

Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/08/16
7.0	2023/04/04	1681364-00019	Date of first issue: 2017/05/17

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Sulfadoxine / Trimethoprim Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

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

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 2

GHS label elements

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

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prolonged or repeated exposure.
 H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe mist or vapours.
 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.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
1,3-Dioxan-5-ol	4740-78-7	>= 30 - < 40	
1,3-Dioxolan-4-ylmethanol	5464-28-8	>= 30 - < 40	
Sulfadoxine	2447-57-6	>= 10 - < 20	
Trimethoprim	738-70-5	>= 3 - < 10	
Sodium hydroxide	1310-73-2	>= 2 - < 3	1-410

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.

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- | | | |
|---|---|---|
| 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. |

5. FIREFIGHTING MEASURES

- | | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
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. |

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.

7. HANDLING AND STORAGE

Handling

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.

Avoidance of contact : Oxidizing agents
Acids

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.

Storage

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

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Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / 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	OEL-C	2 mg/m ³	JP OEL JSOH
		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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Colour	:	light brown, yellow
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	Not applicable
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit	:	
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	9.3 - 10.0
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Density and / or relative density	:	
Relative density	:	No data available
Density	:	1.210 - 1.250 g/cm ³
Relative vapour density	:	No data available
Explosive properties	:	Not explosive

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Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle characteristics	:	
Particle size	:	Not applicable

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.

11. TOXICOLOGICAL INFORMATION

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

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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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
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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.
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Skin corrosion/irritation

Not classified based on available information.

Product:

Result	:	No skin irritation
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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
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Serious eye damage/eye irritation

Causes serious eye damage.

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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 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

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Result : Not a skin sensitizer.

Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)
 Exposure routes : 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

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

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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 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 - As- : Suspected of damaging the unborn child.

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Assessment**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
 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,

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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

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

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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

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

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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): 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

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

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

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.

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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 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

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

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15. REGULATORY INFORMATION

Related Regulations**Fire Service Law**

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
5-[(3,4,5-trimethoxyphenyl)methyl]pyrimidine-2,4-diamine	>=1 - <10	From April 1st, 2024
Sodium hydroxide	>=1 - <10	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
5-[(3,4,5-trimethoxyphenyl)methyl]pyrimidine-2,4-diamine	From April 1st, 2024
Sodium hydroxide	-

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

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Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Until March 31st, 2023

Not applicable

From April 1st, 2023

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

|| Marine Pollution and Sea Disaster Prevention etc Law

|| Bulk transportation : Not classified as noxious liquid substance

Marine Pollution and Sea Disaster Prevention etc Law

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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16. OTHER INFORMATION

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 : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / C : Ceiling limit
 JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be

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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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