



# SDS: Trimethoprim Sulfate and Polymyxin B Sulfate Ophthalmic Solution

## SAFETY DATA SHEET

### 1. Identification

**Product Identifier:** Trimethoprim Sulfate and Polymyxin B Sulfate  
Ophthalmic Solution

**Synonyms:** 2,4-Pyrimidinediamine, 5-[(3,4,5-trimethoxyphenyl)methyl]-; Polymyxin B, sulfate

**National Drug Code (NDC):** 17478-703-11

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. Hazard(s) Identification

**Physical Hazards:** Not classifiable.  
**Health Hazards:** Not classifiable.  
**Symbol(s):** None.  
**Signal Word:** None.  
**Hazard Statement(s):** None.  
**Precautionary Statement(s):** None.  
**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Trimethoprim	738-70-5	2,4-Pyrimidinediamine, 5-[(3,4,5-trimethoxyphenyl)methyl]-	$C_{14}H_{18}N_4O_3$	290.32	0.1%
Polymyxin B Sulfate	1405-20-5	Polymyxin B, sulfate	$C_{43}H_{82}N_{16}O_{12} \cdot xH_2O_4S$	1701.97	10,000 units

\*The formula also contains Benzalkonium Chloride, 0.04 mg (0.004%) as a preservative. Sodium Chloride, Sulfuric Acid and Sodium Hydroxide may be added to adjust pH between 3.0 – 5.5 and Purified Water.

4. **First Aid Measures**

**Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:** Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Inhalation:** Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Protection of First-Aiders:** Use personal protective equipment (see section 8).

**Signs and Symptoms:** Not determined.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to antibiotics or any of the components of the product.

Impairment of fertility: Polymyxin B Sulfate has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown. No adverse effects on fertility or general reproductive performance were observed in rats given trimethoprim in oral doses as high as 70 mg/kg/day for males and 14mg/kg/day for females.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with Polymyxin B Sulfate. It is not known whether polymyxin B sulfate can cause fetal harm when

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administered to a pregnant woman or can affect reproductive capacity. Teratogenic tests of trimethoprim in rats show 40 times the human dose can cause birth defects. Fetal loss (dead and resorbed and malformed fetuses) were shown in rabbits given six times the human dose. Trimethoprim may inhibit folic acid metabolism and should only be used during pregnancy if the potential benefit outweighs the risk to the fetus.

**Notes to Physician:** None.

### 5. Firefighting Measures

**Suitable Extinguishing Media:** Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

**Unsuitable Extinguishing Media:** Not determined.

#### Specific Hazards Arising from the Chemical:

**Hazardous Combustion Products:** Emits sulfur oxides, nitrogen oxides, and toxic fumes.

**Other Specific Hazards:** Not determined.

**Special Protective Equipment/  
Precautions for Firefighters:** Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material. Wear self-contained breathing apparatus and full and protective gear.

### 6. Accidental Release Measures

**Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste.

**Environmental Precautions:** Product administered to patients presents a negligible impact on the environment.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

**Precautions for Safe Handling:** Avoid contact with product and use caution to prevent puncturing containers. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.



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**Conditions for Safe Storage,  
Including Any Incompatibilities:**

Store according to label and/or product insert information.

**Specific End Use:**

Pharmaceuticals.

### 8. Exposure Controls/Personal Protection

**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Trimethoprim	Not established.
Polymyxin B Sulfate	Not established.
Sulfuric Acid	TLV: 1 mg/m <sup>3</sup> PEL: 1 mg/m <sup>3</sup>

**Engineering Controls:**

In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Safety Data Sheets.

**Respiratory Protection:**

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134). WARNING: Do not use air purifying respirators in oxygen depleted environments.

**Eyes Protection:**

Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand Protection:**

Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:**

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

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**Contaminated Equipment:** Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

### 9. Physical and Chemical Properties

**Physical State/Color:** Clear, colorless solution.  
**Odor:** No data available.  
**Odor Threshold:** No data available.  
**pH:** 3.0 – 5.5.  
**Melting Point:** No data available.  
**Freezing Point:** No data available.  
**Boiling Point:** No data available.  
**Flash Point:** No data available.  
**Evaporation Rate:** No data available.  
**Flammability (solid, gas):** No data available.  
**Flammability Limit - Lower:** No data available.  
**Flammability Limit - Upper:** No data available.  
**Vapor Pressure:** No data available.  
**Vapor Density:** No data available.  
**Relative Density:** No data available.  
**Solubility(ies):** Miscible in water.  
**Partition Coefficient (n-octanol/water):** No data available.  
**Auto-Ignition Temperature:** No data available.  
**Decomposition Temperature:** No data available.  
**Viscosity:** ~Aqueous.  
**Specific Gravity:** 1.007 g/mL

### 10. Stability and Reactivity

**Reactivity:** No data available.

**Chemical Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** No data available.

**Conditions to Avoid (e.g., static discharge, shock, or vibration):** Extreme heat or cold; Protect from light.

**Incompatible Materials:** Strong oxidizers and flame.

**Hazardous Decomposition Products:** Emits sulfur oxides, nitrogen oxides, toxic fumes.

**Hazardous Polymerization:** Should not occur.

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### 11. Toxicological Information

#### Information on the Likely Routes of Exposure:

- Inhalation:** May cause irritation and hypersensitivity in some individuals.
- Ingestion:** May cause irritation and hypersensitivity in some individuals. Ingestion of very large quantities can induce gastric disturbances including nausea, vomiting, headaches, and dizziness.
- Skin Contact:** May cause hypersensitivity in some individuals. Possible hypersensitivity responses include rash, pruritus (itching) and exfoliative dermatitis. Although sensitivity reactions are rare, an isolated incident of photosensitivity was reported in a patient who received the drug orally.
- Eye Contact:** When used topically Polymyxin B Sulfate is rarely irritating and absorption from intact skin or mucous membranes is insignificant. Exposure can also cause local irritation upon installation and hypersensitivity (anaphylaxis) in some individuals. The most frequent adverse reactions are localized irritation consisting of transient burning or stinging or increased redness on installation. Trimethoprim Sulfate and Polymyxin B Sulfate Ophthalmic Solution has a low incidence of hypersensitivity (less than 2 of 100 patients) consisting of lid edema, itching, increased redness of the eye (conjunctival erythema), tearing (lacrimation) and/or a rash around the eye (circumocular rash). Although sensitivity reactions are rare, an isolated incident of photosensitivity was reported in a patient who received the drug orally.

#### **Symptoms Related to the Physical, Chemical and Toxicological Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

#### **Delayed and Immediate Effects of Exposure:**

No data available.

#### **Acute Toxicity:**

Compound	Species	Route	Type	Dose
Polymyxin B Sulfate	Mouse	Oral	LD <sub>50</sub>	790 mg/kg
Polymyxin B Sulfate	Mouse	Intraperitoneal	LD <sub>50</sub>	20.5 mg/kg
Polymyxin B Sulfate	Mouse	Intravenous	LD <sub>50</sub>	5.4 mg/kg
Polymyxin B Sulfate	Mouse	Subcutaneous	LD <sub>50</sub>	59.5 mg/kg
Trimethoprim Sulfate	Mouse	Oral	LD <sub>50</sub>	3,960 mg/kg
Trimethoprim Sulfate	Rat	Oral	LD <sub>50</sub>	200 mg/kg
Trimethoprim Sulfate	Mouse	Intraperitoneal	LD <sub>50</sub>	3,500 mg/kg
Trimethoprim Sulfate	Rat	Intraperitoneal	LD <sub>50</sub>	1,460 mg/kg

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<b>Polymyxin B Sulfate:</b>	May cause irritation to skin, mucous membranes and respiratory tract. Prolonged and repeated contact can produce hypersensitivity in some individuals. Overexposure may produce dizziness, diminished muscular coordination, kidney damage (nephrotoxicity), and sensory disturbances. This material is not readily absorbed into the gut and does not present a toxicological hazard.
<b>Trimethoprim Sulfate:</b>	May cause irritation to the mucous membranes of the eyes, skin, digestive and respiratory tract. Overexposure symptoms due to ingestion of more than one gram include nausea, vomiting, headaches, confusion, mental depression, dizziness, and bone marrow depression. Possible hypersensitivity responses include rash, pruritus (itching), exfoliative dermatitis. Teratogenic tests in rats show 40 times the human dose can cause birth defects. Fetal loss (dead and resorbed and malformed fetuses) were shown in rabbits given six times the human dose. Trimethoprim may inhibit folic acid metabolism and should only be used during pregnancy if the potential benefit outweighs the risk to the fetus.
<b>Acute Toxicity – Dermal:</b>	No data available.
<b>Acute Toxicity – Inhalation:</b>	No data available.
<b>Corrosivity:</b>	No data available.
<b>Dermal Irritation:</b>	No data available.
<b>Eye Irritation:</b>	No data available.
<b>Sensitization:</b>	No data available.
<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	Eyes, skin and digestive tract.
<b>Reproductive Effects:</b>	No data available.
<b>Carcinogenicity:</b>	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	No data available.
<b>Chronic Effects:</b>	May cause irritation and hypersensitivity. As with other antibiotic preparations, prolonged use may result in the overgrowth on non-susceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

12. **Ecological Information**

**Ecotoxicity**

<b>Aquatic:</b>	No data available.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

13. **Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

14. **Transport Information**

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.
<b>Department of Transportation:</b>	Not regulated as a hazardous material.
<b>International Air Transport Association (IATA):</b>	Not regulated as a dangerous good.
<b>International Maritime Dangerous Good (IMDG):</b>	Not regulated as a dangerous good.

15. **Regulatory Information**

**US Federal Regulations:**

<b>Toxic Substance Control Act (TSCA):</b>	Not listed.
<b>CERCLA Hazardous Substance and Reportable Quantity:</b>	Not listed.
<b>SARA 313:</b>	Not listed.
<b>SARA 302:</b>	Not listed.

**State Regulations**

<b>California Proposition 65:</b>	Not listed.
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16. **Other Information**

Not made with natural rubber latex.





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