SAFETY DATA SHEET

SULFAMETHOXAZOLE & TRIMETHOPRIM INJECTION USP

1. Product and Company Information

Product Identifier:	Sulfamethoxazole & Trimethoprim Injection USP
Synonyms:	None
National Drug Code:	70069- 361-10 (5 mL), 70069- 362-10 (10 mL) 70069- 363-01 (30 mL)
Recommended Use:	Pharmaceutical Injection
Company:	Somerset Therapeutics LLC Hollywood, FL 33024
Contact Telephone:	1800-417-9175
E-Mail:	
Emergency Phone Number:	1800-417-9175

2. Hazardous(s) Identification

Physical Hazards:	None
Health Hazards:	None
Symbol(s):	None.
Signal Word:	None.
Hazard Statement(s):	None.
Precautionary Statement(s):	None.
Hazards Not Otherwise Classified:	None
Supplementary Information:	Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System

3. Composition and Information on Ingredients

Chemical Name	CAS Number
Sulfamethoxazole USP	723-46-6
Trimethoprim USP	738-70-5
Benzyl Alcohol NF	100-51-6
Propylene Glycol USP	57-55-6
Alcohol USP (ethanol 96% v/v)	64-17-5
Diethanolamine NF	203-868-0
Sodium Metabisulfite NF	7681-57-4
Sodium hydroxide	1310-73-2
Hydrochloric Acid NF	7647-01-0
Nitrogen NF	7727-37-9
Water for Injection USP	7732-18-5

The exact percentage (concentration) of the composition is being withheld as a trade secret is required.

4. First Aid Measures

Eye Contact Flush eyes with plenty of water. Get medical attention.

Skin Contact: Remove contaminated clothing and flush exposed area with large amount of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.

Inhalation: Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.

Ingestion: If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.

5. Fire-Fighting Measures

Extinguishing Media: Water spray, carbon dioxide, dry chemical powder or ABC type.

Hazardous Combustion Products: Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Fire Fighting Procedures: 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.

Fire / Explosion Hazards: Assume that this product is capable of sustaining combustion.

6. Accidental Release Measures

Health and Safety Precautions: Wear protective clothing, nitrile gloves and equipment consistent with the degree of hazard.

Measures for Cleaning / Collecting: Collect and place it in a suitable, properly labelled container for recovery or disposal.

Measures for Environmental Protections: For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

7. Handling and Storage:

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

Storage: Store the product 20 to 25°C (68 to 77°F).

8. Exposure Controls / Personal Protection

Exposure Limits	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.
Hands:	Use surgical/nitrile gloves.
Eyes:	Use splash goggles or safety goggle as appropriate.
Respiratory protection:	Use nose mask.

9. Physical and Chemical Properties

Appearance:	Pale yellow.
pH:	9.5-10.5
Decomposition Temperature (°C):	No data available.
Evaporation Rate (Gram/s):	No data available
Vapour Pressure (kPa):	No data available
Vapour Density (g/ml):	No data available
Specific Gravity:	1.252 g/Cm^3
Viscosity:	No data available
Flammability:	Not flammable
Flash Point (Liquid) (°C):	Not flammable
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under recommended storage conditions
Incompatible Materials:	Strong acids and bases. Avoid materials that are incompatible with water.
Hazardous Decomposition Products	No data available
Hazardous Polymerization	No data available

11. Toxicological Information

Toxicity Data --- Sulfamethoxazole:
Oral LD50 (rat) =6200 mg/kg IP LD50 (rat) = 2690 mg/kg Sub Q LD50 (rat) >5 g/kg
Oral LD50 (mouse) = 2300 mg/kg IV LD50 (mouse) = 1460 mg/kg Sub Q LD50 (mouse) > 5g/kg
Toxicity Data – Trimethoprim:
Oral LD50 (rat) = 500 mg/kg IP LD50 (rat) = 500 mg/kg Sub Q LD50 (rat) >5 g/kg
Oral LD50 (mouse) = 2764 mg/kg IP LD50 (mouse) = 400 mg/kg Sub Q LD50 (mouse) >5 g/kg IV LD50 (mouse) = 132 mg/kg
Suspected Cancer Agent: Long-term studies in animals to evaluate carcinogenic potential have not been conducted. However, sulfamethoxazole was tested by oral administration in one study in rats. It produced follicular-cell adenomas and carcinomas of the thyroid. It has not been listed as carcinogenic by NTP, IARC or OSHA.
Irritancy of Product: This product is expected to be irritating to contaminated skin, eyes and other tissues.
Sensitization to the Product: Sulfamethoxazole belongs to a class of drugs (sulfonamides) that are considered sensitizers. The combination product has been reported to cause allergic responses when given systemically.
Target Organ(s): Fatalities associate with administration of sulfonamides, although rare, have occurred due to severe reactions, including Steven-Johnson Syndrome, toxic epidermal necrolysis, fulminant heptatic necrosis, acranulocytosis, aplastic anemia and other blood dyscrasias.
Reproductive Toxicity Information: Listed below is information concerning the effects of Trimethoprim and Sulfamethoxazole on human and animal reproductive systems. This material is classified as a Pregnancy Category C: (Risk to Fetus Cannot be Ruled-Out)
Mutagenicity: Bacterial mutagenic studies have not been performed with sulfamethoxazole / trimethoprim in combination. Trimethoprim was demonstrated to be non-mutagenic in the Ames assay. In studies at two laboratories, no chromosomal damage was detected in cultured Chinese hamster ovary cells at concentrations approximately 500 times human plasma levels; at concentrations approximately 1000 times human plasma levels in these same cells, a low level of chromosomal damage was induced at one of the laboratories. No chromosomal abnormalities were observed in cultured human leukocytes at concentrations of trimethoprim up to 20 times human steady-state plasma levels.
No chromosomal effects were detected in peripheral lymphocytes of human subjects receiving 320 mg of trimethoprim in combination with up to 1600 mg of sulfamethoxazole per day for as long as 112 weeks.
Embryo toxicity/Teratogenicity/Reproductive Toxicity: Negative for fertility impairment in rats treated with the combination of 350 mg/kg of sulfamethoxazole and 70 mg/kg of trimethoprim.
In rats, very high oral doses of 533 mg/kg sulfamethoxazole or 200 mg/kg
Trimethoprim produced teratologic effects manifested mainly as cleft palates. The Highest dose which did not cause cleft palates in rats was 512 mg/kg
Sulfamethoxazole or 192 mg/kg trimethoprim when administered separately. In two studies in rats, no teratogenicity was observed when 512 mg/kg of

sulfamethoxazole was used in combination with 128 mg/kg of trimethoprim. In one study, however, cleft palates were observed in one litter out of 9 when 355 mg/kg of sulfamethoxazole was used in combination with 88 mg/kg of trimethoprim. In some rabbit studies, an overall increase in fetal loss (dead and resorbed and malformed conceptuses) was associated with doses of trimethoprim 6 times the human therapeutic dose.

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 v PvB 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.

13. Disposal Conditions

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.
U.S. EPA Waste Number: None

14. Transportation Information

IATA/ICAO - Not Regulated
IATA Proper shipping Name: N/A
IATA UN/ID No: N/A
IATA Hazard Class: N/A
IATA Packaging Group: N/A
IATA Label: N/A
IMDG - Not Regulated
IMDG Proper shipping Name: N/A
IMDG UN/ID No: N/A
IMDG Hazard Class: N/A
IMDG Flash Point: N/A
IMDG Label: N/A
DOT - Not Regulated
DOT Proper shipping Name: N/A
DOT UN/ID No: N/A
DOT Hazard Class: N/A
DOT Flash Point: N/A

DOT Packing Group: N/A
DOT Label: N

15. Regulatory Information

DOT Designations: Non-hazardous
RCRA Hazardous Waste: Not Listed
U.S. REGULATIONS
U.S. SARA Reporting Requirements: The component diethanolamine is subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.
U.S. SARA Threshold Planning Quantity: NA
U.S. CERCLA Reportable Quantities (RQ):
NA
U.S. TSCA Inventory Status: NA
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause cancer or reproductive effects.
Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Blood borne Pathogen Standard (29 CFR 1910.1030) are applicable.

FDA Designations: Prescription only medication.

NDC No. 70069- 361-10 (5 mL),
70069- 362-10 (10 mL)
70069- 363-01 (30 mL)

16. Other Information

NFPA Rating:

Health:	2 (Moderate)
Flammability:	2 (Moderate)
Reactivity:	0

Revision Date: 10/01/2019
Revision Number: 01

Disclaimer: As of the date of issuance, we are providing available information relevant to the handling of this material. All information contained herein is offered with the good faith belief that it is accurate. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.