



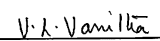
SAFETY DATA SHEET

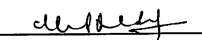
Product Name: Sulfamethoxazole and Trimethoprim Oral Suspension, USP 200 mg/40 mg per 5 mL

Version: 00

Issued Date: February 25, 2022

Prepared By:  2/25/22
(Date)

Reviewed By:  02/25/22
(Date)

Approved By:  02/25/2022
(Quality Assurance) (Date)



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1. Identification:

Product Identifier: Sulfamethoxazole and Trimethoprim Oral Suspension, USP 200 mg/40 mg per 5 mL

Other means of Identification Synonyms: Not available

Recommended use: This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions: No other uses are advised.

Manufacturer: Novitium Pharma LLC
70 Lake Drive, East Windsor, NJ – 08520
Online Assistance: www.novitiumpharma.com

2. Hazard(s) Identification:

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk

GHS Classification: Not classified

OSHA Specific - Classification: Not classified.

Label Elements

Signal Word: Warning

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

Precautionary Statement: 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.
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/advise.
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.





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Prevention: P 201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves. Wear eye or face protection. Wear protective clothing. P271 - Use only outdoors or in a well-ventilated area. P273 - Avoid release to the environment. P260 - Do not breathe dust. P270 - Do not eat, drink or smoke when using this product. P264 - Wash hands thoroughly after handling.

Response: P314 - Get medical attention if you feel unwell.
P308 + P313 - IF exposed or concerned: Get medical attention.

Disposal: Please refer to Section 7 for Storage and Section 13 for Disposal information.

Hazard(s) Not Otherwise Classified (HNOC): Not classified

3. Composition/Information on Ingredients:

Chemical Name	CAS Number
Sulfamethoxazole, USP	723-46-6
Trimethoprim, USP	738-70-5
Microcrystalline Cellulose and Carboxymethylcellulose Sodium, NF	9004-34-6 and 9004-32-4
Sorbitol Solution Non-Crystallizing, NF	50-70-4
Polysorbate 80, NF	9005-65-6
Methylparaben, NF	99-76-3
Sodium Benzoate, NF	532-32-1
Glycerin, USP	56-81-5
Sodium Saccharin Monohydrate, USP	82385-42-0
FD&C Red No. 40 Powder	N/A



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N-C Cherry Flavor Art 825.0597U	N/A
Citric Acid Anhydrous powder, USP	77-92-9

4. First-aid measures:

General Information:

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222.

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.

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.

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.

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.

5. Fire-Fighting 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: Not determined.



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

Fire/Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Special Protective Equipment and Precautions for Firefighters: Wear suitable protective equipment. Prevent contact with skin and eyes.

Fire-Fighting Equipment/Instructions: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

6. Accidental Release Measures:

Personal Precautions, Protective Equipment and Emergency Procedures: Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

Methods and Materials for Containment and Cleaning Up: Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

Additional Consideration for Large Spills: Cleaning operations should only be undertaken by trained personnel.

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: Keep container tightly closed. Store in accordance with information listed on the product insert. Store between 20° to 25°C (68° to 77°F).

8. Exposure Control/Personal Protection:

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Biological Limit Values: No data available.

Appropriate Engineering Controls: Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Individual Protection Measures, Such as Personal Protective Equipment

Eye/Face Protection: Safety glasses with side shields are recommended in laboratory, medical, or industrial settings. 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.

Skin Protection Hand Protection: Long sleeved clothing. Chemical resistant apron. Chemically compatible gloves for laboratory, medical, or industrial settings. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other: For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

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).



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Thermal Hazards: Not available.

General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice. When using, do not eat, drink or smoke. Avoid contact with skin, eyes and clothing. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash hands before breaks and immediately after handling the product. Do not take internally.

9. Physical and Chemical Properties:

Appearance	Pink
Physical state	Liquid
Odor	No data available
Solubility	No data available

10. Stability and Reactivity:

Reactivity:	No data available.
Chemical Stability:	Stable at normal conditions.
Possibility of Hazardous Reaction:	No data available.
Condition to Avoid:	No data available.
Incompatible Materials:	Keep away from acids, caustics and avoid extreme pH conditions.
Corrosivity:	No data available.
Polymerization:	No data available.

11. Toxicological Information:

Information on likely routes of exposure:

Ingestion:	No data available.
Inhalation:	No data available.
Skin Contact:	No data available.
Eye Contact:	No data available.
Cross Sensitivity:	No data available.

Acute Toxicity:

Ingredient	Result	Species	Dose
Sulfamethoxazole	LD50 Oral	Rat	28270 µg/kg
Trimethoprim	LD50 Oral	Rat	6,370 mg/kg

12. Ecological Information:

Ecotoxicity	Not available.
BOD5 and COD	Not available.
Products of biodegradation	Not available.
Toxicity products of degradation	Not available.

13. Disposal considerations:

Disposal Instructions: Dispose of contents/container in accordance with local/regional/national/international regulations.



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Local Disposal Regulations: Not available.

Hazardous Waste Code: Not regulated.

Waste from Residues / Unused Products: Dispose of as above.

Contaminated Packaging: Dispose of as above.

14. Transport information:

DOT	Not available (for finished dosage form).
UN Number	Not available (for finished dosage form).
UN Shipping name	Not available (for finished dosage form).
Transport hazard class	Not available (for finished dosage form).
Packing group	Not available (for finished dosage form).
Environmental hazard	Not available (for finished dosage form).
Transport in Bulk	Not available (for finished dosage form).
Special precautions needed with transport	Not available (for finished dosage form).

15. Regulatory information:

No data available – a Chemical Safety Assessment has not been conducted.

16. Other information:

Reference: 1. Sulfamethoxazole and Trimethoprim Oral Suspension, USP SDS (Akom)

17. Repackaging/ Bulk Handling Precautions:

In cases where rebottling or repackaging may take place, additional precautions should be considered as these operations may generate dust, and may leave behind powder residue.

Appropriate Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, or proved endosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. Local exhaust ventilation, vacuum accessories, or other vented enclosure is recommended, particularly during dust-generating procedures (such as de-bottling/ packaging).

Individual Protection Measures, Such as Personal Protective Equipment

Eye/Face Protection: Safety glasses with side shields are recommended in laboratory, medical, or industrial settings. 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.

Skin Protection Hand Protection: Long sleeved clothing. Chemical resistant apron. Chemically compatible gloves for laboratory, medical, or industrial settings. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

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Contaminated Residual Packaging Materials: Empty containers/ bottles & caps should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings eve after container is emptied.

Special Considerations: Not Available.

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Disclaimer: The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

This Safety Data Sheet is prepared as a reference document in consultation with the safety data sheet prepared by the API manufacturer. The hazards outlined are based on quantity, duration, and type of exposure and may not be reflective of the product finished dosage form.

Revision History

Version 00: Date 2/25/2022