



Sulfamethoxazole and Trimethoprim Injection

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Sulfamethoxazole and Trimethoprim Injection

Synonyms: Sulfamethoxazole and Trimethoprim Injection, USP; Sulfamethoxazole 80 mg/mL and Trimethoprim 16 mg/mL Injection; Sulfamethoxazole 400 mg/5 mL and Trimethoprim 80 mg/5 mL Injection, Single-Dose Vials; Sulfamethoxazole 2400 mg/30 mL and Trimethoprim 480 mg/30 mL Injection, Multiple-Dose Vial

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: Not for direct injection.

Details of the supplier of the safety data sheet

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Contact e-mail:

SDScontact@viatris.com

Emergency telephone number

Emergency Telephone:

24 hr. Emergency Contact ChemTel

International: +1-813-248-0585

US & Canada: 1-800-255-3924

Mexico: 800-099-0731

2. HAZARDS IDENTIFICATION

Classification

Serious eye damage/eye irritation, Category 2A

Respiratory sensitization, Category 1B

Skin sensitization, Category 1B

Flammable liquids Category 3

Label elements



Signal word:

Danger

Hazard statements:

H226 - Flammable liquid and vapor

H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation

	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
<u>Precautionary Statements - Prevention:</u>	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking Keep container tightly closed Wash face, hands and any exposed skin thoroughly after handling Wear protective gloves/protective clothing/eye protection/face protection Ground/bond container and receiving equipment Use explosion-proof electrical/ ventilating/ lighting/ equipment Use only non-sparking tools Take precautionary measures against static discharge Avoid breathing dust/fume/gas/mist/vapors/spray In case of inadequate ventilation wear respiratory protection Contaminated work clothing should not be allowed out of the workplace
<u>Precautionary Statements - Response:</u>	Specific treatment (see supplemental first aid instructions on this label)
<u>Eyes:</u>	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention
<u>Skin:</u>	If skin irritation or rash occurs: Get medical advice/attention Wash contaminated clothing before reuse IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
<u>Inhalation:</u>	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
<u>Fire:</u>	In case of fire: Use CO ₂ , dry chemical, or foam for extinction
<u>Precautionary Statements - Storage:</u>	Store in a well-ventilated place. Keep cool
<u>Precautionary Statements - Disposal:</u>	Dispose of contents/container to an approved waste disposal plant
<u>Other Hazards</u>	No information available.
<u>Contains:</u>	Benzyl Alcohol
<u>Unknown acute toxicity</u>	No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Chemical name	CAS No	Weight-%	Hazard statements
Ethanol	64-17-5	5 - 15%	H225 - Highly flammable liquid and vapor H319 - Causes serious eye irritation
Sulfamethoxazole	723-46-6	8%	H317 - May cause an allergic skin reaction H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Trimethoprim	738-70-5	1.6%	H302 - Harmful if swallowed
Benzyl Alcohol	100-51-6	0.5 - 2%	H302 - Harmful if swallowed H319 - Causes serious eye irritation H332 - Harmful if inhaled H401 - Toxic to aquatic life

4. FIRST AID MEASURES

Description of first aid measures

General advice: Show this safety data sheet to the doctor in attendance.

Inhalation: May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Get immediate medical advice/attention.

Skin contact: Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion: May produce an allergic reaction. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

Self-protection of the first aider: Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Most important symptoms and effects, both acute and delayed

Symptoms: Burning sensation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing, Itching, Rashes, Hives, Gastrointestinal discomfort, and Steven-Johnson syndrome.

Indication of any immediate medical attention and special treatment needed

May cause sensitization in susceptible persons. Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO₂). Water spray. Alcohol resistant foam.

Unsuitable extinguishing media: CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

Fire hazard: Flammable liquid.

Explosive hazard: Not an explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Hazardous combustion products: Carbon oxides. Oxides of sulfur. Nitrogen oxides.

Advice for firefighters

Precautionary measures in case of fire: Standard procedure for chemical fires.

Firefighting instructions: Use water spray or fog; do not use straight streams.

Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Other Information: Refer to Section 9 for flammability properties.

Sensitivity to Static Discharge Yes

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions: Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information.

Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Other Information: Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Should not be released into the environment. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment: Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

Methods for cleaning up: Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Pick up and transfer to properly labeled containers. Avoid breathing dust or spray mist.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Advice on safe handling: Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use with local exhaust ventilation. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Provide extract ventilation to points where emissions occur. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers. Do not store near combustible materials. Store in accordance with the particular national regulations. Store in accordance with local regulations. Keep out of the reach of children. Store locked up.

Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves.

Eye/face protection: If splashes are likely to occur: Wear safety glasses with side shields (or goggles).

Skin and body protection: Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.

Respiratory protection: Avoid breathing dust or spray mist. If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn.

General hygiene considerations: Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	solution
Color:	Clear, colorless to yellow solution
Odor:	No data available
Odor threshold:	No data available
pH:	9.5 - 10.5
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	= 46 °C
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
<u>Other Information</u>	
VOC Content (%):	No data available

10. STABILITY AND REACTIVITY**Reactivity**

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Heat, flames and sparks. Extremes of temperature and direct sunlight.

Incompatible materials

Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION**Information on toxicological effects****Information on likely routes of exposure**

Inhalation: May cause irritation of respiratory tract. May cause sensitization in susceptible persons.

Ingestion: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May produce an allergic reaction.

Eye contact: May cause redness, itching, and pain.

Skin contact: Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. May cause sensitization by skin contact. May cause irritation. Prolonged contact may cause redness and irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Burning sensation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing, Itching, Rashes, Hives, Gastrointestinal discomfort, and Steven-Johnson syndrome.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: May cause skin irritation.

Serious eye damage/eye irritation: May cause eye irritation.

Respiratory or skin sensitization: May cause sensitization by inhalation and skin contact.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity

Acute toxicity: No information available

12. ECOLOGICAL INFORMATION**Ecotoxicity**

No information available.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging: Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

DOT

UN/ID no UN 1170
Proper shipping name Ethanol solution
Hazard Class 3
Packing Group III



Special Provisions DOT - 24; DOT - B1; DOT - IB3; DOT - T2; DOT - TP1
TDG Not regulated
IATA

UN/ID no UN 1170
Proper shipping name Ethanol solution
Hazard Class 3
Packing Group III



Special Provisions IATA - A3; IATA - A58; IATA - A180
 [IATA - A58]: An aqueous solution containing 24% or less alcohol by volume is not subject to these Regulations.

IMDG
UN/ID no UN 1170
Proper shipping name ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Hazard Class 3
Packing Group III



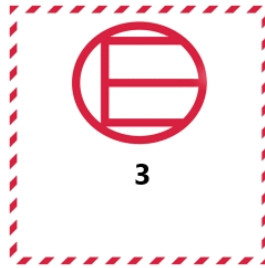


Special Provisions IMDG - 144; IMDG - 223
 [IMDG - 144]: An aqueous solution containing not more than 24% alcohol by volume is not subject to the provisions of this Code.
Marine pollutant No

	DOT	TDG	IATA	IMDG
Limited Quantity	60 L	N/A	10 L	5 L

**Limited quantities provide the maximum quantity per inner packaging or article for carrying dangerous goods as limited quantities in accordance with the regulations.

	DOT	TDG	IATA	IMDG
Excepted Quantity - Inner Packaging #	30 mL	N/A	30 mL	30 mL
Excepted Quantity - Outer				

Packaging #	1000 mL	N/A	1000 mL	1000 mL
				

Dangerous goods regulations may not be applicable to a shipment that satisfies the quantity limits and other excepted quantity regulations.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Right-to-Know Regulations

US State Regulations:

Chemical name	New Jersey	Massachusetts	Pennsylvania
Propylene Glycol 57-55-6	X	-	X
Ethanol 64-17-5	X	X	X
Diethanolamine 111-42-2	X	X	X
Sodium metabisulfite 7681-57-4	X	X	X

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION

Revision Date: 21-June-2023

Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:

Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:

Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology
Phone number: +1 304-559-2595

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.

Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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