

Sulfadoxine / Trimethoprim Formulation

Version 6.1 Revision Date: 08/16/2022 SDS Number: 1681370-00019 Date of last issue: 06/03/2022
Date of first issue: 05/17/2017

SECTION 1. IDENTIFICATION

Product name : Sulfadoxine / Trimethoprim Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Serious eye damage : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity : Category 1 (Bone marrow)
- repeated exposure

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (Bone marrow) through prolonged or repeated exposure.

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.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

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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.

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

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	>= 1 - < 5
Sodium hydroxide	1310-73-2	>= 2 - < 5

Actual concentration is withheld as a trade secret

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.
 Causes damage to organs through prolonged or repeated

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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 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.

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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.
 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.
- 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
		C	2 mg/m ³	NIOSH REL
		TWA	2 mg/m ³	OSHA Z-1

- 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

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containment devices).
Minimize open handling.

Personal protective equipment

- Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
- 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.
- 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 brown, yellow
- Odor : No data available
- Odor Threshold : No data available
- pH : 9.3 - 10.0

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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

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 reac- : Can react with strong oxidizing agents.

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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

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

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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
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

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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
 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

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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 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.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

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identified as a known or anticipated carcinogen by NTP.

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
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

Causes 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

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

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:

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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
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1,3-Dioxolan-4-ylmethanol:

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

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

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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.

Domestic regulation

49 CFR

UN/ID/NA number : UN 3082
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Sodium hydroxide)
 Class : 9
 Packing group : III
 Labels : CLASS 9
 ERG Code : 171
 Marine pollutant : yes(Sulfadoxine, Trimethoprim)
 Remarks : THE ABOVE INFORMATION ONLY APPLIES TO PACKAGE SIZES WHERE THE HAZARDOUS SUBSTANCE MEETS THE REPORTABLE QUANTITY.

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

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium hydroxide	1310-73-2	1000	48076

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

Sulfadoxine / Trimethoprim Formulation

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SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations**Pennsylvania Right To Know**

1,3-Dioxan-5-ol	4740-78-7
1,3-Dioxolan-4-ylmethanol	5464-28-8
Water	7732-18-5
Sulfadoxine	2447-57-6
Trimethoprim	738-70-5
Sodium hydroxide	1310-73-2

California List of Hazardous Substances

Sodium hydroxide	1310-73-2
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California Permissible Exposure Limits for Chemical Contaminants

Sodium hydroxide	1310-73-2
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The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION**Further information**

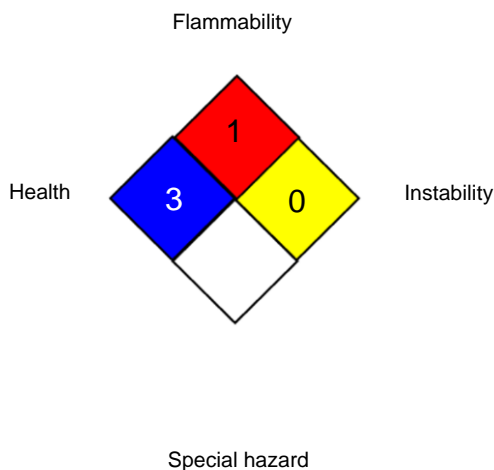
SAFETY DATA SHEET



Sulfadoxine / Trimethoprim Formulation

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Date of first issue: 05/17/2017

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / C : Ceiling limit
NIOSH REL / C : Ceiling value not be exceeded at any time.
OSHA Z-1 / TWA : 8-hour time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act;

Sulfadoxine / Trimethoprim Formulation

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REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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/>

Revision Date : 08/16/2022

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.

US / Z8