

Sulfadoxine / Trimethoprim Formulation

Version 5.2 Revision Date: 04.04.2023 SDS Number: 1681353-00019 Date of last issue: 16.08.2022
Date of first issue: 17.05.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfadoxine / Trimethoprim Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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 in accordance with ABNT NBR 14725 Standard**

Serious eye damage : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - : Category 2 (Bone marrow)
repeated exposure
Short-term (acute) aquatic : Category 2
hazard
Long-term (chronic) aquatic : Category 2
hazard

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Bone marrow) through

Sulfadoxine / Trimethoprim Formulation

Version 5.2 Revision Date: 04.04.2023 SDS Number: 1681353-00019 Date of last issue: 16.08.2022
 Date of first issue: 17.05.2017

prolonged or repeated exposure.
 H411 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:

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.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7	Flammable liquids, Category 4 Eye irritation, Category 2A	>= 30 -< 50
1,3-Dioxolan-4-ylmethanol	5464-28-8	Eye irritation, Category 2A	>= 30 -< 50
Sulfadoxine	2447-57-6	Skin irritation, Category 2 Eye irritation, Category 2A Specific target organ toxicity - single expo- sure, Category 3 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 10 -< 20
Trimethoprim	738-70-5	Acute toxicity (Oral), Category 4 Reproductive toxicity, Category 2 Specific target organ	>= 3 -< 5

Sulfadoxine / Trimethoprim Formulation

Version 5.2 Revision Date: 04.04.2023 SDS Number: 1681353-00019 Date of last issue: 16.08.2022
 Date of first issue: 17.05.2017

		toxicity - repeated exposure (Bone marrow), Category 1 Short-term (acute) aquatic hazard, Category 3 Long-term (chronic) aquatic hazard, Category 2	
Sodium hydroxide	1310-73-2	Corrosive to Metals, Category 1 Skin corrosion, Category 1A Serious eye damage, Category 1	>= 2 -< 3

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.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
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.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes serious eye damage.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.
- 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)

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

Unsuitable extinguishing media	:	Dry chemical None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal 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	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe mist or vapors. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin.

Sulfadoxine / Trimethoprim Formulation

Version 5.2 Revision Date: 04.04.2023 SDS Number: 1681353-00019 Date of last issue: 16.08.2022
 Date of first issue: 17.05.2017

- Wash skin thoroughly after handling.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Keep container tightly closed.
 Do not eat, drink or smoke when using this product.
 Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
 When using do not eat, drink or smoke.
 Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage** : Keep in properly labeled containers.
 Store locked up.
 Keep tightly closed.
 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
Sulfadoxine	2447-57-6	TWA	30 µg/m ³ (OEB 3)	Internal
		Wipe limit	300 µg/100 cm ²	Internal
Trimethoprim	738-70-5	TWA	400 µg/m ³ (OEB 2)	Internal
Sodium hydroxide	1310-73-2	C	2 mg/m ³	ACGIH

- 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.
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
 Minimize open handling.

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

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	:	Particulates type
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	light brown, yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	9,3 - 10,0
Melting point/freezing point	:	Not applicable
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

Sulfadoxine / Trimethoprim Formulation

Version 5.2 Revision Date: 04.04.2023 SDS Number: 1681353-00019 Date of last issue: 16.08.2022
Date of first issue: 17.05.2017

Relative vapor density : No data available

Relative density : No data available

Density : 1,210 - 1,250 g/cm³

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

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 : Not applicable

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

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

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

1,3-Dioxolan-4-ylmethanol:

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

Sulfadoxine:

Acute oral toxicity : LD50 (Mouse): 5.200 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

Sodium hydroxide:

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

Skin corrosion/irritation

Not classified based on available information.

Product:

Result : No skin irritation

Components:

1,3-Dioxan-5-ol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:

Species : Rabbit

Sulfadoxine / Trimethoprim Formulation

Version 5.2 Revision Date: 04.04.2023 SDS Number: 1681353-00019 Date of last issue: 16.08.2022
Date of first issue: 17.05.2017

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

Sulfadoxine:

Species : Rabbit
Method : OECD Test Guideline 404
Result : irritating

Sodium hydroxide:

Result : Corrosive after 3 minutes or less 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

1,3-Dioxolan-4-ylmethanol:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Sulfadoxine:

Result : irritating

Sodium hydroxide:

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

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

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

Result : negative
 Remarks : Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:

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

Trimethoprim:

Test Type : Maximization Test
 Routes of exposure : Dermal
 Species : Guinea pig
 Result : Not a skin sensitizer.

Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)
 Routes of exposure : Skin contact
 Result : negative

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

1,3-Dioxolan-4-ylmethanol:

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

Sulfadoxine / Trimethoprim Formulation

Version 5.2 Revision Date: 04.04.2023 SDS Number: 1681353-00019 Date of last issue: 16.08.2022
Date of first issue: 17.05.2017

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.

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 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

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

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

Not classified based on available information.

Components:**Sulfadoxine:**

Assessment : May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs (Bone marrow) through prolonged or repeated exposure.

Components:**Trimethoprim:**

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

Repeated dose toxicity**Components:****Trimethoprim:**

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

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

Species : Dog
 NOAEL : 2,5 mg/kg

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

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:****Sulfadoxine:**

Ingestion	:	Target Organs: Blood Symptoms: The most common side effects are:, Nausea, Vomiting, Headache, anemia, Rash, Stevens-Johnson syndrome
-----------	---	---

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
----------------------------	---	--

1,3-Dioxolan-4-ylmethanol:

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

- 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

Sulfadoxine:

- Toxicity to fish : LC50 (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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae (cyanobacterium)): 17 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- NOEC (Anabaena flos-aquae (cyanobacterium)): 3,9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0,13 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

EC50 (Microcystis aeruginosa (blue-green algae)): 0,135 mg/l
 Exposure time: 7 d
 Method: ISO 8692
 Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 6,2 mg/l
 Exposure time: 21 d
 Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Remarks: Based on data from similar materials

NOEC: 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Remarks: Based on data from similar materials

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

Sulfadoxine / Trimethoprim Formulation

Version 5.2 Revision Date: 04.04.2023 SDS Number: 1681353-00019 Date of last issue: 16.08.2022
Date of first issue: 17.05.2017

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

1,3-Dioxolan-4-ylmethanol:

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

Sulfadoxine:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 5 %
Exposure time: 28 d
Remarks: Based on data from similar materials

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

Trimethoprim:

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

Mobility in soil

No data available

Other adverse effects

No data available

Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 16.08.2022
5.2 04.04.2023 1681353-00019 Date of first issue: 17.05.2017

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 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(Sulfadoxine, Trimethoprim)
Class : 9
Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Sulfadoxine, Trimethoprim)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo : 964
aircraft)
Packing instruction (passen- : 964
ger aircraft)
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(Sulfadoxine, Trimethoprim)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

Not applicable for product as supplied.

Domestic regulation**ANTT**

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(Sulfadoxine, Trimethoprim)

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.08.2022
5.2	04.04.2023	1681353-00019	Date of first issue: 17.05.2017

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

BR / Z8