

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Sulfamethoxazole / Trimethoprim Injection Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Skin corrosion, Sub-category 1B	H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

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 through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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.  
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.  
P391 Collect spillage.

**Hazardous components which must be listed on the label:**

Ethanolamine  
Trimethoprim

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

---

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7 225-248-9	Eye Irrit. 2; H319	>= 70 - < 90
Sulfamethoxazole	723-46-6 211-963-3	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 10 - < 20
Ethanolamine	141-43-5 205-483-3 603-030-00-8	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT SE 3; H335 Aquatic Chronic 3; H412 <hr/> specific concentration limit STOT SE 3; H335 >= 5 % <hr/> Acute toxicity esti- mate  Acute oral toxicity: 1,089 mg/kg Acute inhalation tox- icity (vapour): 11 mg/l Acute dermal toxicity: 1,018 mg/kg	>= 5 - < 10
Trimethoprim	738-70-5 212-006-2	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow) Aquatic Chronic 2; H411	>= 3 - < 10

For explanation of abbreviations see section 16.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- 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.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : 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.

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

#### 5.2 Special hazards arising from the substance or mixture

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

#### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

---

### SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |   |
|-------------------------|---|---|
| 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.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>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.<br>Do not eat, drink or smoke when using this product.<br>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.<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.  |

### 7.2 Conditions for safe storage, including any incompatibilities

- |   |   |   |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in |
|---|---|---|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sulfamethoxazole	723-46-6	TWA	OEB 2 ( $\geq 100 < 1000$ $\mu\text{g}/\text{m}^3$ )	Internal
Ethanolamine	141-43-5	TWA	1 ppm 2.5 mg/m <sup>3</sup>	2006/15/EC
		Further information: Indicative, Identifies the possibility of significant uptake through the skin		
		STEL	3 ppm 7.6 mg/m <sup>3</sup>	2006/15/EC
		Further information: Indicative, Identifies the possibility of significant uptake through the skin		
		OELV - 8 hrs (TWA)	1 ppm 2.5 mg/m <sup>3</sup>	IE OEL
		Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body		
		OELV - 15 min (STEL)	3 ppm 7.6 mg/m <sup>3</sup>	IE OEL
		Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body		
Trimethoprim	738-70-5	TWA	400 $\mu\text{g}/\text{m}^3$ (OEB 2)	Internal

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanolamine	Workers	Inhalation	Long-term local effects	3.3 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	1 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	2 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic	0.24 mg/kg

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

			effects	bw/day
	Consumers	Ingestion	Long-term systemic effects	3.75 mg/kg bw/day

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Trimethoprim	Water	0.9 mg/l
Ethanolamine	Fresh water	0.085 mg/l
	Freshwater - intermittent	0.028 mg/l
	Marine water	0.0085 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	0.434 mg/kg dry weight (d.w.)
	Marine sediment	0.0434 mg/kg dry weight (d.w.)
	Soil	0.0367 mg/kg dry weight (d.w.)

## 8.2 Exposure controls

### 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

Eye/face 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.

Hand protection  
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to I.S. EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : liquid  
Colour : light yellow  
Odour : No data available  
Odour Threshold : No data available



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	9.5 - 10.5
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	1.050 - 1.230 g/cm <sup>3</sup>
Relative vapour density	:	No data available
Particle characteristics		
Particle size	:	Not applicable

### 9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : None known.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents  
Acids

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

### SECTION 11: Toxicological information

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

#### Acute toxicity

Not classified based on available information.

#### Product:

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

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.

### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

---

### Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

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

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 21 days  
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:

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

##### Ethanolamine:

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

##### Trimethoprim:

Test Type : Maximisation Test  
Exposure routes : Dermal

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

Species : Guinea pig  
Result : Not a skin sensitizer.

### Germ cell mutagenicity

Not classified based on available information.

### Components:

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

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

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

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

#### **Sulfamethoxazole:**

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

Test Type: Chromosome aberration test in vitro  
Result: negative

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

---

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

### 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  
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 through prolonged or repeated exposure.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

---

### 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  
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



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

##### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### 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

### 12.1 Toxicity

##### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

---

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

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

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

M-Factor (Chronic aquatic toxicity) : 10

### 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  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (*Pseudomonas putida*): > 1,000 mg/l

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

---

Exposure time: 30 min  
Method: OECD Test Guideline 209

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

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

### 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 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

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

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

### 12.2 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

### 12.3 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

### Trimethoprim:

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

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

---

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN	: UN 2491
ADR	: UN 2491
RID	: UN 2491
IMDG	: UN 2491
IATA	: UN 2491

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version 3.2      Revision Date: 04.04.2023      SDS Number: 7858259-00009      Date of last issue: 01.10.2022  
Date of first issue: 03.03.2021

---

### 14.2 UN proper shipping name

**ADN** : ETHANOLAMINE, SOLUTION  
**ADR** : ETHANOLAMINE, SOLUTION  
**RID** : ETHANOLAMINE, SOLUTION  
**IMDG** : ETHANOLAMINE SOLUTION  
(Sulfamethoxazole)  
**IATA** : Ethanolamine solution

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	: 8	
<b>ADR</b>	: 8	
<b>RID</b>	: 8	
<b>IMDG</b>	: 8	
<b>IATA</b>	: 8	

### 14.4 Packing group

**ADN**  
Packing group : III  
Classification Code : C7  
Hazard Identification Number : 80  
Labels : 8

**ADR**  
Packing group : III  
Classification Code : C7  
Hazard Identification Number : 80  
Labels : 8  
Tunnel restriction code : (E)

**RID**  
Packing group : III  
Classification Code : C7  
Hazard Identification Number : 80  
Labels : 8

**IMDG**  
Packing group : III  
Labels : 8  
EmS Code : F-A, S-B

**IATA (Cargo)**  
Packing instruction (cargo aircraft) : 856  
Packing instruction (LQ) : Y841  
Packing group : III  
Labels : Corrosive

**IATA (Passenger)**

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

Packing instruction (passenger aircraft) : 852  
Packing instruction (LQ) : Y841  
Packing group : III  
Labels : Corrosive

### 14.5 Environmental hazards

#### ADN

Environmentally hazardous : yes

#### ADR

Environmentally hazardous : yes

#### RID

Environmentally hazardous : yes

#### IMDG

Marine pollutant : yes

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3  
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable  
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable  
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable  
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable  
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable  
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
----	-----------------------	---------------------	---------------------

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : 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 H-Statements

H302	:	Harmful if swallowed.
H312	:	Harmful in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H332	:	Harmful if inhaled.
H335	:	May cause respiratory irritation.
H361d	:	Suspected of damaging the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H411	:	Toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
2006/15/EC	:	Europe. Indicative occupational exposure limit values
IE OEL	:	Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

2006/15/EC / TWA	:	Limit Value - eight hours
2006/15/EC / STEL	:	Short term exposure limit
IE OEL / OELV - 8 hrs (TWA)	:	Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL)	:	Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

Skin Corr. 1B	H314
Eye Dam. 1	H318
Repr. 2	H361d
STOT SE 3	H335
STOT RE 2	H373

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.2	04.04.2023	7858259-00009	Date of first issue: 03.03.2021

---

Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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.

IE / EN