# Sulfamethoxazole / Trimethoprim Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
|---|---|---|---|
| 6.0 | 14.04.2025 | 7954347-00012 | Date of first issue: 09.04.2021 |

## 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 Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

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

Company : MSD
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A
Çubuk Yolu 2. Km
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

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

### 1.4 Emergency telephone number

National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification T.R. SEA No 28848 and subsequent amendments**

| | |
|---|---|
| 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 T.R. SEA No 28848 and subsequent amendments**

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

None known.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

**Components**

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>KKDIK Registration No. | SEA Classification | Concentration (% w/w) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 1,3-Dioxan-5-ol | 4740-78-7<br>225-248-9 | Eye Irrit. 2; H319 | >= 70 - < 90 |
| Sulfamethoxazole | 723-46-6<br>211-963-3 | Aquatic Acute 1; H400<br>Aquatic Chronic 1; H410<br>---<br>M-Factor (Acute aquatic toxicity): 10<br>M-Factor (Chronic aquatic toxicity): 10 | >= 10 - < 20 |
| Ethanolamine | 141-43-5<br>205-483-3<br>603-030-00-8 | Acute Tox. 4; H302<br>Acute Tox. 4; H332<br>Acute Tox. 4; H312<br>Skin Corr. 1B; H314<br>Eye Dam. 1; H318<br>STOT SE 3; H335<br>Aquatic Chronic 3; H412<br>---<br>specific concentration limit<br>STOT SE 3; H335<br>>= 5 % | >= 5 - < 10 |
| Trimethoprim | 738-70-5<br>212-006-2 | Acute Tox. 4; H302<br>Repr. 2; H361d<br>STOT RE 1; H372 (Bone marrow)<br>Aquatic Chronic 2; H411 | >= 3 - < 10 |

For explanation of abbreviations see section 16.

## 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.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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 (NOx)<br>Sulphur oxides<br>Carbon oxides |

### 5.3 Advice for firefighters

| | | |
|---|---|---|
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |

## SECTION 6: Accidental release measures

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

| | | |
|---|---|---|
| Personal precautions | : | Use personal protective equipment.<br>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.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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 accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>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 (>= 100 < 1000 µg/m3) | Internal |
| Ethanolamine | 141-43-5 | TWA (8 Hour) | 1 ppm<br>2,5 mg/m3 | TR OEL |
| | Further information: A skin notation assigned to the OEL identifies the possibility of significant uptake through the skin. | | | |
| | | STEL 15 min | 3 ppm<br>7,6 mg/m3 | TR OEL |
| | Further information: A skin notation assigned to the OEL identifies the possibility of significant uptake through the skin. | | | |
| | | TWA | 1 ppm<br>2,5 mg/m3 | 2006/15/EC |
| | Further information: Indicative, Identifies the possibility of significant uptake through the skin | | | |
| | | STEL | 3 ppm<br>7,6 mg/m3 | 2006/15/EC |
| | Further information: Indicative, Identifies the possibility of significant uptake through the skin | | | |
| Trimethoprim | 738-70-5 | TWA | 400 µg/m3 (OEB 2) | Internal |

**Derived No Effect Level (DNEL)**

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|---|---|---|---|---|
| Ethanolamine | Workers | Inhalation | Long-term local effects | 3,3 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 1 mg/kg bw/day |
| | Consumers | Inhalation | Long-term local effects | 2 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 0,24 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 3,75 mg/kg bw/day |
| Ethanolamine | Workers | Inhalation | Long-term local effects | 3,3 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 1 mg/kg bw/day |
| | Consumers | Inhalation | Long-term local effects | 2 mg/m3 |

| | | | | |
|---|---|---|---|---|
| | Consumers | Skin contact | Long-term systemic effects | 0,24 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 3,75 mg/kg bw/day |

**Predicted No Effect Concentration (PNEC):**

| 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.
Filter should conform to TS 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

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

| | | |
|---|---|---|
| Odour Threshold | : | No data available |
| pH | : | 9,5 - 10,5 |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | 1,050 - 1,230 g/cm³ |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |

**9.2 Other information**

| | | |
|---|---|---|
| Molecular weight | : | No data available |
| Particle size | : | Not applicable |

## 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 toxicological effects

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

| | | |
|---|---|---|
| Acute dermal toxicity | : | LD50 (Rat): > 2.000 mg/kg<br>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<br>Exposure time: 4 h<br>Test atmosphere: vapour<br>Method: Expert judgement<br>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<br><br>LD50 (Mouse): 1.910 - 7.000 mg/kg |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 400 - 500 mg/kg<br>Application Route: Intraperitoneal<br><br>LD50 (Dog): 90 mg/kg<br>Application Route: Intravenous<br><br>LD50 (Mouse): 132 mg/kg<br>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 |
| 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 Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |

**Trimethoprim:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Dermal |
| Species | : | Guinea pig |
| Result | : | Not a skin sensitizer. |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

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

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Result: negative<br>Remarks: Based on data from similar materials |

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Humans<br>Result: negative |

**Ethanolamine:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion |

Method: OECD Test Guideline 474
Result: negative

**Trimethoprim:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Rat<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Species: Humans<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 416<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal develop- | : | Test Type: Embryo-foetal development |

| | | |
|---|---|---|
| ment | | Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 414<br>Result: negative |

**Trimethoprim:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 70 mg/kg body weight<br>Result: No effects on fertility |
| Effects on foetal development | : | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 70 mg/kg body weight<br>Result: Effects on newborn<br>Remarks: Maternal toxicity observed.<br><br>Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 70 mg/kg body weight<br>Result: Embryotoxic effects.<br>Remarks: Maternal toxicity observed.<br><br>Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 15 mg/kg body weight<br>Result: Embryotoxic effects., Teratogenic effects<br><br>Test Type: Development<br>Species: Hamster<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 1,7 mg/kg body weight<br>Result: Embryotoxic effects., No teratogenic effects<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 100 mg/kg body weight<br>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.

**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 |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Trimethoprim:**

| | | |
|---|---|---|
| Ingestion | : | Target Organs: Bone marrow<br>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<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l<br>Exposure time: 72 h<br>Remarks: Based on data from similar materials<br><br>NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : | EC10 : > 1.000 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209<br>Remarks: Based on data from similar materials |

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): 562,5 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 0,21 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (Synechococcus leopoliensis (blue-green algae)): 0,0268 mg/l<br>Exposure time: 96 h<br><br>NOEC (Synechococcus leopoliensis (blue-green algae)): 0,0059 mg/l<br>Exposure time: 96 h |
| M-Factor (Acute aquatic toxicity) | : | 10 |
| Toxicity to microorganisms | : | NOEC (activated sludge): 3,76 mg/l<br>Method: OECD Test Guideline 301D |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 0,533 mg/l<br>Exposure time: 21 d<br>Species: Danio rerio (zebra fish) |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,01 mg/l<br>Exposure time: 30 d<br>Species: Daphnia magna (Water flea) |
| M-Factor (Chronic aquatic toxicity) | : | 10 |

**Ethanolamine:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Cyprinus carpio (Carp)): 349 mg/l<br>Exposure time: 96 h<br>Method: Directive 67/548/EEC, Annex V, C.1. |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 65 mg/l<br>Exposure time: 48 h<br>Method: Directive 67/548/EEC, Annex V, C.2. |
| Toxicity to algae/aquatic plants | : | ErC50 (Pseudokirchneriella subcapitata (green algae)): 2,8 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to microorganisms | : | EC10 (Pseudomonas putida): > 1.000 mg/l<br>Exposure time: 30 min<br>Method: OECD Test Guideline 209 |

| | | |
|---|---|---|
| Toxicity to fish (Chronic toxicity) | : | NOEC: 1,24 mg/l<br>Exposure time: 41 d<br>Species: Oryzias latipes (Orange-red killifish)<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,85 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea) |

**Trimethoprim:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 100 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna Straus): 92 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (microalgae)): 80,3 mg/l<br>Exposure time: 72 h<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l<br>Exposure time: 72 h<br><br>EC50 (Anabaena flos-aquae): 253 mg/l<br>Exposure time: 72 h<br><br>EC10 (Anabaena flos-aquae): 26 mg/l<br>Exposure time: 72 h |
| Toxicity to microorganisms | : | EC10 : 16,7 mg/l<br>Exposure time: 3 hrs<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>EC50 : > 1.000 mg/l<br>Exposure time: 3 hrs<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 0,157 mg/l<br>Exposure time: 21 d<br>Species: Zebrafish |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 6 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea) |

### 12.2 Persistence and degradability

**Components:**

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

| | | |
|---|---|---|
| Biodegradability | : | Result: Inherently biodegradable.<br>Remarks: Based on data from similar materials |

**Sulfamethoxazole:**

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

**Ethanolamine:**

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

**Trimethoprim:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 4 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301D<br><br>Result: Not inherently biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>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)<br>Bioconcentration factor (BCF): < 120 |
| Partition coefficient: n-octanol/water | : | log Pow: 0,89 |

**Ethanolamine:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -2,3<br>Method: OECD Test Guideline 107 |

**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

Not relevant

### 12.6 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

| | | |
|---|---|---|
| Product | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.<br>Waste management needs to comply with provisions laid down in Waste Management Regulation (TR Official Gazette, 2015, Number: 29314) and with the respective national provisions legally enforced<br>Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.<br>Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14: Transport information

### 14.1 UN number

| | | |
|---|---|---|
| **ADN** | : | UN 2491 |
| **ADR** | : | UN 2491 |
| **RID** | : | UN 2491 |
| **IMDG** | : | UN 2491 |
| **IATA** | : | UN 2491 |

### 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 |
|---|---|---|---|
| **ADN** | : | 8 | |
| **ADR** | : | 8 | |
| **RID** | : | 8 | |
| **IMDG** | : | 8 | |
| **IATA** | : | 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)**

| | | |
|---|---|---|
| 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 Transport in bulk according to Annex II of Marpol and the IBC Code**

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**

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published) : Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702

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

**Other regulations:**

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.
Regulation on health and safety measures regarding working with chemicals (Number:28733, 2013 as amended (Nr. 32345, 2023). Occupational Exposure Limit Values (Annex 1)
Regulation on Import and Export of Certain Hazardous Chemicals, No. 32087, 2023 : Not 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.<br>The SDS has been prepared by: Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025 |

**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. |

**The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.**

**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 |
| TR OEL | : | Türkiye. Chemical Agents at Work - Annex I: Indicative occupational exposure limit values |
| 2006/15/EC / TWA | : | Limit Value - eight hours |
| 2006/15/EC / STEL | : | Short term exposure limit |
| TR OEL / TWA (8 Hour) | : | Measured or calculated in relation to a reference period of eight-hour time-weighted average |
| TR OEL / STEL 15 min | : | A limit value above which exposure should not occur and is related to a 15-minute period, unless otherwise specified |

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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

**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:** | | **Classification procedure:** |
|---|---|---|
| Skin Corr. 1B | H314 | Calculation method |
| Eye Dam. 1 | H318 | Calculation method |
| Repr. 2 | H361d | Calculation method |
| STOT SE 3 | H335 | Calculation method |
| STOT RE 2 | H373 | Calculation method |
| Aquatic Acute 1 | H400 | Calculation method |
| Aquatic Chronic 1 | H410 | Calculation method |

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

TR / EN