the workplace, exposure by inhalation and eye contact may cause irritation. May be harmful by skin contact, if swallowed or inhaled. In therapeutic use, common adverse effects are gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions (such as rash and urticaria). This product contains a sulfonamide; severe allergic reactions can occur. May cause harm to the fetus, based on human and animal information. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects. **Flammability Hazards:** This product is combustible and may ignite if heated to high temperature for a prolonged period. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** This product may cause harm to animals and aquatic organisms if accidentally released to the environment. **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 #	EINECS #	% w/v	LABEL ELEMENTS EU Classification (67/548/EEC) GHS and EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENT				
Sulfamethoxazole 1-(5-methyl-3-isoxazolyl)sulfanilamide	723-46-6	204-523-7	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Irritant Risk Phrase Codes: R36/37/38 Hazard Symbols: Xi GHS and EU 1272/2008 Classification: Eye Irritation Cat. 2B, Skin Sensitization Cat. 1, Respiratory Sensitization Cat. 1 Hazard Codes: H320, H317, H334 Hazard Symbol/Pictogram: GHS08
Trimethoprim 2,4-diamino-5-(3,4,5-trimethoxybenzyl) pyrimidine	738-70-5	212-006-2	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Risk Phrase Codes: Hazard Symbols: Xi GHS and EU 1272/2008 Classification: Respiratory Sensitization Cat. 1 Hazard Codes: H361d, H334 Hazard Symbol/Pictogram: GHS08
EXCIPIENTS				
Benzyl Alcohol	100-51-5	202-859-9	Proprietary	EU 67/548 Classification: Risk Phrase Codes: R20/22 Hazard Symbols: Xn/Xi GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Acute Inhalation Toxicity Cat. 4 Hazard Codes: H302, H332 Hazard Symbol/Pictogram: GHS07
Diethanolamine	111-42-2	203-868-0	Proprietary	EU 67/548 Classification: Harmful, Irritant Risk Phrases: R22, R48/22, R38, R41 Symbols: Xn/Xi GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, STOT RE Cat. 2, Skin Irritation Cat. 2, Eye Damage Cat. 1 Hazard Statement Codes: H302, H373, H315, H318 Hazard Symbols/Pictograms: GHS05, GHS07, GHS08
Ethyl Alcohol	64-17-5	200-578-6	Proprietary	EU 67/548 Classification: Highly Flammable Risk Phrases: R11 Symbols: F GHS & EU 1272/2008 Classification: Flammable Liquid Cat. 2 Hazard Statement Codes: H225 Hazard Symbols/Pictograms: GHS02
Propylene Glycol	57-55-6	200-338-0	Proprietary	EU 67/548 CLASSIFICATION: Not Applicable GHS AND EU 1272/2008 Classification: Not Applicable
Sodium Metabisulfite	7681-57-4	231-673-0	Proprietary	EU 67/548 Classification: Harmful, Irritant Risk Phrases: R22, R41 Symbols: Xn/Xi GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Eye Damage Cat. 1 Hazard Statement Codes: H302, H318 Hazard Symbols/Pictograms: GHS05, GHS07
Water	7732-18-5	231-791-2	Balance	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable

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. Take a copy of this SDS to health professional with victim.

SKIN OR EYE EXPOSURE: Flush affected area with water for 20 minutes.

INHALATION: Remove victim to fresh air if dusts are inhaled.

INGESTION: CALL PHYSICIAN OR POISON CONTROL CENTER. Give victim up to three glasses of water. Do not induce vomiting.

INJECTION: Not likely route of exposure.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing hypersensitivity to components, megaloblastic anemia, hepatic and renal insufficiency, folate deficiency may be aggravated by exposures to this material.

4. FIRST-AID MEASURES (Continued)

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. General principles of treatment include the administration of intravenous fluids if urine output is low and renal function is normal. Acidification of the urine will increase renal elimination of Trimethoprim. The patient should be monitored with blood counts and appropriate blood chemistries, including electrolytes. If a significant blood dyscrasia or jaundice occurs, specific therapy should be instituted for these complications. Peritoneal dialysis is not effective and hemodialysis is only moderately effective in eliminating Trimethoprim and Sulfamethoxazole.

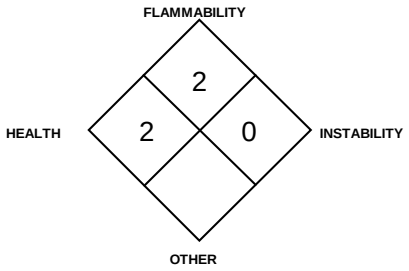
5. FIRE-FIGHTING MEASURES

FLASH POINT: 43.5°C (110.5°F)
AUTOIGNITION TEMPERATURE: Not available.
FLAMMABLE LIMITS (in air by volume, %): Not available.
FIRE EXTINGUISHING MEDIA: Carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon.
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.
SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: This solution is combustible and may ignite if exposed to direct flame or high temperature for a prolonged period. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, nitrogen and sulfur oxides).

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

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Firefighters are recommended to wear Self-Contained Breathing Apparatus and full protective equipment. 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 should be kept in or near material handling areas. Avoid generating airborne aerosols of this product during spill response procedures.

PROTECTIVE EQUIPMENT:

Small Spills: Nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection.

Large Spills: Double nitrile or other appropriate gloves, protective clothing (i.e., disposable Tyvek coveralls) and eye/face protection. When there is any danger of airborne aerosols being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter or Self-Contained Breathing Apparatus (SCBA).

METHODS FOR CLEAN-UP AND CONTAINMENT:

Small Spills: Clean with absorbent pads and dispose of properly. Decontaminate the spill area using a bleach and detergent solution and rinse with clean water.

Large Spills: Restrict access to the spill areas. Clean with wet absorbent pads and dispose of properly. Decontaminate the spill area using a bleach and detergent solution and rinse with clean water. Do not apply chemical in-activators as they may produce hazardous by-products.

All Spills: Place all spill residues in an appropriate, labeled container and seal. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered material and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.
REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup.

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

7. HANDLING and STORAGE

NOTE: Consistent with the OSHA Bloodborne Pathogen regulation (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.
PRECAUTIONS FOR SAFE HANDLING: All employees who handle this material should be thoroughly trained to handle it safely. Do not eat or drink while handling this material. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection).
CONDITIONS FOR SAFE STORAGE: Containers of this material must be properly labeled. Recommended Storage Temperature: 20-25°C (68-77°F). Storage areas should be made of fire resistant materials. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.
SPECIFIC END USE(S): This is a human pharmaceutical.
PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear appropriate personal protective equipment.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used.

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS: There are no occupational exposure limits for this product. Exposure limits for the active ingredient or excipients are available from Teva.

PROTECTIVE EQUIPMENT:

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132), *equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

RESPIRATORY PROTECTION: None needed for normal handling of this product. For large spill response or tasks involving generation of aerosols, use the appropriate Self-Contained Breathing Apparatus (SCBA) pressure-demand or other positive-pressure mode.

EYE PROTECTION: Wear splash goggles or safety glasses as appropriate for the task.

HAND PROTECTION: Wear nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response.

SKIN PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.).

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the drug product.

PHYSICAL FORM: Liquid
COLOR: Pale yellow.
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
pH: 9.5-10.5 (adjusted)
HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The color is a distinguishing characteristic of this product in event of accidental release.

The following information is for the Sulfamethoxazole active ingredient.

FORM: Crystalline solid.
COLOR: Pale, yellow.
MOLECULAR FORMULA: $C_{10}H_{11}N_3O_3S$
MOLECULAR WEIGHT: 253.28
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
MELTING POINT: 199-203°C (390.2-397.4°F)
SPECIFIC GRAVITY: 1.252 g/cm^3
BOILING POINT @ 760 mmHg: 525.9°C (978.6°F) [predict.]
FLASH POINT: 271.9°C (521.4°F) [predict.]
VAPOR PRESSURE @ 25°C: 1.31E-32 mmHg [predict.]
pH: Not applicable to solid.
SOLUBILITY IN WATER: 12.1 mg/mL
OTHER SOLUBILITIES: Not available.
COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): Log P: 0.594 (predict.)

The following information is for the Trimethoprim active ingredient.

FORM: Crystalline solid.
COLOR: White to light yellow.
MOLECULAR FORMULA: $C_{14}H_{18}N_4O_3$
MOLECULAR WEIGHT: 290.3
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
MELTING POINT: 167-171°C (332.6-339.8°F)
SPECIFIC GRAVITY: 1.463 g/cm^3
BOILING POINT @ 760 mmHg: 482.1°C (899.8°F) [predict.]
FLASH POINT: 245.4°C (473.7°F) [predict.]
VAPOR PRESSURE @ 25°C: 0 mmHg [predict.]
pH: Not applicable to solid.
SOLUBILITY IN WATER: 610 mg/L
OTHER SOLUBILITIES: Not available.
COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): Log Kow: 0.89; Log P: 0.659 (predict.)

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Normally stable.
DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include carbon, nitrogen and sulfur oxides. *Hydrolysis:* None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong acids and bases. Avoid materials that are incompatible with water.
POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: None known.
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 expected routes of occupational exposure to this product are via inhalation of aerosols, eye and skin contact. Exposure may cause allergic reaction. Exposure may also cause effects described under 'Other Potential Health Effects'.

INHALATION: May be harmful by inhalation. Aerosols may irritate the nose and upper respiratory system. Symptoms may include sneezing, coughing, and nasal congestion.

CONTACT WITH SKIN or EYES: Mild irritation possible. Symptoms may include itching and redness and swelling.

SKIN ABSORPTION: Potentially harmful.

INGESTION: May irritate the mouth, throat, and gastrointestinal system. Chronic exposure may cause nausea and vomiting, and acidification of urine. Ingestion may cause allergic skin reaction. Higher exposure causes unconsciousness.

INJECTION: Effects may be those listed under 'Other Potential Health Effects'.

OTHER POTENTIAL HEALTH EFFECTS: The most common adverse effects are gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions (such as rash and urticaria).). May cause harm to fetus during pregnancy. The actual risk in the workplace is not known. Body systems adversely affected during therapeutic use are provided below. The actual risk in the workplace is not known. More details can be obtained from Teva.

- Blood System
- Allergic Reactions
- Gastrointestinal System
- Genitourinary System
- Neurological System
- Central Nervous System
- Endocrine System
- Musculoskeletal System
- Respiratory System

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	See Section 8		See Section 8

For Routine Industrial Use and Handling Applications

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

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: This product may be harmful by ingestion and inhalation or skin contact. May cause irritation by inhalation and skin or eye contact.

Chronic: Dermatitis (inflammation and redness of the skin) may occur after chronic, low-level skin contact. This product contains a sulfonamide, severe allergic reactions can occur. No other chronic effects have been reported from workplace exposure. Chronic exposure may also lead to symptoms described under 'Other Potential Health Effects'.

TARGET ORGANS: It is anticipated that for Occupational Exposure the target organs are:

Acute: Eyes, skin, respiratory system.

Chronic: Skin.

TOXICITY DATA: Contact Teva for specific toxicity details on the active ingredient or any of the excipients.

CARCINOGENIC POTENTIAL OF COMPONENTS: No long-term studies in animals have been performed to evaluate the carcinogenic potential of this product. The components found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH are:

DIETHANOLAMINE: ACGIH TLV-A3 (Animal Carcinogen with Unknown Relevance to Humans); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B (Substances for Which in vitro tests or animal studies have yielded evidence of carcinogenic effect that is not sufficient for classification of he substance in one of the other categories. Further studies are required before a final classification can be made.)

ETHYL ALCOHOL: ACGIH TLV-A3 (Animal Carcinogen with Unknown Relevance to Humans); MAK-5 (Substances with Carcinogenic and Genotoxic Effects, the potency of which is considered to be so low that, provided the MAK and BAT values are observed, no significant contribution to human cancer risk is to be expected.)

SODIUM METABISULFITE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

IRRITANCY OF PRODUCT: May cause respiratory, skin or eye irritation.

SENSITIZATION TO THE PRODUCT: Allergic skin reactions (such as rash and urticaria) to this product has been reported. Fatalities associated with the administration of sulfonamides, although rare, have occurred due to severe reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia and other blood dyscrasias.

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

Mutagenicity: Negative in all tests performed.

Embryotoxicity/Teratogenicity: Some animal studies show adverse effects in doses approaching the recommended human dose.

Reproductive Toxicity: No adverse effects on fertility or general reproductive performance were observed in animal studies. It is not known whether this drug is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.
MOBILITY IN SOIL: This product has not been tested for mobility in soil.
PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that some biodegradation will occur to this product; however, no specific information is known.
BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.
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.
RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.
OTHER ADVERSE EFFECTS: The components of this product are not listed as having ozone depletion potential.
ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This 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 protective clothing, 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 and/or regulated medical waste requirements. 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. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.
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.
EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101. A dehydrated alcohol solution, such as this product, has the proper shipping name of ethanol solution.

UN IDENTIFICATION NUMBER:	UN 1170
PROPER SHIPPING NAME:	Ethanol solution
HAZARD CLASS NUMBER and DESCRIPTION:	3 (Flammable)
PACKING GROUP:	PG III
DOT LABEL(S) REQUIRED:	Class 3 (Flammable)

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2012): 128
MARINE POLLUTANT: The components of this product are not classified by the DOT as Marine Pollutants (as defined by 49 CFR 172.101, Appendix B).

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

UN IDENTIFICATION NUMBER:	UN 1170
PROPER SHIPPING NAME:	Ethanol solution
HAZARD CLASS NUMBER and DESCRIPTION:	3 (Flammable)
PACKING GROUP:	PG III
HAZARD SHIPPING LABEL(S) REQUIRED:	Class 3 (Flammable)
SPECIAL PROVISIONS:	None
EXPLOSIVE LIMIT & LIMITED QUANTITY INDEX:	1
ERAP INDEX:	None
PASSENGER CARRYING SHIP INDEX:	None

PASSENGER CARRYING ROAD OR RAIL VEHICLE INDEX: 5

14. TRANSPORTATION INFORMATION (Continued)

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

UN IDENTIFICATION NUMBER: UN 1170
PROPER SHIPPING NAME/DESCRIPTION Ethanol solution
HAZARD CLASS or DIVISION: 3 (Flammable)
HAZARD LABEL(S) REQUIRED: Class 3 (Flammable)
PACKING GROUP: III
EXCEPTED QUANTITIES: E1
PASSENGER and CARGO AIRCRAFT PACKING INSTRUCTION: 309
PASSENGER and CARGO AIRCRAFT MAXIMUM NET QUANTITY PER PKG: 10 L
PASSENGER and CARGO AIRCRAFT LIMITED QUANTITY PACKING INSTRUCTION: Y309
PASSENGER and CARGO AIRCRAFT LIMITED QUANTITY MAXIMUM NET QUANTITY PER PKG: 60 L
CARGO AIRCRAFT ONLY PACKING INSTRUCTION: 310
CARGO AIRCRAFT ONLY MAXIMUM NET QUANTITY PER PKG: 220 L
SPECIAL PROVISIONS: A58
ERG CODE: 3L

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

UN No.: 1170
PROPER SHIPPING NAME: Ethanol solution
HAZARD CLASS NUMBER: 3
PACKING GROUP: III
SPECIAL PROVISIONS: 144
LIMITED QUANTITIES: 5 L
EXCEPTED QUANTITIES: E2
PACKING: Instructions: P001, LP01 Provisions: None
IBCs: Instructions: IBC03, Provisions: None
TANKS: Instructions: T1, Provisions: TP1
EmS: F-E, S-D
STOWAGE CATEGORY: Category A.
MARINE POLLUTANT: The components of this product do not meet the criteria of a Marine Pollutant under UN criteria.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product meets the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

UN NO.: 1170
NAME and DESCRIPTION: Ethanol solution
CLASS: 3
CLASSIFICATION CODE: F1
PACKING GROUP: III
LABELS: 3
SPECIAL PROVISIONS: 144
LIMITED QUANTITIES: 5 L
EXCEPTED QUANTITIES: E1
PACKING INSTRUCTIONS: Instructions: P001, IBC03, LP01, R001
SPECIAL PACKING PROVISIONS: None
PORTABLE TANKS AND BULK CONTAINERS: Instructions: T2, Provisions: TP1
HAZARD IDENTIFICATION No.: 30

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

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and no component is specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

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

CHEMICAL NAME	SARA 302 (40 CFR 355, Appendix A)	SARA 304 (40 CFR Table 302.4)	SARA 313 (40 CFR 372.65)
Diethanolamine	No	No	Yes
Propylene Glycol (as a glycol ether compound)	No	No	N230

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for this material. 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: No; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No

15. REGULATORY INFORMATION (Continued)

ADDITIONAL U.S. REGULATIONS (continued):

U.S. CERCLA REPORTABLE QUANTITY (RQ): Diethanolamine: 100 lb (45.4 kg); As a Glycol Ether compound, Propylene Glycol is a CERCLA Hazardous Material, although it has no specific CERCLA RQ.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA.

OTHER U.S. FEDERAL REGULATIONS: This product is regulated under FDA regulations.

STATE REGULATIONS: Regulated Medical Waste.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The Diethanolamine component is listed on the California Proposition Lists. WARNING! This product contains a compound known to the State of California to cause cancer.

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDSL STATUS: This product is regulated by the Therapeutic Products Programme (TPP) 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: Requirements under the Canadian Heath Canada, Laboratory Biosafety Guidelines may be applicable.

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

ADDITIONAL EUROPEAN REGULATIONS:

SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT: Formulated, finished medicinal products for human use, are subject to Directive 2001/83/EC and subsequent amendments to the directive.

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

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **WARNING!** MAY BE HARMFUL IF INGESTED, INHALED OR BY SKIN CONTACT. MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. INGESTION MAY CAUSE SKIN SENSITIZATION AND ALLERGIC REACTION DUE TO PRESENCE OF SULFONAMIDE. MAY CAUSE HARM TO FETUS DURING PREGNANCY. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES.

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; give victim up to three glasses of water. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. If inhaled, remove to fresh air. If not breathing, give artificial respiration or oxygen if necessary.

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.

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

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

CLASSIFICATION FOR COMPONENTS:

FULL TEXT GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008:

SULFAMETHOXAZOLE: This is a self-classification.

Classification: Eye Irritation Category 2B, Skin Sensitization Category 1, Respiratory Sensitization Category 1

Hazard Statement Codes: H320: Causes eye irritation. H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

TRIMETHOPRIM: This is a self-classification

Classification: Reproductive Toxicity Category 2, Respiratory Sensitization Category 1

Hazard Statements: H361d: Suspected of damaging the unborn child. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

BENZYL ALCOHOL: The following is a Published Classification.

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

Hazard Statements: H302: Harmful if swallowed. H332: Harmful if inhaled.

DIETHANOLAMINE: The following is a Published Classification.

Classification: Acute Oral Toxicity Category 4, Specific Target Organ Toxicity Repeated Exposure Category 2, Skin Irritation Category 2, Eye Damage Category 1

Hazard Statements: H302: Harmful if swallowed. H373: May cause damage to organs through prolonged or repeated exposure. H315: Causes skin irritation. H318: Causes serious eye damage.

16. OTHER INFORMATION (Continued)

CLASSIFICATION FOR COMPONENTS (continued):

FULL TEXT GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 (continued):

ETHYL ALCOHOL: The following is a Published Classification.
Classification: Flammable Liquid Category 2
Hazard Statements: H225: Highly flammable liquid and vapor.

SODIUM METABISULFITE: The following is a Published Classification.
Classification: Acute Oral Toxicity Category 4, Eye Damage Category 1
Hazard Statements: H302: Harmful if swallowed. H318: Causes serious eye damage.

ALL OTHER COMPONENTS:
An official classification for these substances has not been published in the CLP 1272: 2008 and is not applicable for self-classification.

FULL TEXT EU 67/548/EEC:

SULFAMETHOXAZOLE: This is a self-classification.
Classification: Irritant
Risk Phrases: R36/37/38: Irritating to eyes, respiratory system and skin.

TRIMETHOPRIM: The following is a Self Classification.
Classification: Reproductive Toxicity Category 3, Irritant
Risk Phrases: R63: Possible risk of harm to the unborn child. R37: Irritating to respiratory system.

BENZYL ALCOHOL: The following is a Published Classification.
Classification: Harmful/Irritant
Risk Phrases: R20/22: Harmful by inhalation and if swallowed.

ETHYL ALCOHOL: The following is a Published Classification.
Classification: Highly Flammable
Risk Phrases: R11: Highly Flammable

DIETHANOLAMINE: The following is a Published Classification.
Classification: Harmful/Irritant
Risk Phrases: R22: Harmful if swallowed. R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed. R38: Irritating to skin. R41: Risk of serious damage to eyes.

SODIUM METABISULFITE: The following is a Published Classification.
Classification: Harmful
Risk Phrases: R22: Harmful if swallowed. R41: Risk of serious damage to eyes.

ALL OTHER COMPONENTS:
An official classification for these substances has not been published in Commission Directives 93/72/EEC, 94/69 EC, 96/54/EC or subsequent directives and is not applicable for self-classification.

REFERENCES AND DATA SOURCES: Contact the supplier for information.
METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

PREPARED BY: Teva Pharmaceuticals, Inc., EHS Department (215) 591-3000
DATE OF PRINTING: April 28, 2015
REVISION HISTORY: April 2015: Update shipping regulations, update format and classifications of actives.

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:

EXPOSURE LIMITS IN AIR:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.
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 Quantitation.
MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.
NE: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.
NIC: Notice of Intended Change.
NIOSH CEILING: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.
NIOSH RELs: NIOSH's Recommended Exposure Limits.
PEL-Permissible Exposure Limit: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL that was vacated by Court Order.
SKIN: Used when a there is a danger of cutaneous absorption.
STEL-Short Term Exposure Limit: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.
TLV-Threshold Limit Value: An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.
TWA-Time Weighted Average: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.
HEALTH HAZARD: 0 (Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation*: Essentially non-irritating. PII or Draize = "0". *Eye Irritation*: Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. Draize = "0". *Oral Toxicity LD_{50} Rat*: < 5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: < 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: < 20 mg/L.); **1** (Slight Hazard: Minor reversible Injury may occur; slightly or mildly irritating. *Skin Irritation*: Slightly or mildly irritating. *Eye Irritation*: Slightly or mildly irritating. *Oral Toxicity LD_{50} Rat*: > 500-5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 1000-2000 mg/kg. *Inhalation Toxicity LC_{50}* 4-hrs *Rat*: > 2-20 mg/L); **2** (Moderate Hazard: Temporary or transitory injury may occur. *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize > 0, < 5. *Eye Irritation*: Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. Draize > 0, ≤ 25. *Oral Toxicity LD_{50} Rat*: > 50-500 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 200-1000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.5-2 mg/L.); **3** (Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may destroy dermal tissue, cause skin burns, dermal necrosis. PII or Draize > 5-8 with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD_{50} Rat*: > 1-50 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 20-200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05-0.5 mg/L.); **4** (Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure. *Skin Irritation*: Not appropriate. Do not rate as a "4", based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a "4", based on eye irritation alone. *Oral Toxicity LD_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L).
FLAMMABILITY HAZARD: 0 (Minimal Hazard-Materials that will not burn in air when exposure to a temperature of 815.5°C [1500°F] for a period of 5 minutes.); **1** (Slight Hazard-Materials that must be pre-heated before ignition can occur. Material require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur, Including: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C [200°F] (e.g. OSHA Class IIIB, or; Most ordinary combustible materials [e.g. wood, paper, etc.]; **2** (Moderate Hazard-Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres in air, Including: Liquids having a flash-point at or above 37.8°C [100°F];

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 2 (continued): Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp; Solids and semisolids that readily give off flammable vapors). **3** (Serious Hazard- Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] [e.g. OSHA Class IB and IC]; Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air [e.g., dusts of combustible solids, mists or droplets of flammable liquids]; Materials that burn extremely rapidly, usually by reason of self-contained oxygen [e.g. dry nitrocellulose and many organic peroxides]); **4** (Severe Hazard-Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and which will burn readily, including: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C [73°F] and a boiling point below 37.8°C [100°F] [e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C [130°F] or below [e.g. pyrophoric]).
PHYSICAL HAZARD: 0 (*Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. Unstable *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No "0" rating allowed. *Unstable Reactives*: Substances that will not polymerize, decompose, condense or self-react.); **1** (*Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy. *Explosives*: Division 1.5 and 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 and 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability "4". *Oxidizers*: No "4" rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD_{50} for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. **1** Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **2** Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC_{50} for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators.

DEFINITIONS OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

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

FLAMMABILITY HAZARD: **0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand: Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D. Liquids, solids and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendation on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85 percent by weight. Liquids that have no fire point when tested by ASTM D 92 Standard Test Method for Flash and Fire Points by Cleveland Open Cup, up to a boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent. Most ordinary combustible materials. **2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air: Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures in air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that, on account of their physical form or environmental conditions, can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with a representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily: Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air, Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

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

FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD (continued): **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 **N**ational **F**ire **P**rotection **A**ssociation (**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 and liquids) which kills 50% of the exposed animals; **LC_{50}** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m^3** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include. **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, and **LDo**, or **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information: BEI** - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

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

United States FDA Pharmaceutical Pregnancy Categories: Pregnancy Category A: Adequate and well-controlled human studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters). **Pregnancy Category B:** Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester. **Pregnancy Category C:** Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. **Pregnancy Category D:** There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. **Pregnancy Category X:** Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits. **Pregnancy Category N:** FDA has not classified this drug.

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. **O**ccupational **S**afety and **H**ealth **A**dministration (**OSHA**). **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act **(SARA)**; the Canadian Domestic/Non-Domestic Substances List **(DSL/NDSL)**; the U.S. Toxic Substance Control Act **(TSCA)**; Marine Pollutant status according to the **DOT**; the Comprehensive Environmental Response, Compensation, and Liability Act **(CERCLA or Superfund)**; and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label. **OSHA** - U.S. Occupational Safety and Health Administration.

EUROPEAN and INTERNATIONAL:

The DFG: This is the Federal Republic of Germany's Occupation Health Agency, similar to the U.S. OSHA. **EU** is the European Community (formerly known as the **EEC,** European Economic Community). **EINECS:** This is the European Inventory of Now-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. **AICS** is the Australian Inventory of Chemical Substances.