



SAFETY DATA SHEET

1. Identification

Product identifier	Sulfisoxazole Acetyl	
Other means of identification		
Catalog number	1639003	
Chemical name	Acetamide, N-[(4-aminophenyl)sulfonyl]-N-(3,4-dimethyl-5-isoxazolyl)-	
Synonym(s)	N1-Acetyl Sulfisoxazole; Acetyl sulphafurazole	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, respiratory	Category 1B
	Sensitization, skin	Category 1B
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Precautionary statement		
Prevention	Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.	
Response	If on skin: Wash with plenty of water/and soap. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.	
Storage	Not available.	
Disposal	Dispose of contents/container to an approved disposal site.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Sulfisoxazole Acetyl	N1-Acetyl Sulfisoxazole; Acetyl sulphafurazole	80-74-0	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Skin contact	Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention. May cause irritation. Flush with copious quantities of water.
Eye contact	Rinse with water. Flush eyes with water as a precaution.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	May cause allergic skin reaction. May cause allergic respiratory reaction.
Indication of immediate medical attention and special treatment needed	Treatment of sulfonamide overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. For hypotension, infuse with 10 to 20 mL/kg isotonic fluid, place in Trendelenburg position. If hypotension persists, administer dopamine or norepinephrine. If kidney function is normal, consider diuresis to obtain a urine flow of 3 to 6 mL/kg/hr. For anuria or agranulocytosis, dialysis and/or isolation should be considered. Obtain a baseline CBC, hepatic and renal function test. For seizures, administer a benzodiazepine. Consider phenobarbital if seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. Sodium bicarbonate may be given to raise the pH of the urine and reduce the danger of crystalluria. For anaphylaxis, establish open airway and treat with epinephrine and diphenhydramine. Hemodialysis is only moderately effective in eliminating sulfonamides; peritoneal dialysis is not effective. (Meditext) (USP DI)
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. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields 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.
Skin protection	
Hand protection	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 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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White or slightly yellow crystalline powder
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	377.6 - 383 °F (192 - 195 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Practically insoluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Aromatic sulfanilamide derivative (sulfonamide)
Molecular formula	C13H15N3O4S
Molecular weight	309.34

Solubility (other)

Sparingly soluble in chloroform; slightly soluble in alcohol and in methanol.

10. Stability and reactivity**Reactivity**

No reactivity hazards known.

Chemical stability

Material is stable under normal conditions.

Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid

None known.

Incompatible materials

None known.

Hazardous decomposition products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx.

11. Toxicological information**Information on likely routes of exposure****Ingestion**

Due to lack of data the classification is not possible.

Inhalation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin contact

May cause an allergic skin reaction.

Eye contact

Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Sulfonamides: Nausea. Vomiting. Diarrhea. Loss of appetite. Dizziness. Headache. Skin rash. Fever. Itching. Increased sensitivity of skin to sunlight. Sore throat. Unusual bleeding or bruising. Difficulty swallowing. Vision problems. Yellow eyes or skin. Lower back pain. Difficult or painful urination. Blood in urine. Joint pain. Muscle pain. Redness, peeling or loosening of skin. Fatigue.

Delayed and immediate effects of exposure

Jaundice. Crystalluria. Unconsciousness.

Chronic effects

Pseudomembranous colitis.

Cross sensitivity

Persons sensitive to sulfonamides or to furosemide, thiazide diuretics, sulfonyleureas, or carbonic anhydrase inhibitors may be sensitive to this material also.

Medical conditions aggravated by exposure

Asthma. HIV or AIDS. Systemic lupus erythematosus. Blood disorders. Impaired kidney function. Impaired liver function. Porphyria.

Acute toxicity**Product****Species****Test Results**

Sulfisoxazole Acetyl (CAS 80-74-0)

Oral

LD50

Rat

> 5000 mg/kg

Skin corrosion/irritation

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

Serious eye damage/eye irritation

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

Local effects**Eye**

Result: Practically non-irritating

Species: Rabbit

Skin

Result: Practically non-irritating

Species: Rabbit

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization

May cause an allergic skin reaction.

Germ cell mutagenicity

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

MutagenicityAmes test (*S. typhimurium*)

Result: Negative (with and without activation)

Assay (*E. coli* Sd-4-73)

Result: Negative (no activation)

In vitro chromosomal aberration test (Chinese hamster ovary cells)

Result: Negative (with and without activation)

Carcinogenicity

Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

2000 mg/kg 103 Week Gavage study

Result: Not carcinogenic

Species: Mouse

400 mg/kg 103 Week Gavage study
Result: Not carcinogenic
Species: Rat

Reproductive toxicity Based on available data, the classification criteria are not met. Sulfonamides given to pregnant women prior to delivery may cause jaundice, brain damage, and hemolytic anemia in the offspring. A study by the Collaborative Perinatal Project found no increase in malformations in 796 offspring of mothers treated with sulfisoxazole in the first four months of pregnancy.

Reproductivity

1000 mg/kg Gestational study
Result: Increased cleft palate and skeletal defects
Species: Rat
780 mg/kg Gestational study
Result: No increase in birth defects.
Species: Rat

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

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

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Not available.

Hazardous waste code Not regulated.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 01-26-2009

Revision date 12-12-2012

Version # 02

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.