

Sulfadoxine / Trimethoprim Formulation

Version 6.0 Revision Date: 04.04.2023 SDS Number: 1681368-00018 Date of last issue: 16.08.2022
 Date of first issue: 17.05.2017

Section 1: Identification

Product name : Sulfadoxine / Trimethoprim Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

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: Hazard identification

GHS Classification

Serious eye damage/eye irritation : Category 2

Reproductive toxicity : Category 2

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

Hazardous to the aquatic environment - chronic hazard : Category 2

GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

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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 vapours.
 P264 Wash skin thoroughly after handling.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.
 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 | >= 30 -< 50 |
| 1,3-Dioxolan-4-ylmethanol | 5464-28-8 | >= 30 -< 50 |
| Sulfadoxine | 2447-57-6 | >= 10 -< 20 |
| Trimethoprim | 738-70-5 | >= 2.5 -< 10 |
| Sodium hydroxide | 1310-73-2 | >= 1 -< 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

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- 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 irritation.
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)
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 : 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
- Hazchem Code : 3Z
-

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.

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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 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.

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 vapours. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. 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 labelled 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 |

Section 8: Exposure controls/personal protection

Components with workplace control parameters

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| 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 | WES-Ceiling | 2 mg/m ³ | NZ OEL |
| | | 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.

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

Colour : light brown, yellow

Odour : No data available

Odour Threshold : No data available

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| | | |
|--|---|--|
| 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 |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | 1.210 - 1.250 g/cm ³ |
| Solubility(ies) Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| 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. |

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| 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

| | | |
|-----------------|---|--|
| Exposure routes | : | 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 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 |

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 |

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

Sodium hydroxide:

| | | |
|---------------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: 500 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation. |
| Acute inhalation toxicity | : | Assessment: Corrosive to the respiratory tract. |
| Acute dermal toxicity | : | Acute toxicity estimate: 1,100 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation. |

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 |
| 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 irritation.

Components:**1,3-Dioxan-5-ol:**

| | | |
|---------|---|--|
| Species | : | Rabbit |
| Result | : | Irritation to eyes, reversing within 21 days |
| Method | : | OECD Test Guideline 405 |

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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 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

1,3-Dioxolan-4-ylmethanol:

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

Trimethoprim:

Test Type : Maximisation Test
 Exposure routes : Dermal
 Species : Guinea pig
 Result : Not a skin sensitizer.

Sodium hydroxide:

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

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Chronic toxicity**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

Trimethoprim:

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

Test Type: Chromosomal aberration
 Result: negative

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

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

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

Test Type: Chromosomal aberration
 Species: Humans

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||| 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 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

||| Not classified based on available information.

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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
 || 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

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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:

| | | |
|---|---|--|
| 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 |

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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

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

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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): 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

1,3-Dioxolan-4-ylmethanol:

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

Sulfadoxine:

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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

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

Sulfadoxine / Trimethoprim Formulation

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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 aircraft) : 964
 Packing instruction (passenger aircraft) : 964
 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.

National Regulations**NZS 5433**

UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
 N.O.S.
 (Sulfadoxine, Trimethoprim)
 Class : 9
 Packing group : III
 Labels : 9
 Hazchem Code : 3Z

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****HSNO Approval Number**

not allocated

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

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| | | |
|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

Section 16: Other information

Revision Date : 04.04.2023

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/>

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / C : Ceiling limit
 NZ OEL / WES-Ceiling : Workplace Exposure Standard - Ceiling

AllC - 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 Sub-

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stances 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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