

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.0      Revision Date: 2023/04/04      SDS Number: 7848286-00008      Date of last issue: 2022/10/01  
Date of first issue: 2021/03/03

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfamethoxazole / Trimethoprim Injection Formulation

#### Manufacturer or supplier's details

Company : MSD  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone number : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION


#### GHS Classification

Skin corrosion/irritation : Category 1B  
Serious eye damage/eye irritation : Category 1  
Reproductive toxicity : Category 2  
Specific target organ toxicity - single exposure : Category 3  
Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow)  
Short-term (acute) aquatic hazard : Category 1  
Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

- 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.  
H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapours.  
P264 Wash skin thoroughly after handling.  
P271 Use only outdoors or in a well-ventilated area.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**  
P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.  
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. Immediately call a POISON CENTER/ doctor.  
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.  
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/ doctor.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P363 Wash contaminated clothing before reuse.  
P391 Collect spillage.
- Storage:**  
P405 Store locked up.
- Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

None known.

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.0      Revision Date: 2023/04/04      SDS Number: 7848286-00008      Date of last issue: 2022/10/01  
Date of first issue: 2021/03/03

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7	$\geq 60$ - $\leq 100$
Sulfamethoxazole	723-46-6	$\geq 10$ - $< 25$
Ethanolamine	141-43-5	$\geq 5$ - $< 10$
Trimethoprim	738-70-5	$\geq 3$ - $< 10$

### 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.
- 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 centre 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 digestive tract burns.  
Causes serious eye damage.  
May cause respiratory irritation.  
Suspected of damaging the unborn child.  
May cause damage to organs through prolonged or repeated exposure.  
Causes severe 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.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

		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> ) Sulphur 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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

### 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.

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.0      Revision Date: 2023/04/04      SDS Number: 7848286-00008      Date of last issue: 2022/10/01  
Date of first issue: 2021/03/03

- Do not breathe mist or vapours.  
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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
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 labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Oxidizing agents  
Explosives

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components 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	NAB	3 ppm	ID OEL
		PSD	6 ppm	ID OEL
		TWA	3 ppm	ACGIH
		STEL	6 ppm	ACGIH
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 : If adequate local exhaust ventilation is not available or expo-

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

---

	sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	: Combined particulates and organic vapour type
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.

---

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: light yellow
Odour	: No data available
Odour 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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

---

Vapour pressure	:	No data available
Relative vapour 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
Auto-ignition 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

---

### 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.

---

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
--	---	--

#### Acute toxicity

Not classified based on available information.

#### Product:

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

---

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 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: vapour  
Method: Expert judgement  
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

#### **Skin corrosion/irritation**

Causes severe burns.



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.0      Revision Date: 2023/04/04      SDS Number: 7848286-00008      Date of last issue: 2022/10/01  
Date of first issue: 2021/03/03

---

### 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 sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

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

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
Remarks	: Based on data from similar materials

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

### Sulfamethoxazole:

Test Type	: Magnusson-Kligman-Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

### Ethanolamine:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

### Trimethoprim:

Test Type	: Maximisation Test
Exposure routes	: 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
Genotoxicity in vivo	: 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
Genotoxicity in vivo	: 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
	Result: negative

#### Ethanolamine:

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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.0      Revision Date: 2023/04/04      SDS Number: 7848286-00008      Date of last issue: 2022/10/01  
Date of first issue: 2021/03/03

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  
Result : negative

### Reproductive toxicity

Suspected of damaging the unborn child.

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.0      Revision Date: 2023/04/04      SDS Number: 7848286-00008      Date of last issue: 2022/10/01  
Date of first issue: 2021/03/03

### 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 foetal development	:	Test Type: Embryo-foetal 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 foetal 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.
		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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

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

May cause 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  
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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

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
-----------	--

## 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
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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.0	Revision Date: 2023/04/04	SDS Number: 7848286-00008	Date of last issue: 2022/10/01 Date of first issue: 2021/03/03
----------------	------------------------------	------------------------------	---

Remarks: Based on data from similar materials

### Sulfamethoxazole:

Toxicity to fish	:	LC50 ( <i>Oryzias latipes</i> (Japanese medaka)): 562.5 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Ceriodaphnia dubia</i> (water flea)): 0.21 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 ( <i>Synechococcus leopoliensis</i> (blue-green algae)): 0.0268 mg/l Exposure time: 96 h
	:	NOEC ( <i>Synechococcus leopoliensis</i> (blue-green algae)): 0.0059 mg/l Exposure time: 96 h
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to fish (Chronic toxicity)	:	NOEC ( <i>Danio rerio</i> (zebra fish)): 0.533 mg/l Exposure time: 21 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC ( <i>Daphnia magna</i> (Water flea)): 0.01 mg/l Exposure time: 30 d
M-Factor (Chronic aquatic toxicity)	:	10
Toxicity to microorganisms	:	NOEC (activated sludge): 3.76 mg/l Method: OECD Test Guideline 301D

### Ethanolamine:

Toxicity to fish	:	LC50 ( <i>Cyprinus carpio</i> (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 ( <i>Daphnia magna</i> (Water flea)): 65 mg/l Exposure time: 48 h Method: Directive 67/548/EEC, Annex V, C.2.
Toxicity to algae/aquatic plants	:	ErC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): 2.8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	:	NOEC ( <i>Pseudokirchneriella subcapitata</i> (green algae)): 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC ( <i>Oryzias latipes</i> (Orange-red killifish)): 1.24 mg/l Exposure time: 41 d Method: OECD Test Guideline 210

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

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): 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 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 / Trimethoprim Injection Formulation

Version 3.0      Revision Date: 2023/04/04      SDS Number: 7848286-00008      Date of last issue: 2022/10/01  
Date of first issue: 2021/03/03

---

### 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

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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

### 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.

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : UN 2491  
 Proper shipping name : ETHANOLAMINE SOLUTION  
 Class : 8  
 Packing group : III  
 Labels : 8

##### 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)  
 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.

#### 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.

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

---

### 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Ethanolamine

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

**The components of this product are reported in the following inventories:**

DSL : not determined

AICS : not determined

IECSC : not determined

---

### 16. OTHER INFORMATION

Revision Date : 2023/04/04

**Further information**

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
3.0	2023/04/04	7848286-00008	Date of first issue: 2021/03/03

---

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
ID OEL / NAB : Long term exposure limit  
ID OEL / PSD : Short term exposure limit

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - 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; WHMIS - Workplace Hazardous Materials Information System

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.

ID / EN