

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

### SECTION 1. IDENTIFICATION

Product name : Sulfamethoxazole / Trimethoprim Injection Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin corrosion : Category 1B  
Serious eye damage : Category 1  
Reproductive toxicity : Category 2  
Specific target organ toxicity - single exposure : Category 3  
Specific target organ toxicity - repeated exposure : Category 1 (Bone marrow)

#### GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.  
H335 May cause respiratory irritation.  
H361d Suspected of damaging the unborn child.  
H372 Causes damage to organs (Bone marrow) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

and understood.  
P260 Do not breathe mist or vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

### Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER.  
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Immediately call a POISON CENTER.  
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER.  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P363 Wash contaminated clothing before reuse.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7	>= 65.0407 - <= 76.1905
Sulfamethoxazole	723-46-6	>= 16.2602 - <= 19.0476
Ethanolamine	141-43-5	>= 6.5041 - <= 7.619
Trimethoprim	738-70-5	>= 3.252 - <= 3.8095

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7	Revision Date: 09/30/2023	SDS Number: 7848267-00009	Date of last issue: 04/04/2023 Date of first issue: 03/03/2021
If inhaled	:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.	
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.	
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.	
If swallowed	:	If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.	
Most important symptoms and effects, both acute and delayed	:	Causes serious eye damage. May cause respiratory irritation. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. Causes severe burns. Causes digestive tract burns.	
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).	
Notes to physician	:	Treat symptomatically and supportively.	

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Nitrogen oxides (NO <sub>x</sub> ) Sulfur oxides Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

---

### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapors.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

Materials to avoid : Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sulfamethoxazole	723-46-6	TWA	OEB 2 ( $\geq 100 < 1000 \mu\text{g}/\text{m}^3$ )	Internal
Ethanolamine	141-43-5	TWA	3 ppm	ACGIH
		STEL	6 ppm	ACGIH
		TWA	3 ppm	NIOSH REL
			8 mg/m <sup>3</sup>	
		ST	6 ppm	NIOSH REL
			15 mg/m <sup>3</sup>	
		TWA	3 ppm	OSHA Z-1
			6 mg/m <sup>3</sup>	
Trimethoprim	738-70-5	TWA	400 $\mu\text{g}/\text{m}^3$ (OEB 2)	Internal

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

#### Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

---

adequate protection.

Hand protection  
Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.  
Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : light yellow

Odor : No data available

Odor Threshold : No data available

pH : 9.5 - 10.5

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.050 - 1.230 g/cm <sup>3</sup>
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents Acids
Hazardous decomposition products	:	No hazardous decomposition products are known.

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

---

### Acute toxicity

Not classified based on available information.

### Product:

Acute oral toxicity : Acute toxicity estimate: 4,367 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 144.38 mg/l  
Exposure time: 4 h  
Test atmosphere: vapor  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

### Components:

#### **1,3-Dioxan-5-ol:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

#### **Sulfamethoxazole:**

Acute oral toxicity : LD50 (Mouse): 2,300 mg/kg

#### **Ethanolamine:**

Acute oral toxicity : LD50 (Rat): 1,089 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 11 mg/l  
Exposure time: 4 h  
Test atmosphere: vapor  
Method: Expert judgment  
Remarks: Based on national or regional regulation.

Acute dermal toxicity : LD50 (Rabbit, female): 1,018 mg/kg

#### **Trimethoprim:**

Acute oral toxicity : LD50 (Rat): 1,500 - 5,300 mg/kg  
LD50 (Mouse): 1,910 - 7,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 400 - 500 mg/kg  
Application Route: Intraperitoneal

LD50 (Dog): 90 mg/kg  
Application Route: Intravenous

LD50 (Mouse): 132 mg/kg  
Application Route: Intravenous



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

### Skin corrosion/irritation

Causes severe burns.

#### Components:

##### 1,3-Dioxan-5-ol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

##### Sulfamethoxazole:

Species	:	Rabbit
Result	:	No skin irritation

##### Ethanolamine:

Species	:	Rabbit
Result	:	Corrosive after 3 minutes to 1 hour of exposure

### Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

##### 1,3-Dioxan-5-ol:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

##### Ethanolamine:

Species	:	Rabbit
Result	:	Irreversible effects on the eye

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

##### 1,3-Dioxan-5-ol:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

Result : negative  
Remarks : Based on data from similar materials

### **Sulfamethoxazole:**

Test Type : Magnusson-Kligman-Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

### **Ethanolamine:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

### **Trimethoprim:**

Test Type : Maximization Test  
Routes of exposure : Dermal  
Species : Guinea pig  
Result : Not a skin sensitizer.

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **1,3-Dioxan-5-ol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Result: negative  
Remarks: Based on data from similar materials

#### **Sulfamethoxazole:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Humans

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

Result: negative

### Ethanolamine:

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo

: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative

### Trimethoprim:

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosomal aberration  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Genotoxicity in vivo

: Test Type: Micronucleus test  
Species: Rat  
Result: negative

Test Type: Chromosomal aberration  
Species: Humans  
Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### Sulfamethoxazole:

Species : Mouse  
Application Route : Ingestion  
Exposure time : 26 weeks

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

---

Result : negative

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### **Ethanolamine:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

#### **Trimethoprim:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 70 mg/kg body weight  
Result: No effects on fertility.

Effects on fetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 70 mg/kg body weight  
Result: Effects on newborn.  
Remarks: Maternal toxicity observed.

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 70 mg/kg body weight  
Result: Embryotoxic effects.  
Remarks: Maternal toxicity observed.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 15 mg/kg body weight  
Result: Embryotoxic effects., Teratogenic effects.

Test Type: Development  
Species: Hamster  
Application Route: Oral  
Developmental Toxicity: LOAEL: 1.7 mg/kg body weight  
Result: Embryotoxic effects., No teratogenic effects.

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryotoxic effects., No teratogenic effects.

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

### **STOT-single exposure**

May cause respiratory irritation.

#### **Components:**

##### **Ethanolamine:**

Assessment : May cause respiratory irritation.

### **STOT-repeated exposure**

Causes damage to organs (Bone marrow) through prolonged or repeated exposure.

#### **Components:**

##### **Ethanolamine:**

Assessment : No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

##### **Trimethoprim:**

Target Organs : Bone marrow  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

#### **Components:**

##### **Ethanolamine:**

Species : Rat  
NOAEL : > 120 mg/kg  
Application Route : Ingestion  
Exposure time : > 75 Days

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

---

Remarks : Based on data from similar materials

Species : Rat  
NOAEL :  $\geq 0.15$  mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 28 Days  
Method : OECD Test Guideline 412

### Trimethoprim:

Species : Rat  
NOAEL : 100 mg/kg  
LOAEL : 300 mg/kg  
Application Route : Oral  
Exposure time : 6 Months  
Target Organs : Bone marrow, Liver, Pituitary gland, Thyroid

Species : Rat  
LOAEL : 300 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Bone marrow

Species : Dog  
NOAEL : 2.5 mg/kg  
LOAEL : 45 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Blood, Thyroid

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Trimethoprim:

Ingestion : Target Organs: Bone marrow  
Symptoms: Abdominal pain, Nausea, Vomiting, skin rash,  
Dizziness, Headache, mental depression, confusion

---

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### 1,3-Dioxan-5-ol:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)):  $> 100$  mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

---

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

Toxicity to daphnia and other aquatic invertebrates : EL50 (*Daphnia magna* (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (*Pseudokirchneriella subcapitata* (green algae)): > 100 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials

NOELR (*Pseudokirchneriella subcapitata* (green algae)): > 1 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10: > 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

### Sulfamethoxazole:

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): 562.5 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Ceriodaphnia dubia* (water flea)): 0.21 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (*Synechococcus leopoliensis* (blue-green algae)): 0.0268 mg/l  
Exposure time: 96 h

NOEC (*Synechococcus leopoliensis* (blue-green algae)): 0.0059 mg/l  
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : NOEC (*Danio rerio* (zebra fish)): 0.533 mg/l  
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 0.01 mg/l  
Exposure time: 30 d

Toxicity to microorganisms : NOEC (activated sludge): 3.76 mg/l  
Method: OECD Test Guideline 301D

### Ethanolamine:

Toxicity to fish : LC50 (*Cyprinus carpio* (Carp)): 349 mg/l  
Exposure time: 96 h  
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 65 mg/l  
Exposure time: 48 h

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

---

Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Orange-red killifish)): 1.24 mg/l  
Exposure time: 41 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.85 mg/l  
Exposure time: 21 d

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 1,000 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

### Trimethoprim:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 100 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna Straus (Water flea)): 92 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l  
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l  
Exposure time: 72 h

EC50 (Anabaena flos-aquae): 253 mg/l  
Exposure time: 72 h

EC10 (Anabaena flos-aquae): 26 mg/l  
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : NOEC (Zebrafish): 0.157 mg/l  
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 6 mg/l  
Exposure time: 21 d

Toxicity to microorganisms : EC10: 16.7 mg/l  
Exposure time: 3 hrs  
Test Type: Respiration inhibition



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

Method: OECD Test Guideline 209

EC50: > 1,000 mg/l  
Exposure time: 3 hrs  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### **1,3-Dioxan-5-ol:**

Biodegradability : Result: Inherently biodegradable.  
Remarks: Based on data from similar materials

##### **Sulfamethoxazole:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D

##### **Ethanolamine:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: > 90 %  
Exposure time: 21 d  
Method: OECD Test Guideline 301A

##### **Trimethoprim:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 4 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D

Result: Not inherently biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 302B

### Bioaccumulative potential

#### Components:

##### **1,3-Dioxan-5-ol:**

Partition coefficient: n-octanol/water : log Pow: -0.65

##### **Sulfamethoxazole:**

Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): < 120

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

Partition coefficient: n-octanol/water : log Pow: 0.89

### Ethanolamine:

Partition coefficient: n-octanol/water : log Pow: -2.3  
Method: OECD Test Guideline 107

### Trimethoprim:

Partition coefficient: n-octanol/water : log Pow: 0.91

### Mobility in soil

No data available

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 2491  
Proper shipping name : ETHANOLAMINE SOLUTION  
Class : 8  
Packing group : III  
Labels : 8  
Environmentally hazardous : no

#### IATA-DGR

UN/ID No. : UN 2491  
Proper shipping name : Ethanolamine solution  
Class : 8  
Packing group : III  
Labels : Corrosive  
Packing instruction (cargo aircraft) : 856  
Packing instruction (passenger aircraft) : 852

#### IMDG-Code

UN number : UN 2491  
Proper shipping name : ETHANOLAMINE SOLUTION  
(Sulfamethoxazole)

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

Class : 8  
Packing group : III  
Labels : 8  
EmS Code : F-A, S-B  
Marine pollutant : yes

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

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

UN/ID/NA number : UN 2491  
Proper shipping name : Ethanolamine solutions  
Class : 8  
Packing group : III  
Labels : CORROSIVE  
ERG Code : 153  
Marine pollutant : yes(Sulfamethoxazole)

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Skin corrosion or irritation  
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

1,3-Dioxan-5-ol	4740-78-7
Sulfamethoxazole	723-46-6
Water	7732-18-5
Ethanolamine	141-43-5

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 2.7      Revision Date: 09/30/2023      SDS Number: 7848267-00009      Date of last issue: 04/04/2023  
Date of first issue: 03/03/2021

Trimethoprim 738-70-5

### California List of Hazardous Substances

Sulfamethoxazole 723-46-6  
Ethanolamine 141-43-5

### California Permissible Exposure Limits for Chemical Contaminants

Ethanolamine 141-43-5

The ingredients of this product are reported in the following inventories:

DSL : not determined

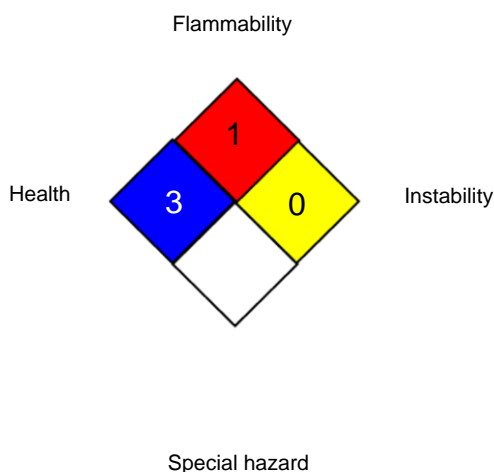
AICS : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/30/2023

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
2.7	09/30/2023	7848267-00009	Date of first issue: 03/03/2021

---

US / Z8