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: 06.04.2024

 7.0
 28.09.2024
 6289831-00015
 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 Sub- : Veterinary product

stance/Mixture

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 H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate- H400: Very toxic to aquatic life.

gory 1

egory 1

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

effects.

2.2 Label elements

Labelling T.R. SEA No 28848 and subsequent amendments

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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 protec-

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

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: 06.04.2024

 7.0
 28.09.2024
 6289831-00015
 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 ————————————————————————————————————	>= 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 ad-

vice 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).

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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 contact, immediately flush eyes with plenty of water In case of eye contact

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

fighting

Specific hazards during fire- : Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

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: 06.04.2024

 7.0
 28.09.2024
 6289831-00015
 Date of first issue: 25.08.2020

ucts Nitrogen oxides (NOx)

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective 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 absor-

bent.

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 deter-

mine 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.

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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 as-

sessment

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 contami-

nated 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-N	o. Value type (Form	Control parameters	Basis
------------------	---------------------	--------------------	-------

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: 06.04.2024

 7.0
 28.09.2024
 6289831-00015
 Date of first issue: 25.08.2020

		of exposure)		
Sulfamethoxazole	723-46-6	TWA	OEB 2 (>= 100 < 1000	Internal
			μg/m3)	
Trimethoprim	738-70-5	TWA	400 μg/m3 (OEB 2)	Internal
Sodium hydroxide	1310-73-2	TWA (8 Hour)	2 mg/m3	TR OEL

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium hydroxide	Consumers	Inhalation	Long-term local ef- fects	1 mg/m3
	Workers	Inhalation	Long-term local ef- fects	1 mg/m3

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended 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

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: 06.04.2024 7.0 28.09.2024 6289831-00015 Date of first issue: 25.08.2020

pH : 9,5 - 12,5

Melting point/freezing point : No data available

Initial boiling point and boiling

range

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

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/cm³

Solubility(ies)

Water solubility
Partition coefficient: n-

octanol/water

No data available

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

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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 : Inhalation

exposure 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 : LD50 (Rat): 400 - 500 mg/kg

administration)

Application Route: Intraperitoneal

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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

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: 06.04.2024

 7.0
 28.09.2024
 6289831-00015
 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 syn-

thesis 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.

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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 develop-

ment

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.

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: 06.04.2024 7.0 28.09.2024 6289831-00015 Date of first issue: 25.08.2020

sessment

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: DogNOAEL: 2,5 mg/kgLOAEL: 45 mg/kgApplication Route: OralExposure time: 3 MonthsTarget 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

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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

aquatic invertebrates

Toxicity to daphnia and other : 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 ma/l

Exposure time: 96 h

M-Factor (Acute aquatic tox- :

icity)

Toxicity to microorganisms NOEC (activated sludge): 3,76 mg/l

Method: OECD Test Guideline 301D

Toxicity to fish (Chronic tox-

icity)

NOEC: 0,533 mg/l

Exposure time: 21 d

Species: Danio rerio (zebra fish)

Toxicity to daphnia and other : NOEC: 0,01 mg/l aquatic invertebrates (Chron-

ic toxicity)

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

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna Straus): 92 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

: EC50 (Pseudokirchneriella subcapitata (microalgae)): 80,3

Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 16

Exposure time: 72 h

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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 tox-

icity)

NOEC: 0,157 mg/l Exposure time: 21 d

Species: Zebrafish

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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 han-

dling 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

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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

ino code .

IATA (Cargo)

Packing instruction (cargo : 855

aircraft)

Packing instruction (LQ) : Y840 Packing group : II

Labels : Corrosive

IATA (Passenger)

Packing instruction (passen- : 851

ger aircraft)

Packing instruction (LQ) : Y840
Packing group : II

Labels : Corrosive

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

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: 06.04.2024 7.0 28.09.2024 6289831-00015 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.

Not applicable

Regulation on Persistent Organic Pollutants (Number

30595 and subsequent amendments published)

Regulation on prevention of major industrial accidents. Reg number 30702

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

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 : Not applicable

Chemicals, No. 32087, 2023

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: 06.04.2024

 7.0
 28.09.2024
 6289831-00015
 Date of first issue: 25.08.2020

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.

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

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

TR OEL : Türkiye. Chemical Agents at Work - Annex I: Indicative occu-

pational exposure limit values

TR OEL / TWA (8 Hour) : Measured or calculated in relation to a reference period of

eight-hour time-weighted average

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

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: 06.04.2024

 7.0
 28.09.2024
 6289831-00015
 Date of first issue: 25.08.2020

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. 1A	H314	Calculation method
Eye Dam. 1	H318	Calculation method
Repr. 2	H361d	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

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: 06.04.2024

 7.0
 28.09.2024
 6289831-00015
 Date of first issue: 25.08.2020

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