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  IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
P312
P308  IF exposed or concerned: Get medical attention/advice.
P313
P330  Rinse mouth.
P370  In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary to extinguish.
P378
P403  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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
<th>Synonyms</th>
<th>Chemical Formula</th>
<th>Molecular Weight</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzenesulfonamide, 4-amino-N-(5-methyl-3-isoxazolyl)-</td>
<td>723-46-6</td>
<td>Sulfamethoxazole; 5-Methyl-3-sulfanilamidoisoxazole</td>
<td>C10H11N3O3S</td>
<td>253.28</td>
<td>4%</td>
</tr>
<tr>
<td>2,4-Pyrimidinediamine, 5-[(3,4,5-trimethoxyphenyl)methyl]-</td>
<td>738-70-5</td>
<td>Trimethoprim</td>
<td>C14H18N4O3</td>
<td>290.32</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

*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.
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:** For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 – Toxicological Information.

**Medical Conditions Aggravated by Exposure:** May include akin, blood and liver disorders.

**Other Health Warnings:** Sulfamethoxazole and Trimethoprim should be discontinued at the first appearance of skin rash or any sign of adverse reaction.

**Notes to Physician:** Treat supportively and symptomatically.
5. **Firefighting Measures**

   **Suitable Extinguishing Media:** Extinguish fires with CO2, 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:

<table>
<thead>
<tr>
<th>Common or Chemical Name</th>
<th>Employee Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimethoprim</td>
<td>Pfizer OEL: 100 μg/m³, 8 Hour TWA</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Pfizer OEB: 1,000 μg/m³ to 3,000 μg/m³</td>
</tr>
</tbody>
</table>

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.
Evaporation Rate: Same as water.
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: >1.
Relative Density: No data available.
Solubility(ies): Soluble in water.
Partition Coefficient (n-octanol/water): No data available.
Auto-Ignition Temperature: No data available.
Decomposition Temperature: No data available.
Viscosity: No data available.
Specific Gravity: 1.21180.

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): Heat and contact with incompatible materials.
Incompatible Materials: Keep away from acids, caustics and avoid extreme pH conditions.
Hazardous Decomposition Products: No data available.
Hazardous Polymerization: Will not occur.

11. **Toxicological Information**

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

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.
**Ingestion:** May be harmful if swallowed.
**Skin Contact:** May be harmful if absorbed through the skin. May cause irritation.
**Eye Contact:** May cause eye irritation.

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

### Acute Toxicity:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>Test Type</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium benzoate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>4,070 mg/kg</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>1,600 mg/kg</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Rat</td>
<td>Intravenous</td>
<td>LD₅₀</td>
<td>200 mg/kg</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Rat</td>
<td>Sub-tenon injection (eye)</td>
<td>LD₅₀</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>2,764 mg/kg</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD₅₀</td>
<td>200 mg/kg</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>LD₅₀</td>
<td>1,870 mg/kg</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Rat</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>6,370 mg/kg</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>2,650 mg/kg</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD₅₀</td>
<td>2,690 mg/kg</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>LD₅₀</td>
<td>2,300 mg/kg</td>
</tr>
</tbody>
</table>

### Repeated Dose Toxicity:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>Type</th>
<th>Dose</th>
<th>Duration</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Benzoate</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL</td>
<td>27,370 mg/kg</td>
<td>10 Days</td>
<td>Liver, Blood</td>
</tr>
<tr>
<td>Sodium Benzoate</td>
<td>Mouse</td>
<td>Oral</td>
<td>LOAEL</td>
<td>45 g/kg</td>
<td>10 Days</td>
<td>Liver, Kidney, Blood, Ureter, Bladder</td>
</tr>
</tbody>
</table>

### Reproduction & Development Toxicity:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Type</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Benzoate</td>
<td>Embryo/Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOEL</td>
<td>44 g/kg</td>
<td>Developmental toxicity</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Reproductive &amp; Fertility - Males</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL</td>
<td>70 mg/kg/day</td>
<td>Fertility</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Reproductive &amp; Fertility - Females</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL</td>
<td>14 mg/kg/day</td>
<td>Fertility</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Embryo/Fetal Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>LOAEL</td>
<td>30 mg/kg</td>
<td>Embryotoxicity</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Embryo/Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL</td>
<td>200 mg/kg</td>
<td>Maternal toxicity, Teratogenic</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Embryo/Fetal Development</td>
<td>Mouse</td>
<td>Oral</td>
<td>NOAEL</td>
<td>70 mg/kg</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Embryo/Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>NOEL</td>
<td>512 mg/kg/day</td>
<td>Teratogenic</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL</td>
<td>350 mg/kg/day</td>
<td>No effects at maximum dose</td>
</tr>
</tbody>
</table>
## Genetic Toxicity:

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

**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, agranulocytosis aplastic anemia and other blood dyscrasias.

**Reproductive Effects:** No data available.

**Carcinogenicity:**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>Type</th>
<th>Dose</th>
<th>Duration</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole</td>
<td>Rat</td>
<td>Oral</td>
<td>LOEL</td>
<td>60</td>
<td>60 Weeks</td>
<td>Tumors, Thyroid</td>
</tr>
</tbody>
</table>

**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.
12. **Ecological Information**

**Ecotoxicity**

**Aquatic:**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Method</th>
<th>Test Type</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimethoprim</td>
<td>Daphnia magna</td>
<td>OECD</td>
<td>LC$_{50}$</td>
<td>141 mg/l (48 hours)</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Daphnia magna</td>
<td>N/A</td>
<td>EC$_{50}$</td>
<td>75 mg/l (48 hours)</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Oncorhynchus mykiss</td>
<td>N/A</td>
<td>EC$_{50}$</td>
<td>&gt;1,000 mg/l</td>
</tr>
</tbody>
</table>

**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.
16. **Other Information**

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

**Revision Number:** 3

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