

# Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/06/07 14.0 2024/09/28 1737572-00023 Date of first issue: 2017/06/08

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

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

Menuma 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

Skin corrosion/irritation : Sub-category 1B

Serious eye damage/eye irri-

tation

Category 1

Respiratory sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - : Cat

single exposure

Category 3

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



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Hazard pictograms









Signal word Danger

Hazard statements H314 Causes severe skin burns and eye damage.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H335 May cause respiratory irritation.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs (Bone marrow) through

prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

P284 Wear respiratory protection.

#### Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.

P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a

POISON CENTER/ doctor.

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.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

P363 Wash contaminated clothing before reuse.

P391 Collect spillage.

### Storage:

P405 Store locked up.



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#### 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.
sulfadiazine	68-35-9	20	-
Trimethoprim	738-70-5	4	-
Sodium hydroxide	1310-73-2	3	1-410
2,2'-Iminodiethanol	111-42-2	0.6	2-302, 2-354
Polyethylene glycol sorbitan monolaurate	9005-64-5	0.01	7-110, 8-55, 8- 55

#### 4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

In case of skin contact : In case of contact, immediately flush skin with plenty of water

for at least 15 minutes while removing contaminated clothing

and shoes.

Get medical attention immediately.

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.

If vomiting occurs have person lean forward.

Call a physician or poison control centre immediately.



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Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Causes serious eye damage.

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

May cause respiratory irritation.

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Causes severe burns.
Causes digestive tract burns.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

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 (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 prod: :

ucts

Carbon oxides Metal oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec-:

tive equipment and emer-

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-



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gency procedures tective 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 absor-

bent.

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 deter-

mine 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 : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Already sensitised individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-

tory irritants or sensitisers.

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



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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.

Keep in a cool, well-ventilated place.

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 parameters / Concentration standard / Permissible concentration	Basis
sulfadiazine	68-35-9	TWA	2 mg/m3 (OEB 1)	Internal
Trimethoprim	738-70-5	TWA	400 μg/m3 (OEB 2)	Internal
Sodium hydroxide	1310-73-2	OEL-C	2 mg/m3	JP OEL JSOH
		С	2 mg/m3	ACGIH
2,2'-Iminodiethanol	111-42-2	8h-OEL-M	1 mg/m3	JP ISHL OEL 577-2(2)
		TWA (Inhalable fraction and vapor)	1 mg/m3	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.

Laboratory operations do not require special containment.



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Personal protective equipment

Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material Chemical-resistant gloves

Remarks Impermeable protective gloves

Wear safety glasses with side shields or goggles. Eye protection

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state liquid

Colour off-white to beige

Odour No data available

Odour Threshold No data available

Melting point/freezing point No data available

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- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point No data available

Decomposition temperature No data available

рΗ 10.0 - 10.5

Evaporation rate No data available



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Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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 reac-

tions

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

Components:

sulfadiazine:

Acute oral toxicity : LD50 (Mouse): 1,500 mg/kg

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg

Remarks: Based on data from similar materials

Acute toxicity (other routes of :

administration)

LD50 (Rat): 880 mg/kg

Application Route: Intravenous

LD50 (Mouse): 180 mg/kg Application Route: Intravenous

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.

2,2'-Iminodiethanol:

Acute oral toxicity : LD50 (Rat): 1,600 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): > 3.35 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Polyethylene glycol sorbitan monolaurate:

Acute inhalation toxicity : LC50 (Rat): > 5.1 mg/l



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Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Skin corrosion/irritation

Causes severe burns.

**Components:** 

sulfadiazine:

Result : Skin irritation

Remarks : Based on data from similar materials

Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

2,2'-Iminodiethanol:

Species : Rabbit Result : Skin irritation

Polyethylene glycol sorbitan monolaurate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

**Components:** 

sulfadiazine:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days Remarks : Based on data from similar materials

Sodium hydroxide:

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

2,2'-Iminodiethanol:

Species : Rabbit

Result : Irreversible effects on the eye

Polyethylene glycol sorbitan monolaurate:

Species : Rabbit



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Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### **Components:**

### sulfadiazine:

Test Type : Maximisation Test

Species : Guinea pig

Result : Not a skin sensitizer.

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

#### 2,2'-Iminodiethanol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

# Polyethylene glycol sorbitan monolaurate:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

#### Germ cell mutagenicity

Not classified based on available information.



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#### **Components:**

sulfadiazine:

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

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: negative

Remarks: Based on data from similar materials

Trimethoprim:

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

Result: negative

Test Type: Chromosomal aberration

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat Result: negative

Test Type: Chromosomal aberration

Species: Humans Result: negative

2,2'-Iminodiethanol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo



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cytogenetic assay) Species: Mouse

Application Route: Skin contact

Result: negative

# Polyethylene glycol sorbitan monolaurate:

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

Result: negative

### Carcinogenicity

Not classified based on available information.

### **Components:**

#### 2,2'-Iminodiethanol:

Species : Mouse
Application Route : Skin contact
Exposure time : 103 weeks
Result : positive

Remarks : The mechanism or mode of action may not be relevant in

humans.

Species : Rat

Application Route : Skin contact Exposure time : 103 weeks Result : negative

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

# Reproductive toxicity

Suspected of damaging the unborn child.

### **Components:**

#### sulfadiazine:

Effects on foetal develop- : Test Type: Development

ment

Species: Mouse Application Route: Oral

General Toxicity Maternal: NOAEL: 1,000 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Trimethoprim:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 70 mg/kg body weight

Result: No effects on fertility



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Effects on foetal develop-

ment

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-

sessment

Suspected of damaging the unborn child.

2,2'-Iminodiethanol:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion
Method: OECD Test Guideline 443

Result: positive

Effects on foetal develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 443

Result: positive

Reproductive toxicity - As-

sessment

: Some evidence of adverse effects on sexual function and

fertility, and/or on development, based on animal experiments.



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#### Polyethylene glycol sorbitan monolaurate:

Effects on foetal develop- : Test Type: Embryo-foetal development

ment Species: Rat

**Application Route: Ingestion** 

Result: negative

#### STOT - single exposure

May cause respiratory irritation.

### **Components:**

## sulfadiazine:

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.

# 2,2'-Iminodiethanol:

Exposure routes : Ingestion

Target Organs : Kidney, Blood, Liver, Nervous system

Assessment : Shown to produce significant health effects in animals at con-

centrations of >10 to 100 mg/kg bw.

Exposure routes : inhalation (dust/mist/fume)

Target Organs : Kidney, Blood

Assessment : Shown to produce significant health effects in animals at con-

centrations of >0.02 to 0.2 mg/l/6h/d.

Exposure routes : Skin contact

Target Organs : Blood, Liver, Kidney

Assessment : Shown to produce significant health effects in animals at con-

centrations of >20 to 200 mg/kg bw.

## Repeated dose toxicity

#### **Components:**

#### **Trimethoprim:**

Species : Rat NOAEL : 100 mg/kg



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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

2.2'-Iminodiethanol:

Species : Rat, female LOAEL : 14 mg/kg Application Route : Ingestion Exposure time : 13 Weeks

Species : Rat NOAEL : 0.015 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 90 Days

Method : OECD Test Guideline 413

Species : Rat
LOAEL : 32 mg/kg
Application Route : Skin contact
Exposure time : 13 Weeks

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

sulfadiazine:

General Information : May cause eye, skin, and respiratory tract irritation.

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:** 

sulfadiazine:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae): 17 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 3.9 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Microcystis aeruginosa (blue-green algae)): 0.135 mg/l

Exposure time: 7 Days

Method: ISO 8692

M-Factor (Acute aquatic tox- :

city)

. '

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 6.2 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

: 1

Toxicity to microorganisms

EC50: > 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209



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NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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

ma/

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 tox-

icity)

NOEC (Zebrafish): 0.157 mg/l

Exposure time: 21 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

ic toxicity)

NOEC (Daphnia magna (Water flea)): 6 mg/l

Exposure time: 21 d

Toxicity to microorganisms : E

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

2,2'-Iminodiethanol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 30.1 mg/l

Exposure time: 48 h



# Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

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Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 9.5

mg/l

Exposure time: 72 h

EC10 (Pseudokirchneriella subcapitata (green algae)): 1.1

mg/l

Exposure time: 72 h

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

EC10 (Daphnia magna (Water flea)): 1.05 mg/l

Exposure time: 21 d

Toxicity to microorganisms : EC10 (activated sludge): > 1,000 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Polyethylene glycol sorbitan monolaurate:

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Persistence and degradability

**Components:** 

sulfadiazine:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 28 d

Method: OECD Test Guideline 314

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

2,2'-Iminodiethanol:

Biodegradability : Result: Readily biodegradable.



# Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

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Biodegradation: 93 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Polyethylene glycol sorbitan monolaurate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 60 % Exposure time: 28 d

**Bioaccumulative potential** 

**Components:** 

sulfadiazine:

Partition coefficient: n-

octanol/water

log Pow: 0.12

Trimethoprim:

Partition coefficient: n-

octanol/water

log Pow: 0.91

2,2'-Iminodiethanol:

Partition coefficient: n-

octanol/water

log Pow: -2.46

Method: OECD Test Guideline 107

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

**UNRTDG** 

UN number : UN 1824



# Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

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Proper shipping name : SODIUM HYDROXIDE SOLUTION

Class : 8
Packing group : II
Labels : 8
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : UN 1824

Proper shipping name : Sodium hydroxide solution

Class : 8 Packing group : II

Labels : Corrosive Packing instruction (cargo : 855

aircraft)

Packing instruction (passen: 851

ger aircraft)

**IMDG-Code** 

UN number : UN 1824

Proper shipping name : SODIUM HYDROXIDE SOLUTION

(sulfadiazine, Trimethoprim)

Class : 8
Packing group : II
Labels : 8
EmS Code : F-A, S-B
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 : 154

#### 15. REGULATORY INFORMATION

# **Related Regulations**

### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

**Priority Assessment Chemical Substance** 

Chemical name	Number
Diethanolamine	91



# Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

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Mono(or poly)ether of (mono ester of anhydro(or dianhydro)glucitol and dodecanoic acid) and alpha-hydro-omega-hydroxypoly(oxyethylene)

### **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-	>=1 - <10	-
trimethoxyphenyl)methyl]pyrimidine-2,4-		
diamine		
Sodium hydroxide	>=1 - <10	-
Diethanolamine	>=0.1 - <1	-

### **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	-
Sodium hydroxide	-

# Skin and Eye Damage Substances for PPE Requirements (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

#### Ordinance on Prevention of Lead Poisoning

Not applicable

#### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable



# Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

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### **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**

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

#### **Aviation Law**

Corrosive substances (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



# Sulfadiazine (20%) / Trimethoprim (4%) Liquid **Formulation**

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#### 16. OTHER INFORMATION

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**

compile the Safety Data

Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs. OECD eChem Portal search results and European Chemicals Agen-

cy, 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

USA, ACGIH Threshold Limit Values (TLV)

JP ISHL OEL 577-2(2) Concentration standard (Value set by the Minister of Health,

Labour and Welfare stipulated under the Ministerial Ordinance

Article 577-2(2))

JP OEL JSOH Japan. The Japan Society for Occupational Health. Recom-

mendation of Occupational Exposure Limits

ACGIH / TWA 8-hour, time-weighted average

ACGIH / C Ceiling limit

JP ISHL OEL 577-2(2) / 8h-8-hour Occupational Exposure Limit-Mean

OEL-M

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, Bioaccumu-



# Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

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lative 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 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