

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

---

**SECTION 1. IDENTIFICATION**

Product name : Sulfamethoxazole / Trimethoprim Injection Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Acute toxicity (Oral) : Category 5

Skin corrosion/irritation : Sub-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: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

Hazard pictograms

:



Signal Word

:

Danger

Hazard Statements

:

H303 May be harmful if swallowed.  
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 vapors.  
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 or 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.  
P312 Call a POISON CENTER/ doctor if you feel unwell.  
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	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

**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	$\geq 70$ -< 90
Sulfamethoxazole	723-46-6	$\geq 10$ -< 20
Ethanolamine	141-43-5	$\geq 5$ -< 10
Trimethoprim	738-70-5	$\geq 3$ -< 5

**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.
- 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 digestive tract burns.  
May be harmful if swallowed.  
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.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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.

**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.

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 4.0      Revision Date: 14.04.2025      SDS Number: 7848265-00010      Date of last issue: 30.09.2023  
Date of first issue: 03.03.2021

### 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.  
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:  
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	CMP	3 ppm	AR OEL
		CMP - CPT	6 ppm	AR 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-

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.   |
| Filter type              | : | Combined particulates and organic vapor type   |
| Hand protection          | : |  |
| Material                 | : | Chemical-resistant gloves  |
| Eye protection           | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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    |

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
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 characteristics	:	
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**

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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

**Acute toxicity**

May be harmful if swallowed.

**Product:**

Acute oral toxicity	: Acute toxicity estimate: 4.368 mg/kg Method: Calculation method
Acute inhalation toxicity	: Acute toxicity estimate: > 40 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

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

Application Route: Intravenous

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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

cytogenetic test, chromosomal analysis)  
Species: Humans  
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

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

Exposure time	: 26 weeks
Result	: negative

**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.  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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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

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 : >= 0,15 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 28 Days  
Method : OECD Test Guideline 412

#### Trimethoprim:

Species : Rat

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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
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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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

M-Factor (Acute aquatic toxicity) : 10

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

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 (*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  
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

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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  
Method: OECD Test Guideline 209

EC50: > 1.000 mg/l  
Exposure time: 3 hrs  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

**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:**

Biaccumulation	:	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:**

**Sulfamethoxazole / Trimethoprim Injection  
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
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)
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.

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

### 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

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

Argentina. Carcinogenic Substances and Agents : Not applicable  
Registry.

Control of precursors and essential chemicals for the : Not applicable  
preparation of drugs.

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

DSL : not determined

AICS : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025  
Date format : dd.mm.yyyy

### Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD  
compile the Material Safety eChem Portal search results and European Chemicals Agen-  
Data Sheet cy, <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.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
AR OEL / CMP : TLV (Threshold Limit Value)  
AR OEL / CMP - CPT : STEL (Short Term Limit Value)

AIIC - 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;

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.0	14.04.2025	7848265-00010	Date of first issue: 03.03.2021

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.

AR / Z8