SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
3.0	04.04.2023	7848265-00008	Date of first issue: 03.03.2021

SECTION 1. IDENTIFICATION

Product name : Sulfamethoxazole / Trimethoprim Injection Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 5

Skin corrosion/irritation : Sub-category 1B

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure : Category 3

Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements :
H303 May be harmful if swallowed.
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 (Bone marrow) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.
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.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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.
P312 Call a POISON CENTER/ doctor if you feel unwell.
P363 Wash contaminated clothing before reuse.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7	>= 70 -< 90
Sulfamethoxazole	723-46-6	>= 10 -< 20
Ethanolamine	141-43-5	>= 5 -< 10
Trimethoprim	738-70-5	>= 3 -< 5

SECTION 4. 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.

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 center immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Causes digestive tract burns.
May be harmful if swallowed.
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.

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).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

		Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Nitrogen oxides (NOx) Sulfur oxides Carbon oxides
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

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 vapors.
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 sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sulfamethoxazole	723-46-6	TWA	OEB 2 (>= 100 < 1000 µg/m3)	Internal
Ethanolamine	141-43-5	CMP	3 ppm	AR OEL
		CMP - CPT	6 ppm	AR OEL
		TWA	3 ppm	ACGIH
		STEL	6 ppm	ACGIH
Trimethoprim	738-70-5	TWA	400 µg/m3 (OEB 2)	Internal

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

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Combined particulates and organic vapor type
Hand protection		
Material	:	Chemical-resistant gloves
Eye 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.
Skin and body protection	:	Work uniform or laboratory coat.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	light yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	9,5 - 10,5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available

Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1,050 - 1,230 g/cm³
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition 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.
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents Acids
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

May be harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 4.368 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 40 mg/l Exposure time: 4 h Test atmosphere: vapor Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5.000 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: vapor Method: Expert judgment 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
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

Ethanolamine:

Species	:	Rabbit
Result	:	Irreversible effects on the eye

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

1,3-Dioxan-5-ol:

Test Type	:	Maximization Test
Routes of exposure	:	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
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Ethanolamine:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Trimethoprim:

Test Type	:	Maximization Test
Routes of exposure	:	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 fetal development	:	Test Type: Embryo-fetal 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 fetal 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 (Bone marrow) through prolonged or repeated exposure.

Components:

Ethanolamine:

Assessment	:	No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

Trimethoprim:

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

Repeated dose toxicity

Components:

Ethanolamine:

Species	:	Rat
NOAEL	:	> 120 mg/kg
Application Route	:	Ingestion
Exposure time	:	> 75 Days
Remarks	:	Based on data from similar materials

Species	:	Rat
NOAEL	:	>= 0,15 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days
Method	:	OECD Test Guideline 412

Trimethoprim:

Species	:	Rat
NOAEL	:	100 mg/kg
LOAEL	:	300 mg/kg
Application Route	:	Oral
Exposure time	:	6 Months
Target Organs	:	Bone marrow, Liver, Pituitary gland, Thyroid

Species	:	Rat
LOAEL	:	300 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Target Organs	:	Bone marrow

Species	:	Dog
NOAEL	:	2,5 mg/kg
LOAEL	:	45 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Target Organs	:	Blood, Thyroid

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Trimethoprim:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

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 fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 0,533 mg/l Exposure time: 21 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,01 mg/l Exposure time: 30 d
M-Factor (Chronic aquatic toxicity)	:	10
Toxicity to microorganisms	:	NOEC (activated sludge): 3,76 mg/l Method: OECD Test Guideline 301D

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 fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Orange-red killifish)): 1,24 mg/l Exposure time: 41 d Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,85 mg/l Exposure time: 21 d
Toxicity to microorganisms	:	EC10 (Pseudomonas putida): > 1.000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

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 (Water flea)): 92 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (microalgae)): 80,3 mg/l Exposure time: 72 h NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l Exposure time: 72 h EC50 (Anabaena flos-aquae): 253 mg/l Exposure time: 72 h EC10 (Anabaena flos-aquae): 26 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	NOEC (Zebrafish): 0,157 mg/l Exposure time: 21 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 6 mg/l Exposure time: 21 d
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

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

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations. 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

International Regulations

UNRTDG

UN number	:	UN 2491
Proper shipping name	:	ETHANOLAMINE SOLUTION
Class	:	8
Packing group	:	III
Labels	:	8

IATA-DGR

UN/ID No.	:	UN 2491
Proper shipping name	:	Ethanolamine solution
Class	:	8
Packing group	:	III
Labels	:	Corrosive
Packing instruction (cargo aircraft)	:	856
Packing instruction (passenger aircraft)	:	852

IMDG-Code

UN number	:	UN 2491
Proper shipping name	:	ETHANOLAMINE SOLUTION (Sulfamethoxazole)
Class	:	8
Packing group	:	III
Labels	:	8
EmS Code	:	F-A, S-B
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

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.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

DSL : not determined

AICS : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 04.04.2023
Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

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 other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
AR OEL / CMP : TLV (Threshold Limit Value)
AR OEL / CMP - CPT : STEL (Short Term Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

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