

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

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

1.1 Product identifier

Trade name : Sulfamethoxazole / Trimethoprim 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 1A	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 - 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

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

- Hazard pictograms :
- Signal word : Danger
- Hazard statements : H314 Causes severe skin burns and eye damage.
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.
- Supplemental Hazard Statements : EUH071 Corrosive to the respiratory tract.
- 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:

Trimethoprim

Sodium hydroxide

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. KKDIK Registration No.	SEA Classification	Concentration (% w/w)
Sulfamethoxazole	723-46-6 211-963-3	Aquatic Acute 1; H400	>= 30 - < 50

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

		Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 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
Sodium hydroxide	1310-73-2 215-185-5 011-002-00-6	Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318 specific concentration limit Skin Corr. 1A; H314 >= 5 % Skin Corr. 1B; H314 2 - < 5 % Skin Irrit. 2; H315 0,5 - < 2 % Eye Irrit. 2; H319 0,5 - < 2 % EUH071 >= 2 %	>= 5 - < 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).

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.3	30.09.2023	6289831-00013	Date of first issue: 25.08.2020

-
- | | | |
|-------------------------|---|--|
| 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 serious eye damage.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.
Causes severe burns.
Corrosive to the respiratory tract. Causes digestive tract 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 (CO ₂)
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 prod- | : | Carbon oxides |

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.3	30.09.2023	6289831-00013	Date of first issue: 25.08.2020

ucts

Nitrogen oxides (NO_x)
Sulphur oxides
Metal 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. 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.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

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.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
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.

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. Store in 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	Control parameters	Basis
------------	---------	------------------	--------------------	-------

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

		of exposure)		
Sulfamethoxazole	723-46-6	TWA	OEB 2 ($\geq 100 < 1000$ $\mu\text{g}/\text{m}^3$)	Internal
Trimethoprim	738-70-5	TWA	400 $\mu\text{g}/\text{m}^3$ (OEB 2)	Internal

Derived No Effect Level (DNEL) :

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium hydroxide	Consumers	Inhalation	Long-term local effects	1 mg/m ³
	Workers	Inhalation	Long-term local effects	1 mg/m ³

Predicted No Effect Concentration (PNEC) :

Substance name	Environmental Compartment	Value
Trimethoprim	Water	0,9 mg/l

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 TS EN 143
- Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : suspension
Colour : white to off-white
Odour : No data available
Odour Threshold : No data available
- pH : 9,5 - 12,5

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

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
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	:	1,179 g/cm ³
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

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	Not applicable

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

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

Components:

Sulfamethoxazole:

Acute oral toxicity : LD50 (Mouse): 2.300 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

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

LD50 (Dog): 90 mg/kg
Application Route: Intravenous

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

Sodium hydroxide:

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation

Causes severe burns.

Components:

Sulfamethoxazole:

Species : Rabbit
Result : No skin irritation

Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Sodium hydroxide:

Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Sulfamethoxazole:

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

Trimethoprim:

Test Type : Maximisation Test
Exposure routes : Dermal

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

Species : Guinea pig
Result : Not a skin sensitizer.

Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

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

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.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

Components:

Sulfamethoxazole:

Species : Mouse
Application Route : Ingestion
Exposure time : 26 weeks
Result : negative

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

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 - As- : Suspected of damaging the unborn child.

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

essment

STOT - single exposure

Corrosive to the respiratory tract.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Trimethoprim:

Target Organs : Bone marrow
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

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
Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

SECTION 12: Ecological information

12.1 Toxicity

Components:

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

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

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.3	30.09.2023	6289831-00013	Date of first issue: 25.08.2020

		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)

12.2 Persistence and degradability

Components:

Sulfamethoxazole:

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

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:

Sulfamethoxazole:

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

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.3	30.09.2023	6289831-00013	Date of first issue: 25.08.2020

Partition coefficient: n-octanol/water : log Pow: 0,89

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	:	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

ADN	:	UN 1824
ADR	:	UN 1824
RID	:	UN 1824
IMDG	:	UN 1824
IATA	:	UN 1824

14.2 UN proper shipping name

ADN	:	SODIUM HYDROXIDE SOLUTION
ADR	:	SODIUM HYDROXIDE SOLUTION
RID	:	SODIUM HYDROXIDE SOLUTION
IMDG	:	SODIUM HYDROXIDE SOLUTION (Sulfamethoxazole)
IATA	:	Sodium hydroxide solution

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version 5.3 Revision Date: 30.09.2023 SDS Number: 6289831-00013 Date of last issue: 04.04.2023
Date of first issue: 25.08.2020

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	: II
Classification Code	: C5
Hazard Identification Number	: 80
Labels	: 8
ADR	
Packing group	: II
Classification Code	: C5
Hazard Identification Number	: 80
Labels	: 8
Tunnel restriction code	: (E)
RID	
Packing group	: II
Classification Code	: C5
Hazard Identification Number	: 80
Labels	: 8
IMDG	
Packing group	: II
Labels	: 8
EmS Code	: F-A, S-B
IATA (Cargo)	
Packing instruction (cargo aircraft)	: 855
Packing instruction (LQ)	: Y840
Packing group	: II
Labels	: Corrosive
IATA (Passenger)	
Packing instruction (passenger aircraft)	: 851
Packing instruction (LQ)	: Y840
Packing group	: II
Labels	: Corrosive

14.5 Environmental hazards

ADN	
Environmentally hazardous	: yes
ADR	

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.3	30.09.2023	6289831-00013	Date of first issue: 25.08.2020

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.

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

DSL : not determined

AICS : not determined

IECSC : not determined

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.3	30.09.2023	6289831-00013	Date of first issue: 25.08.2020

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.

The SDS has been prepared by: Name: Gökhan Ardiç; 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

H290 : May be corrosive to metals.
H302 : Harmful if swallowed.
H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.
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.

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
Met. Corr. : Corrosive to metals
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 - Interna-

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfamethoxazole / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.3	30.09.2023	6289831-00013	Date of first issue: 25.08.2020

tional 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; 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:

Skin Corr. 1A	H314
Eye Dam. 1	H318
Repr. 2	H361d
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
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.

TR / EN