SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.5	28.09.2024	7858245-00013	Date of first issue: 03.03.2021

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

1.1 Product identifier

Trade name : Sulfamethoxazole / Trimethoprim Injection Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements :
H314 Causes severe skin burns and eye damage.
H335 May cause respiratory irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

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

Response:

P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Ethanolamine
Trimethoprim

2.3 Other hazards

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

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

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7 225-248-9	Eye Irrit. 2; H319	>= 70 - < 90
Sulfamethoxazole	723-46-6 211-963-3	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 _____ M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 10 - < 20
Ethanolamine	141-43-5 205-483-3 603-030-00-8	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT SE 3; H335 Aquatic Chronic 3; H412 _____ specific concentration limit STOT SE 3; H335 >= 5 % _____ Acute toxicity estimate Acute oral toxicity: 1.089 mg/kg Acute inhalation toxicity (vapour): 11 mg/l Acute dermal toxicity: 1.018 mg/kg	>= 5 - < 10
Trimethoprim	738-70-5 212-006-2	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372	>= 3 - < 10

		(Bone marrow) Aquatic Chronic 2; H411	

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 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.

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

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

Hazardous combustion products : Nitrogen oxides (NOx)
Sulphur oxides
Carbon oxides

5.3 Advice for firefighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil

barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
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.
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.
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. 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:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sulfamethoxazole	723-46-6	TWA	OEB 2 (>= 100 < 1000 µg/m3)	Internal
Ethanolamine	141-43-5	TWA	1 ppm 2,5 mg/m3	FOR-2011-12-06-1358
	Further information: Chemicals that can be absorbed through the skin.			
		TWA	1 ppm 2,5 mg/m3	2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin			
		STEL	3 ppm 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) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanolamine	Workers	Inhalation	Long-term local effects	3,3 mg/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) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Trimethoprim	Water	0,9 mg/l
Ethanolamine	Fresh water	0,085 mg/l
	Freshwater - intermittent	0,028 mg/l
	Marine water	0,0085 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	0,434 mg/kg dry weight (d.w.)
	Marine sediment	0,0434 mg/kg dry weight (d.w.)
	Soil	0,0367 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

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

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	light yellow
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	9,5 - 10,5
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	1,050 - 1,230 g/cm³

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Acids

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2.000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 20 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 2.000 mg/kg Method: Calculation method

Components:

1,3-Dioxan-5-ol:

Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg
Acute dermal toxicity	:	LD50 (Rat): > 2.000 mg/kg Remarks: Based on data from similar materials

Sulfamethoxazole:

Acute oral toxicity	:	LD50 (Mouse): 2.300 mg/kg

Ethanolamine:

Acute oral toxicity	:	LD50 (Rat): 1.089 mg/kg
Acute inhalation toxicity	:	Acute toxicity estimate: 11 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Expert judgement Remarks: Based on national or regional regulation.
Acute dermal toxicity	:	LD50 (Rabbit, female): 1.018 mg/kg

Trimethoprim:

Acute oral toxicity	:	LD50 (Rat): 1.500 - 5.300 mg/kg LD50 (Mouse): 1.910 - 7.000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 400 - 500 mg/kg Application Route: Intraperitoneal LD50 (Dog): 90 mg/kg Application Route: Intravenous LD50 (Mouse): 132 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Causes severe burns.

Components:

1,3-Dioxan-5-ol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Sulfamethoxazole:

Species	:	Rabbit
Result	:	No skin irritation

Ethanolamine:

Species	:	Rabbit
Result	:	Corrosive after 3 minutes to 1 hour of exposure

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)
Result: negative

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

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

Sulfamethoxazole:

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

Test Type: Chromosome aberration test in vitro
Result: negative

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

Species: Humans
Result: negative

Ethanolamine:

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Trimethoprim:

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

Test Type: Chromosomal aberration
Result: negative

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

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Result: negative

Test Type: Chromosomal aberration
Species: Humans
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Sulfamethoxazole:

Species : Mouse

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

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Ethanolamine:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative

Trimethoprim:

Effects on fertility	:	Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 70 mg/kg body weight Result: No effects on fertility
Effects on foetal development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 70 mg/kg body weight Result: Effects on newborn Remarks: Maternal toxicity observed. Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 70 mg/kg body weight Result: Embryotoxic effects. Remarks: Maternal toxicity observed. Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 15 mg/kg body weight Result: Embryotoxic effects., Teratogenic effects Test Type: Development

Species: Hamster
Application Route: Oral
Developmental Toxicity: LOAEL: 1,7 mg/kg body weight
Result: Embryotoxic effects., No teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryotoxic effects., No teratogenic effects

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

STOT - single exposure

May cause respiratory irritation.

Components:

Ethanolamine:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

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

Experience with human exposure

Components:

Trimethoprim:

Ingestion : Target Organs: Bone marrow
Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

SECTION 12: Ecological information

12.1 Toxicity

Components:

1,3-Dioxan-5-ol:

Toxicity to fish	:	LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC10 : > 1.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials

Sulfamethoxazole:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 562,5 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 0,21 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Synechococcus leopoliensis (blue-green algae)): 0,0268 mg/l Exposure time: 96 h NOEC (Synechococcus leopoliensis (blue-green algae)): 0,0059 mg/l Exposure time: 96 h
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to microorganisms	:	NOEC (activated sludge): 3,76 mg/l Method: OECD Test Guideline 301D

Toxicity to fish (Chronic toxicity)	:	NOEC: 0,533 mg/l Exposure time: 21 d Species: Danio rerio (zebra fish)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,01 mg/l Exposure time: 30 d Species: Daphnia magna (Water flea)
M-Factor (Chronic aquatic toxicity)	:	10

Ethanolamine:

Toxicity to fish	:	LC50 (Cyprinus carpio (Carp)): 349 mg/l Exposure time: 96 h Method: Directive 67/548/EEC, Annex V, C.1.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 65 mg/l Exposure time: 48 h Method: Directive 67/548/EEC, Annex V, C.2.
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): 2,8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC10 (Pseudomonas putida): > 1.000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 1,24 mg/l Exposure time: 41 d Species: Oryzias latipes (Orange-red killifish) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,85 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

Trimethoprim:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna Straus): 92 mg/l Exposure time: 48 h
Toxicity to algae/aquatic	:	EC50 (Pseudokirchneriella subcapitata (microalgae)): 80,3

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

12.2 Persistence and degradability

Components:

1,3-Dioxan-5-ol:

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

Sulfamethoxazole:

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

Ethanolamine:

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

Trimethoprim:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Result: Not inherently biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 302B

12.3 Bioaccumulative potential

Components:

1,3-Dioxan-5-ol:

Partition coefficient: n-octanol/water : log Pow: -0,65

Sulfamethoxazole:

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

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

Ethanolamine:

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

Trimethoprim:

Partition coefficient: n-octanol/water : log Pow: 0,91

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

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

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

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

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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

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.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the

working environment.
Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

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

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
2006/15/EC	:	Europe. Indicative occupational exposure limit values
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
2006/15/EC / TWA	:	Limit Value - eight hours
2006/15/EC / STEL	:	Short term exposure limit
FOR-2011-12-06-1358 /	:	Long term exposure limit

TWA

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

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.

NO / EN