

## 1. Identification

**Product identifier** Sulfamethoxazole

**Other means of identification**

**Catalog number** 1631001

**Chemical name** Benzenesulfonamide, 4-amino-N-(5-methyl-3-isoxazolyl)-

**Synonym(s)** 5-Methyl-3-sulfanilamidoisoxazole

**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 & 1-800-424-9300  
Canada  
CHEMTREC outside US & +1 703-527-3887  
Canada

## 2. Hazard(s) identification

**Note** This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

**Physical hazards** Not classified.

**Health hazards** Serious eye damage/eye irritation  
Sensitization, respiratory  
Sensitization, skin

**OSHA hazard(s)** Not classified.

**Label elements**

Category 2B  
Category 1  
Category 1



*14/11/17*

**Signal word**

Danger

**Hazard statement**

May cause an allergic skin reaction. Causes eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Precautionary statement**

**Prevention**

Wash thoroughly after handling. 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. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Storage**

Not available.

**Disposal**

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

**Hazard(s) not otherwise classified (HNOC)**

Not classified.

### 3. Composition/information on ingredients

#### Substance

#### Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Sulfamethoxazole	5-Methyl-3-sulfanilamidoisoxazole	723-46-6	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.

#### Eye contact

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

#### Ingestion

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

#### Most important symptoms/effects, acute and delayed

Irritation of eyes and mucous membranes. 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: 1. Administer activated charcoal as a slurry. 2. For hypotension, infuse with 10 to 20 mL/kg isotonic fluid, place in Trendelenburg position. If hypotension persists, administer dopamine or norepinephrine. 3. If kidney function is normal, consider diuresis to obtain a urine flow of 3 to 6 mL/kg/hr. 4. For anuria or agranulocytosis, dialysis and/or isolation should be considered. Obtain a baseline CBC, hepatic and renal function test. 5. 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. 6. Sodium bicarbonate may be given to raise the pH of the urine and reduce the danger of crystalluria. 7. For anaphylaxis, establish open airway and treat with epinephrine and diphenhydramine. 8. Hemodialysis is only moderately effective in eliminating sulfonamides; peritoneal dialysis is not effective. [Meditext 2008]

#### 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

Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO<sub>2</sub>.

#### Unsuitable extinguishing media

None known.

#### Specific hazards arising from the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

#### Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

#### Fire-fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

#### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

### 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. 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. Clean surface thoroughly to remove residual contamination.



## 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. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

### 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

### Exposure limit values

#### Industrial Use

Material	Type	Value
Sulfamethoxazole (CAS 723-46-6)	TWA	1 mg/m <sup>3</sup>

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### 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 to off-white crystalline powder.

#### Physical state

Solid.

#### Form

Powder.

### Odor

Practically odorless.

### Odor threshold

Not available.

### pH

4 - 6 (10% aqueous solution)

### Melting point/freezing point

332.6 - 341.6 °F (167 - 172 °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.

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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.
Auto-ignition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Sulfonamide.
Dust explosion properties	
St class	2 Strong explosion.
Molecular formula	C10-H11-N3-O3-S
Molecular weight	253.28 g/mol
Solubility (other)	Practically insoluble in ether and in chloroform; freely soluble in acetone and in dilute solutions of sodium hydroxide; sparingly soluble in ethanol; soluble in methanol.

## 10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid exposure to light, extreme heat, ignition sources, and electrostatic charging. Avoid dust formation.
Incompatible materials	Oxidizing agents. Strong mineral acids. Peroxides. Phenols.
Hazardous decomposition products	SOx, NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	Causes eye irritation.
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	Sulfonamides: Pseudomembranous colitis. Crystalluria. Stevens-Johnson syndrome. Blood disorders.
Cross sensitivity	Persons sensitive to sulfonamides or to furosemide, thiazide diuretics, sulfonylureas, or carbonic anhydrase inhibitors may be sensitive to this material also.
Medical conditions aggravated by exposure	Sulfonamides: Allergies. Asthma. HIV or AIDS. Lupus erythematosus. Blood disorders. Impaired kidney or liver function. Porphyria. Glucose-6-phosphate dehydrogenase deficiency.
Acute toxicity	Based on available data, the classification criteria are not met.

Product	Species	Test Results
Sulfamethoxazole (CAS 723-46-6)		
Acute		
Oral		
LD50	Mouse	2650 mg/kg
		2300 mg/kg
	Rat	6370 mg/kg
		3000 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes eye irritation.	

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**Local effects**

Eye irritancy  
Result: Slightly irritating.  
Species: Rabbit  
Skin irritancy  
Result: Not irritating.  
Species: Rabbit

**Respiratory sensitization**

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

**Skin sensitization**

May cause an allergic skin reaction.

**Sensitization**

Sensitization test  
Result: Not sensitizing.  
Species: Guinea pig

**Germ cell mutagenicity**

Due to lack of data the classification is not possible.  
Data from germ cell mutagenicity tests were not found.

**Mutagenicity**

Ames test in *S. typhimurium*  
Result: Mixed results.  
In vitro chromosomal aberration assay in human lymphocytes  
Result: Negative.

**Carcinogenicity**

Based on available data, the classification criteria are not met.  
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.  
IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans.  
Studies in rats have shown that long-term administration of sulfonamides may cause thyroid malignancy. However, rats appear to be especially susceptible to the goitrogenic effects of sulfonamides.

0 - 300 mg/kg/day Carcinogenicity study, administered by gavage.

Result: No thyroid hyperplasia observed.

Species: Monkey

Test Duration: 52 weeks

25 - 600 mg/kg/day Carcinogenicity study, administered orally.

Result: Thyroid follicular cell carcinomas.

Species: Rat

Test Duration: 60 weeks

Epidemiological study

Result: Significantly significant positive associations between use of this material and risks for lung, cervical, and blood cancers were noted.

Species: Human

**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. Studies in rats and mice given high oral doses have shown that certain sulfonamides cause a significant increase in the incidence of cleft palate and other bony abnormalities in the fetus.  
A review of limited human pregnancy data has not demonstrated an increase in developmental effects.

**Reproductivity**

200 mg/kg/day Reproductivity and development

Result: No adverse effect on fertility.

Species: Rat

307 - 512 mg/kg/day Reproductivity and development

Result: Not teratogenic.

Species: Rat

5 - 50 mg/kg/day Reproductivity and development, administered before and during two matings.

Result: No adverse effect on reproduction. Not teratogenic.

Species: Rat

533 - 1000 mg/kg/day Reproductivity and development

Result: Teratogenic (cleft palate).

Species: Rat

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**Specific target organ toxicity - single exposure**

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

**Specific target organ toxicity - repeated exposure**

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

**Aspiration hazard**

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

## 12. Ecological information

### Ecotoxicity

Product	Species		Test Results
Sulfamethoxazole (CAS 723-46-6)			
Acute			
Crustacea	EC50	Daphnia magna	75 mg/l, 48 hours
Fish	EC50	Oncorhynchus mykiss	> 1000 mg/l
Other	EC50	Pseudokirchnerella subcapitata	3.4 mg/l, 72 hours
Persistence and degradability	Not readily biodegradable.		
Bioaccumulative potential	Not available.		
Mobility in soil	Not available.		
Other adverse effects	Not available.		

## 13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. 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.
Local disposal regulations	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	Dispose of in accordance with local regulations. 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

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Sulfamethoxazole)
Transport hazard class(es)	9
Subsidiary class(es)	Not available.
Packing group	III

### IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Sulfamethoxazole)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packaging group	III

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

DOT; IATA



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## 15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable.
	All components are on the U.S. EPA TSCA Inventory List.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	No
<b>SARA 311/312 Hazardous chemical</b>	No
<b>Other federal regulations</b>	
Safe Drinking Water Act (SDWA)	Not regulated.
Food and Drug Administration (FDA)	Not regulated.
<b>US state regulations</b>	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)	Yes
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)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*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**

<b>Issue date</b>	01-21-2009
<b>Revision date</b>	04-15-2014
<b>Version #</b>	02
<b>Further information</b>	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
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<b>Revision Information</b>	This document has undergone significant changes and should be reviewed in its entirety.

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