

## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.0      Revision Date: 04.04.2023      SDS Number: 7848289-00008      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfamethoxazole / Trimethoprim Injection Formulation

#### Manufacturer or supplier's details

Company name of supplier : MSD  
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@msd.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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### 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 1 (Bone marrow)

#### GHS label elements

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.  
H372 Causes damage to organs (Bone marrow) through prolonged or repeated exposure.

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### 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.  
 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/ face protection.

#### Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/ physician.  
 P303 + P361 + P353 + P310 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower. Immediately call a POISON CENTER or doctor/ physician.  
 P304 + P340 + P310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/ physician.  
 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 or doctor/ physician.  
 P312 Call a POISON CENTER or doctor/ physician if you feel unwell.  
 P363 Wash contaminated clothing before reuse.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ 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	>= 70 -< 90
Sulfamethoxazole	723-46-6	>= 10 -< 20
Ethanolamine	141-43-5	>= 5 -< 10
Trimethoprim	738-70-5	>= 1 -< 5

## SECTION 4. FIRST AID MEASURES

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- 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.  
Causes 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.
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### 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.

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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.

### 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 the 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.

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- Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- 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.
- 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	VLE-PPT	3 ppm	NOM-010-STPS-2014
		VLE-CT	6 ppm	NOM-010-STPS-2014
		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.

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### 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.   |
- 

### 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               |
| 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> |
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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

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-  
tions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents  
Acids

Hazardous decomposition : No hazardous decomposition products are known.  
products

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### 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

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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

### **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



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### 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  
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

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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
Genotoxicity in vitro	: 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 vitro	: 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)
	Result: negative
	: Test Type: In vitro mammalian cell gene mutation test
Genotoxicity in vitro	: Method: OECD Test Guideline 476
	Result: negative
Genotoxicity in vitro	: Test Type: Chromosome aberration test in vitro
	Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo)

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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.

### 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

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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  
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.

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### 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  
|| 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

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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
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## 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 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	: EC50 (Ceriodaphnia dubia (water flea)): 0.21 mg/l

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aquatic invertebrates	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
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
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
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC ( <i>Daphnia magna</i> (Water flea)): 0.85 mg/l Exposure time: 21 d
Toxicity to microorganisms	: EC10 ( <i>Pseudomonas putida</i> ): > 1,000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

### Trimethoprim:

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

### Persistence and degradability

#### Components:

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

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

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

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

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

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

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### SECTION 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.

#### Domestic regulation

##### NOM-002-SCT

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

#### 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.

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### SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, : Not applicable

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essential chemical products and machinery for producing capsules, tablets and pills.

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

DSL	:	not determined
AICS	:	not determined
IECSC	:	not determined

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### SECTION 16. OTHER INFORMATION

Revision Date	:	04.04.2023
Date format	:	dd.mm.yyyy

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NOM-010-STPS-2014 / VLE-	:	Time weighted average limit value
PPT	:	
NOM-010-STPS-2014 / VLE-	:	Short term exposure limit value
CT	:	

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; 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,

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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

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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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