

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078828933

N/A

# MSDS Not Required

Date: May 4, 2007

An MSDS is not required for the attached product(s), according to the OSHA Hazard Communication Standard (Right-to-Know). Products such as drugs, cosmetics, food, or alcoholic beverages, wood or wood products, and tobacco or tobacco products as defined in 29 CFR 1910.1200(b)(6), are exempt from the Hazard Communication Standard. Items that are considered articles as defined in 29 CFR 1910.1200(c) are also exempt from this standard.

In addition, the requested product(s) are not regulated as hazardous material for shipping in accordance with the U.S. Department of Transportation, and have no hazardous storage limitations as defined by the National Fire Protection Association.

SMZ/TMP ORAL SUSPENSION 240MG 16OZ CHERRY  
AMITRIPTYLINE TABS 100MG 100CT  
AMITRIPTYLINE TABS 25MG 100CT  
AMITRIPTYLINE TABS 50MG 1000CT  
PHENOBARBITAL TABS 1/4GR 15MG 1000 CT CIV  
PHENOBARBITAL TABS 30MG 1/2GR 1000CT CIV  
PHENOBARBITAL TABS 60MG 1000CT 1GR CIV  
PHENOBARBITAL TABS 1 .5GR 1000CT CIV  
PHENOBARBITAL TABS 1GR 100CT CIV  
PHENOBARBITAL ELIXER 20MG 5ML. 16OZ CIV  
FUROSEMIDE TABLETS 40MG 1000CT  
FUROSEMIDE TABS 40MG 100CT  
AMITRIPTYLINE TABS 10MG 1000CT  
AMITRIPTYLINE TABS 25MG 1000CT  
AMITRIPTYLINE TABS 76MG 100CT  
AMITRIPTYLINE TABS 50MG 100CT  
MICONAZOLE NITRATE CREAM 2% 30GM  
METHOCARBAMOL TABS 750MG 500CT ADR QUALITEST  
METOCLOPRAMIDE TABS 10MG 500CT ADR QUALITEST  
METOCLOPRAMIDE TABS 5MG 100CT ADR QUALITEST  
METOCLOPRAMIDE HCL SYRUP 5MG/ML 16OZ ADR QUA .  
SMZ/TMP TABLETS 960mg 100's  
SMZ/TMP TABLETS 980mg 500's  
SMZ/TMP ORAL SUSPENSION 240MG 16 OZ GRAPE  
SMZ/TMP TABLETS 480MG 100CT (ADR MUTUAL)  
SMZ/TMP TABLETS 480MG 500 CT (ADR MUTUAL)

**MSDS - Material Safety Data Sheet****Product Name: Sulfamethoxazole /Trimethoprim Oral Suspension. (Cherry)**

MSDS No.: 823

**I. Basic Information:**

Manufacturer: Hi-Tech Pharmacal Co., Inc

Address: 369 Bayview Avenue

City, ST Zip: Amityville, NY 11701

Emergency Contact:

Emergency Telephone Number: 631-789-8228

Contact: Jesse Kirsh, VP of Quality

Information Telephone Number: 631-789-8228

Last Update: 07/21/2010

Chemical State:  Liquid  Gas  SolidChemical Type:  Pure  Mixture

0	Health
2	Flammability
0	Reactivity
B	Pers. Protection

**II. Ingredients:** Trade Secret (N/D = Not Disclosed)

CAS No.	Chemical Name	% Range	EHS		IARC		SARA		OSHA PEL	ACGIH TLV	Other Limits
			NTP		SUB Z	313					
64-17-5	Alcohol	0.26%									
723-46-6	Sulfamethoxazole	200.0mg/5ml									
738-70-5	Trimethoprim	40.0mg/5ml									

**III. Hazardous Identification:**

Hazard Category:

 Acute  Chronic  Fire  Pressure  Reactive

Hazardous Identification Information:

None

**IV. First Aid Measures:**

Route(s) of Entry:

Ingestion, Inhalation and skin contact

Health Hazards (Acute and Chronic):

Material is a liquid drug dosage form intended for human use. Solution is not considered hazardous under normal conditions. If desired see package insert for detailed information.

Signs and Symptoms:

Solution is intended for human consumption under guidance of a physician.

Medical Conditions Generally Aggravated by Exposure:

None

Emergency and First Aid Procedures:

## MSDS - Material Safety Data Sheet

**Product Name: Sulfamethoxazole /Trimethoprim Oral Suspension. (Cherry)**

**MSDS No.: 823**

**Eye:** Hold eyelids open and flush with steady stream of water for 15 minutes. See an eye doctor or physician immediately.

**Skin:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of the skin with plenty of soap and water. If irritation develops get medical attention.

**Inhalation:** Move individual to fresh air. Get medical attention if breathing difficulty occurs.

**Ingestion:** Call a physician or poison control center if over dosing has occurred.

**Other Health Warnings:**

None

### V. Fire Fighting Measures:

**Flash Point:** >140 F

**Lower Explosive Limit:** N/A

**Upper Explosive Limit:** N/A

**F.P. Method:** Tag closed

**Fire Extinguishing Media:** Use water, carbon dioxide, dry chemical or foam as necessary.

**Special Fire Fighting Procedures:**

With small quantities use carbon dioxide extinguisher.

For large fires use ample quantities of water with dry chemicals or foam as necessary.

**Unusual Fire and Explosion:**

None, however, observe usual precautions for handling of flammable liquid.

### VI. Accidental Release Measures:

**Steps to be Taken in Case Material is Released or Spilled:**

No special precautions. Pick up in the most efficient manner.  
Soak up with sawdust, sand, oil dry or other absorbent material.

### VII. Handling and Storage:

**Precautions to be Taken:**

Keep container tightly closed.  
Store between 59- 86 F

**Other Precautions:**

### VIII. Exposure Controls/Personal Protection:

**Ventilation Requirements:**

Under normal use and handling no protective equipment is required.

**Personal Protective Equipment:**

Under normal use and handling no protective equipment is required.

Protective Gloves: Recommended

Eye Protection: Splash proof safety Glasses

**MSDS - Material Safety Data Sheet****Product Name: Sulfamethoxazole /Trimethoprim Oral Suspension. (Cherry)**

MSDS No.: 823

**IX. Physical and Chemical Properties:**

Boiling Point: N/A

Melting Point: N/A

Evaporation Rate (Butyl Acetate = 1): Same as water

Vapor Pressure (mm Hg.): N/A

Specific Gravity (H2O = 1): 1.21180

Vapor Density (AIR = 1): &gt;1

Solubility In Water: Soluble

Appearance and Odor: Pink suspension with cherry odor and flavor

Other Information: Use only as directed

**X. Stability and Reactivity:****Stability:**

Stable at normal temperature conditions.  
Avoid sources of ignition

**Incompatibility (Materials to Avoid):**

Strong oxidizer

**Decomposition/By Products:**

Does not undergo explosive decomposition

**Hazardous Polymerization:**

Will not occur

**XI. Toxicological Information:**

If desired see package insert for information

**XII. Ecological Information:**

None

**XIII. Disposal Considerations:**

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State / Provincial and Local Regulations.

**XIV. Transport Information:**

The known properties of this material do not constitute a hazard as defined by the U.S. Department of Transportation.

**XV. Regulatory Information:**

N/A

**XVI. Other Information:**

***MSDS - Material Safety Data Sheet******Product Name: Sulfamethoxazole /Trimethoprim Oral Suspension. (Cherry)******MSDS No.: 823***

To the best of our knowledge the information contained herein is accurate as of the date hereof. Any determination as to the suitability of the product for any particular purpose, its safe use or disposal, shall be the responsibility of the user. The information contained herein is in no way intended to supplement, modify, or supercede the information provided in the package insert with respect to the product for medical purposes. Please refer to the product insert or label for information regarding the use of the product for medical purposes. We reserve the right to revise the Material Safety Data Sheets periodically as new information becomes available.

**SDS: Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP**

**SAFETY DATA SHEET**

**1. Identification**

**Product Identifier:** Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP

**Synonyms:** 5-Methyl-3-sulfanilamidoisoxazole; 2,4-  
Pyrimidinediamine, 5-[(3,4,5-trimethoxyphenyl)methyl]-

**National Drug Code (NDC):** 50383-823-16 (Cherry Flavor)  
50383-824-16 (Grape Flavor)  
50383-824-20  
50383-824-21

**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:** Combustible liquid Category 4

**Health Hazards:** Acute Oral Toxicity Category 4

Reproductive Toxicity Category 2



**Symbol(s):** 

**Signal Word:** Warning.

**Hazard Statement(s):** H227 Combustible liquid.  
H302 Harmful if swallowed.  
H361d Suspected of damaging the unborn child.

**Precautionary Statement(s):** P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P210 Keep away from flames and hot surfaces. No smoking.



**SDS: Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP**

- P264 Wash hands thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P281 Use personal protective equipment as required.
- P301 + P312 IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
- P308 + P313 IF exposed or concerned: Get medical attention/advice.
- P330 Rinse mouth.
- P370 + P378 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary to extinguish.
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with all local and national regulations.

**Hazards Not Otherwise Classified:** None.  
**Supplementary Information:** None.

**3. Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Benzenesulfonamide, 4-amino-N-(5-methyl-3-isoxazolyl)-	723-46-6	Sulfamethoxazole; 5-Methyl-3-sulfanilamidoisoxazole	C <sub>10</sub> H <sub>11</sub> N <sub>3</sub> O <sub>3</sub> S	253.28	4%
2,4-Pyrimidinediamine, 5-[(3,4,5-trimethoxyphenyl)methyl]-	738-70-5	Trimethoprim	C <sub>14</sub> H <sub>18</sub> N <sub>4</sub> O <sub>3</sub>	290.32	0.8%

\*The formula also contains Alcohol, 0.26%; Methylparaben 0.1% and Sodium Benzoate, 0.1% (added as preservatives); Carboxymethylcellulose Sodium, Citrix Acid (anhydrous), Glycerin, Microcrystalline Cellulose, Polysorbate 80, Purified Water, Saccharin Sodium, and Sorbitol.

The light purple, grape flavored suspension contains the following additional inactive ingredients: FD&C Red No. 40, FD&C Blue No. 1 and Natural and Artificial Grape Flavor.

The pink, cherry flavored suspension contains the following additional inactive ingredients: FD&C Red No. 40, FD&C Yellow No. 6 and Artificial Cherry Flavor.



## SDS: Sulfamethoxazole and Trimethoprim Oral Suspension, USP

### 4. First Aid Measures

<b>Ingestion:</b>	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.
<b>Eye Contact:</b>	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.
<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	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.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 – Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	May include akin, blood and liver disorders.
<b>Other Health Warnings:</b>	Sulfamethoxazole and Trimethoprim should be discontinued at the first appearance of skin rash or any sign of adverse reaction.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.



## SDS: Sulfamethoxazole and Trimethoprim Oral Suspension, USP

### 5. Firefighting Measures

**Suitable Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**Unsuitable Extinguishing Media:** With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

#### Specific Hazards Arising from the Chemical:

**Hazardous Combustion Products:** Emits fumes of carbon dioxide sulfur oxides nitrogen oxides.

**Other Specific Hazards:** Not determined.

**Special Protective Equipment/  
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

### 6. Accidental Release Measures

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

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

**Methods for Cleaning Up:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for  
Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**Environmental Precautions:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

### 7. Handling and Storage

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,  
Including Any Incompatibilities:** Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.



## SDS: Sulfamethoxazole and Trimethoprim Oral Suspension, USP

Specific End Use: Pharmaceuticals.

### 8. Exposure Controls/Personal Protection

#### Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Trimethoprim	Pfizer OEL: 100 µg/m <sup>3</sup> , 8 Hour TWA
Sulfamethoxazole	Pfizer OEB: 1,000 µg/m <sup>3</sup> to 3,000 µg/m <sup>3</sup>

#### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

#### 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).

#### Eyes Protection:

Not required for the normal use of this product. 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 are recommended. 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:

Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

**Physical State/Color:**

Pink suspension; Light purple suspension.

**Odor:**

Grape odor; Cherry odor.

**Odor Threshold:**

No data available.

**pH:**

No data available.

**Melting Point:**

No data available.

**Freezing Point:**

No data available.

**Boiling Point:**

No data available.

**Flash Point:**

>140°F.



## SDS: Sulfamethoxazole and Trimethoprim Oral Suspension, USP

<b>Evaporation Rate:</b>	Same as water.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	>1.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.
<b>Specific Gravity:</b>	1.21180.

### 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Heat and contact with incompatible materials.
<b>Incompatible Materials:</b>	Keep away from acids, caustics and avoid extreme pH conditions.
<b>Hazardous Decomposition Products:</b>	No data available.
<b>Hazardous Polymerization:</b>	Will not occur.

### 11. Toxicological Information

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

<b>Inhalation:</b>	May be harmful if inhaled. May cause respiratory tract irritation.
<b>Ingestion:</b>	May be harmful if swallowed.
<b>Skin Contact:</b>	May be harmful if absorbed through the skin. May cause irritation.
<b>Eye Contact:</b>	May cause eye irritation.
<b>Symptoms Related to the Physical, Chemical and Toxicological Characteristics:</b>	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
<b>Delayed and Immediate Effects of Exposure:</b>	No data available.



## SDS: Sulfamethoxazole and Trimethoprim Oral Suspension, USP

### Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Sodium benzoate	Rat	Oral	LD <sub>50</sub>	4,070 mg/kg
Sodium benzoate	Mouse	Oral	LD <sub>50</sub>	1,600 mg/kg
Trimethoprim	Rat	Intravenous	LD <sub>50</sub>	200 mg/kg
Trimethoprim	Rat	Sub-tenon injection (eye)	LD <sub>50</sub>	500 mg/kg
Trimethoprim	Mouse	Oral	LD <sub>50</sub>	2,764 mg/kg
Trimethoprim	Mouse	Intravenous	LD <sub>50</sub>	200 mg/kg
Trimethoprim	Mouse	Intraperitoneal	LD <sub>50</sub>	1,870 mg/kg
Sulfamethoxazole	Rat	Oral	LD <sub>50</sub>	6,370 mg/kg
Sulfamethoxazole	Mouse	Oral	LD <sub>50</sub>	2,650 mg/kg
Sulfamethoxazole	Rat	Intraperitoneal	LD <sub>50</sub>	2,690 mg/kg
Sulfamethoxazole	Mouse	Intraperitoneal	LD <sub>50</sub>	2,300 mg/kg

### Repeated Does Toxicity:

Compound	Species	Route	Type	Dose	Duration	Target Organ
Sodium Benzoate	Rat	Oral	LOAEL	27,370 mg/kg	10 Days	Liver, Blood
Sodium Benzoate	Mouse	Oral	LOAEL	45 g/kg	10 Days	Liver, Kidney, Blood, Ureter, Bladder

### Reproduction & Development Toxicity:

Compound	Study Type	Species	Route	Type	Dose	Effect(s)
Sodium Benzoate	Embryo/Fetal Development	Rat	Oral	LOEL	44 g/kg	Developmental toxicity
Trimethoprim	Reproductive & Fertility - Males	Rat	Oral	NOAEL	70 mg/kg/day	Fertility
Trimethoprim	Reproductive & Fertility - Females	Rat	Oral	NOAEL	14 mg/kg/day	Fertility
Trimethoprim	Embryo/Fetal Development	Rabbit	Oral	LOAEL	30 mg/kg	Embryotoxicity
Trimethoprim	Embryo/Fetal Development	Rat	Oral	LOAEL	200 mg/kg	Maternal toxicity, Teratogenic
Trimethoprim	Embryo/Fetal Development	Mouse	Oral	NOAEL	70 mg/kg	Not Teratogenic
Sulfamethoxazole	Embryo/Fetal Development	Rat	Oral	NOEL	512 mg/kg/day	Teratogenic
Sulfamethoxazole	Reproductive & Fertility	Rat	Oral	NOAEL	350 mg/kg/day	No effects at maximum dose



**SDS: Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP**

**Genetic Toxicity:**

Compound	Study Type	Cell Type/Organism	Results
Trimethoprim	Bacterial Mutagenicity (Ames)	<i>Salmonella, E. coli</i>	Negative
Trimethoprim	<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary cells	Negative
Trimethoprim	<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
Sulfamethoxazole	Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Sulfamethoxazole	<i>In Vivo</i> Chromosome Aberration	Human Lymphocytes	Negative
Sulfamethoxazole	<i>In Vivo</i> Chromosome Aberration	Human Lymphocytes	Negative

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** This product is expected to be irritating to contaminated skin.

**Eye Irritation:** This product is expected to be irritating to contaminated eyes.

**Sensitization:** Sulfamethoxazole belongs to a class of drugs (sulfonamides) that are considered sanitizers. The combination product has been reported to cause allergic responses when given systematically.

**Toxicokinetics/Metabolism:** No data available.

**Target Organ Effects:** Fatalities associated with administration of sulfonamides, although rare, have occurred due to severe reactions, including Stevens-Johnson Syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, acranulocytosis aplastic anemia and other blood dyscrasias.

**Reproductive Effects:** No data available.

**Carcinogenicity:**

Compound	Species	Route	Type	Dose	Duration	Target Organ
Sulfamethoxazole	Rat	Oral	LOEL	60	60 Weeks	Tumors, Thyroid

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.

**Mutagenicity:** No data available.

**Aspiration Hazard:** No data available.

**SDS: Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP**

**12. Ecological Information**

**Ecotoxicity**

**Aquatic:**

Compound	Species	Method	Test Type	Dose
Trimethoprim	Daphnia magna	OECD	LC <sub>50</sub>	141 mg/l (48 hours)
Sulfamethoxazole	Daphnia magna	N/A	EC <sub>50</sub>	75 mg/l (48 hours)
Sulfamethoxazole	Oncorhynchus mykiss	N/A	EC <sub>50</sub>	>1,000 mg/l

**Terrestrial:** No data available.  
**Persistence and Degradability:** No data available.  
**Bioaccumulative Potential:** No data available.  
**Mobility in Soil:** No data available.  
**Mobility in Environment:** No data available.  
**Other Adverse Effects:** No data available.

**13. Disposal Considerations**

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

**14. Transport Information**

**UN Number:** UN3077 (Sulfamethoxazole)  
**UN Proper Shipping Name:** Environmentally hazardous substance, solid, n.o.s. (Sulfamethoxazole)  
**Transport Hazard Class(es):** 9.  
**Packing Group:** III.  
**Department of Transportation:** Regulated as a hazardous material. (Sulfamethoxazole)  
**International Air Transport Association (IATA):** Regulated as a dangerous good. (Sulfamethoxazole)  
**International Maritime Dangerous Good (IMDG):** Regulated as a dangerous good. (Sulfamethoxazole)

**15. Regulatory Information**

**US Federal Regulations:**

**Toxic Substance Control Act (TSCA):** Listed. (Sulfamethoxazole)  
**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.  
**SARA 313:** Not listed.  
**SARA 302:** Not listed.



## SDS: Sulfamethoxazole and Trimethoprim Oral Suspension, USP

### State Regulations

<b>Massachusetts:</b>	Not listed.
<b>New Jersey:</b>	Not listed.
<b>Pennsylvania:</b>	Not listed.
<b>California Proposition 65:</b>	Not listed.

### 16. Other Information

**Revision Date:** 10/05/2015

**Revision Number:** 3

**Disclaimer:** This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.

**SDS: Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP**

**SAFETY DATA SHEET**

**1. Identification**

**Product Identifier:** Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP

**Synonyms:** 5-Methyl-3-sulfanilamidoisoxazole; 2,4-  
Pyrimidinediamine, 5-[(3,4,5-trimethoxyphenyl)methyl]-

**National Drug Code (NDC):** 50383-823-16 (Cherry Flavor)  
50383-824-16 (Grape Flavor)  
50383-824-20  
50383-824-21

**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:** Combustible liquid Category 4

**Health Hazards:** Acute Oral Toxicity Category 4

Reproductive Toxicity Category 2



**Symbol(s):** 

**Signal Word:** Warning.

**Hazard Statement(s):** H227 Combustible liquid.  
H302 Harmful if swallowed.  
H361d Suspected of damaging the unborn child.

**Precautionary Statement(s):** P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P210 Keep away from flames and hot surfaces. No smoking.



**SDS: Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP**

- P264 Wash hands thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P281 Use personal protective equipment as required.
- P301 + P312 IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
- P308 + P313 IF exposed or concerned: Get medical attention/advice.
- P330 Rinse mouth.
- P370 + P378 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary to extinguish.
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with all local and national regulations.

**Hazards Not Otherwise Classified:** None.  
**Supplementary Information:** None.

**3. Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Benzenesulfonamide, 4-amino-N-(5-methyl-3-isoxazolyl)-	723-46-6	Sulfamethoxazole; 5-Methyl-3-sulfanilamidoisoxazole	C <sub>10</sub> H <sub>11</sub> N <sub>3</sub> O <sub>3</sub> S	253.28	4%
2,4-Pyrimidinediamine, 5-[(3,4,5-trimethoxyphenyl)methyl]-	738-70-5	Trimethoprim	C <sub>14</sub> H <sub>18</sub> N <sub>4</sub> O <sub>3</sub>	290.32	0.8%

\*The formula also contains Alcohol, 0.26%; Methylparaben 0.1% and Sodium Benzoate, 0.1% (added as preservatives); Carboxymethylcellulose Sodium, Citrix Acid (anhydrous), Glycerin, Microcrystalline Cellulose, Polysorbate 80, Purified Water, Saccharin Sodium, and Sorbitol.

The light purple, grape flavored suspension contains the following additional inactive ingredients: FD&C Red No. 40, FD&C Blue No. 1 and Natural and Artificial Grape Flavor.

The pink, cherry flavored suspension contains the following additional inactive ingredients: FD&C Red No. 40, FD&C Yellow No. 6 and Artificial Cherry Flavor.



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### 4. First Aid Measures

<b>Ingestion:</b>	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.
<b>Eye Contact:</b>	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.
<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	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.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 – Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	May include skin, blood and liver disorders.
<b>Other Health Warnings:</b>	Sulfamethoxazole and Trimethoprim should be discontinued at the first appearance of skin rash or any sign of adverse reaction.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

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### 5. Firefighting Measures

**Suitable Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**Unsuitable Extinguishing Media:** With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

#### Specific Hazards Arising from the Chemical:

**Hazardous Combustion Products:** Emits fumes of carbon dioxide sulfur oxides nitrogen oxides.

**Other Specific Hazards:** Not determined.

**Special Protective Equipment/  
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

### 6. Accidental Release Measures

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

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

**Methods for Cleaning Up:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for  
Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**Environmental Precautions:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

### 7. Handling and Storage

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,  
Including Any Incompatibilities:** Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.



## SDS: Sulfamethoxazole and Trimethoprim Oral Suspension, USP

Specific End Use: Pharmaceuticals.

### 8. Exposure Controls/Personal Protection

#### Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Trimethoprim	Pfizer OEL: 100 µg/m <sup>3</sup> , 8 Hour TWA
Sulfamethoxazole	Pfizer OEB: 1,000 µg/m <sup>3</sup> to 3,000 µg/m <sup>3</sup>

#### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

#### 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).

#### Eyes Protection:

Not required for the normal use of this product. 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 are recommended. 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:

Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

**Physical State/Color:**

Pink suspension; Light purple suspension.

**Odor:**

Grape odor; Cherry odor.

**Odor Threshold:**

No data available.

**pH:**

No data available.

**Melting Point:**

No data available.

**Freezing Point:**

No data available.

**Boiling Point:**

No data available.

**Flash Point:**

>140°F.

## SDS: Sulfamethoxazole and Trimethoprim Oral Suspension, USP

<b>Evaporation Rate:</b>	Same as water.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	>1.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.
<b>Specific Gravity:</b>	1.21180.

### 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Heat and contact with incompatible materials.
<b>Incompatible Materials:</b>	Keep away from acids, caustics and avoid extreme pH conditions.
<b>Hazardous Decomposition Products:</b>	No data available.
<b>Hazardous Polymerization:</b>	Will not occur.

### 11. Toxicological Information

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

<b>Inhalation:</b>	May be harmful if inhaled. May cause respiratory tract irritation.
<b>Ingestion:</b>	May be harmful if swallowed.
<b>Skin Contact:</b>	May be harmful if absorbed through the skin. May cause irritation.
<b>Eye Contact:</b>	May cause eye irritation.
<b>Symptoms Related to the Physical, Chemical and Toxicological Characteristics:</b>	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

<b>Delayed and Immediate Effects of Exposure:</b>	No data available.
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**SDS: Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP**

**Acute Toxicity:**

Compound	Species	Route	Test Type	Dose
Sodium benzoate	Rat	Oral	LD <sub>50</sub>	4,070 mg/kg
Sodium benzoate	Mouse	Oral	LD <sub>50</sub>	1,600 mg/kg
Trimethoprim	Rat	Intravenous	LD <sub>50</sub>	200 mg/kg
Trimethoprim	Rat	Sub-tenon injection (eye)	LD <sub>50</sub>	500 mg/kg
Trimethoprim	Mouse	Oral	LD <sub>50</sub>	2,764 mg/kg
Trimethoprim	Mouse	Intravenous	LD <sub>50</sub>	200 mg/kg
Trimethoprim	Mouse	Intraperitoneal	LD <sub>50</sub>	1,870 mg/kg
Sulfamethoxazole	Rat	Oral	LD <sub>50</sub>	6,370 mg/kg
Sulfamethoxazole	Mouse	Oral	LD <sub>50</sub>	2,650 mg/kg
Sulfamethoxazole	Rat	Intraperitoneal	LD <sub>50</sub>	2,690 mg/kg
Sulfamethoxazole	Mouse	Intraperitoneal	LD <sub>50</sub>	2,300 mg/kg

**Repeated Does Toxicity:**

Compound	Species	Route	Type	Dose	Duration	Target Organ
Sodium Benzoate	Rat	Oral	LOAEL	27,370 mg/kg	10 Days	Liver, Blood
Sodium Benzoate	Mouse	Oral	LOAEL	45 g/kg	10 Days	Liver, Kidney, Blood, Ureter, Bladder

**Reproduction & Development Toxicity:**

Compound	Study Type	Species	Route	Type	Dose	Effect(s)
Sodium Benzoate	Embryo/Fetal Development	Rat	Oral	LOEL	44 g/kg	Developmental toxicity
Trimethoprim	Reproductive & Fertility - Males	Rat	Oral	NOAEL	70 mg/kg/day	Fertility
Trimethoprim	Reproductive & Fertility - Females	Rat	Oral	NOAEL	14 mg/kg/day	Fertility
Trimethoprim	Embryo/Fetal Development	Rabbit	Oral	LOAEL	30 mg/kg	Embryotoxicity
Trimethoprim	Embryo/Fetal Development	Rat	Oral	LOAEL	200 mg/kg	Maternal toxicity, Teratogenic
Trimethoprim	Embryo/Fetal Development	Mouse	Oral	NOAEL	70 mg/kg	Not Teratogenic
Sulfamethoxazole	Embryo/Fetal Development	Rat	Oral	NOEL	512 mg/kg/day	Teratogenic
Sulfamethoxazole	Reproductive & Fertility	Rat	Oral	NOAEL	350 mg/kg/day	No effects at maximum dose



**SDS: Sulfamethoxazole and Trimethoprim  
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**Genetic Toxicity:**

Compound	Study Type	Cell Type/Organism	Results
Trimethoprim	Bacterial Mutagenicity (Ames)	<i>Salmonella, E. coli</i>	Negative
Trimethoprim	<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary cells	Negative
Trimethoprim	<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
Sulfamethoxazole	Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Sulfamethoxazole	<i>In Vivo</i> Chromosome Aberration	Human Lymphocytes	Negative
Sulfamethoxazole	<i>In Vivo</i> Chromosome Aberration	Human Lymphocytes	Negative

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** This product is expected to be irritating to contaminated skin.

**Eye Irritation:** This product is expected to be irritating to contaminated eyes.

**Sensitization:** Sulfamethoxazole belongs to a class of drugs (sulfonamides) that are considered sanitizers. The combination product has been reported to cause allergic responses when given systematically.

**Toxicokinetics/Metabolism:** No data available.

**Target Organ Effects:** Fatalities associated with administration of sulfonamides, although rare, have occurred due to severe reactions, including Stevens-Johnson Syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, acranulocytosis aplastic anemia and other blood dyscrasias.

**Reproductive Effects:** No data available.

**Carcinogenicity:**

Compound	Species	Route	Type	Dose	Duration	Target Organ
Sulfamethoxazole	Rat	Oral	LOEL	60	60 Weeks	Tumors, Thyroid

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.

**Mutagenicity:** No data available.

**Aspiration Hazard:** No data available.



**SDS: Sulfamethoxazole and Trimethoprim  
Oral Suspension, USP**

**12. Ecological Information**

**Ecotoxicity**

**Aquatic:**

Compound	Species	Method	Test Type	Dose
Trimethoprim	Daphnia magna	OECD	LC <sub>50</sub>	141 mg/l (48 hours)
Sulfamethoxazole	Daphnia magna	N/A	EC <sub>50</sub>	75 mg/l (48 hours)
Sulfamethoxazole	Oncorhynchus mykiss	N/A	EC <sub>50</sub>	>1,000 mg/l

**Terrestrial:** No data available.  
**Persistence and Degradability:** No data available.  
**Bioaccumulative Potential:** No data available.  
**Mobility in Soil:** No data available.  
**Mobility in Environment:** No data available.  
**Other Adverse Effects:** No data available.

**13. Disposal Considerations**

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

**14. Transport Information**

**UN Number:** UN3077 (Sulfamethoxazole)  
**UN Proper Shipping Name:** Environmentally hazardous substance, solid, n.o.s. (Sulfamethoxazole)  
**Transport Hazard Class(es):** 9.  
**Packing Group:** III.  
**Department of Transportation:** Regulated as a hazardous material. (Sulfamethoxazole)  
**International Air Transport Association (IATA):** Regulated as a dangerous good. (Sulfamethoxazole)  
**International Maritime Dangerous Good (IMDG):** Regulated as a dangerous good. (Sulfamethoxazole)

**15. Regulatory Information**

**US Federal Regulations:**

**Toxic Substance Control Act (TSCA):** Listed. (Sulfamethoxazole)  
**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.  
**SARA 313:** Not listed.  
**SARA 302:** Not listed.



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### State Regulations

<b>Massachusetts:</b>	Not listed.
<b>New Jersey:</b>	Not listed.
<b>Pennsylvania:</b>	Not listed.
<b>California Proposition 65:</b>	Not listed.

### 16. Other Information

**Revision Date:** 10/05/2015

**Revision Number:** 3

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