

# SAFETY DATA SHEET



## Sulfadoxine / Trimethoprim Formulation

Version  
12.0

Revision Date:  
2025/04/14

SDS Number:  
1681364-00024

Date of last issue: 2024/09/28  
Date of first issue: 2017/05/17

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### 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 : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

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

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### 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	>= 1 - < 10	-
Sodium hydroxide	1310-73-2	>= 1 - < 10	1-410

## 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

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	vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

## 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) 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.

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### 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 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.

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### 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

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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

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 parame- ters / Concentra- tion standard / Permissible con- centration	Basis
Sulfadoxine	2447-57-6	TWA	30 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	300 µg/100 cm <sup>2</sup>	Internal
Trimethoprim	738-70-5	TWA	400 µg/m <sup>3</sup> (OEB 2)	Internal
Sodium hydroxide	1310-73-2	OEL-C	2 mg/m <sup>3</sup>	JP OEL JSOH
		C	2 mg/m <sup>3</sup>	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 rec-

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Filter type	ommended guidelines, use respiratory protection.
Hand protection	: Particulates type
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving. Impermeable protective gloves
Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. 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.

## 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 / Up- per 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

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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 <sup>3</sup>
Relative vapour density	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle characteristics		
Particle size	:	Not applicable

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## 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.

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## 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

#### Components:

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

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

##### **1,3-Dioxolan-4-ylmethanol:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

##### **Sulfadoxine:**

Acute oral toxicity : LD50 (Mouse): 5,200 mg/kg

##### **Trimethoprim:**

Acute oral toxicity : LD50 (Rat): 1,500 - 5,300 mg/kg  
LD50 (Mouse): 1,910 - 7,000 mg/kg  
Acute toxicity (other routes of administration) : LD50 (Rat): 400 - 500 mg/kg  
Application Route: Intraperitoneal  
LD50 (Dog): 90 mg/kg  
Application Route: Intravenous  
LD50 (Mouse): 132 mg/kg  
Application Route: Intravenous

##### **Sodium hydroxide:**

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

### **Skin corrosion/irritation**

Not classified based on available information.

#### Product:

Result : No skin irritation

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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.

### 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
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#### Sodium hydroxide:

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

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### 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

### 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)

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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.

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### Trimethoprim:

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral

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		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.

### Components:

#### **Sulfadoxine:**

Assessment	:	May cause respiratory irritation.
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### STOT - repeated exposure

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

### Components:

#### **Trimethoprim:**

Target Organs	:	Bone marrow
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: 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
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**Trimethoprim:**

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

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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

##### 1,3-Dioxolan-4-ylmethanol:

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### 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

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## 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  
Environmentally hazardous : yes

##### 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

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

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

#### Substances Subject to be Indicated Names

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

Chemical name	Remarks
5-[(3,4,5-trimethoxyphenyl)methyl]pyrimidine-2,4-diamine	-
Sodium hydroxide	-

#### Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Chemical name
Sodium hydroxide

#### Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

#### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

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### 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

### 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

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

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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In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**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 Recom-

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mendations 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.

JP / EN