

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

Version 10.0 Revision Date: 2023/04/04 SDS Number: 1737572-00019 Date of last issue: 2022/10/01
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 irritation : Category 1

Respiratory sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - 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 protection/ 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.
- Disposal:**
P501 Dispose of contents/ container to an approved waste

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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 advice 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.
 Rinse mouth thoroughly with water.
 Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Causes digestive tract burns.
 Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
 Causes serious eye damage.

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May cause allergy or asthma symptoms or breathing difficulties 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.

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 products : Carbon oxides
 Metal oxides
 Nitrogen oxides (NO_x)

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.
 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-

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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 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 | : | 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 assessment
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 respiratory 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 |
| 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 |

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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
sulfadiazine	68-35-9	TWA	2 mg/m ³ (OEB 1)	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
2,2'-Iminodiethanol	111-42-2	TWA (Inhalable fraction and vapor)	1 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.
 Laboratory operations do not require special containment.

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

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : off-white to beige

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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

pH : 10.0 - 10.5

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 : 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

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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

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

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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
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation 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.

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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
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

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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.

Components:

sulfadiazine:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES)
	Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	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
Genotoxicity in vivo	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
Genotoxicity in vivo	Test Type: Chromosomal aberration
	Species: Humans
	Result: negative

2,2'-Iminodiethanol:

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

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	Test Type: In vitro mammalian cell gene mutation test Result: negative
	Test Type: Chromosome aberration test in vitro Result: negative
	Test Type: In vitro sister chromatid exchange assay in mammalian cells Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo 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
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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 - Assessment	: Weight of evidence does not support classification as a carcinogen
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Reproductive toxicity

Suspected of damaging the unborn child.

Components:

sulfadiazine:

Effects on foetal development	: Test Type: Development Species: Mouse Application Route: Oral General Toxicity Maternal: NOAEL: 1,000 mg/kg body weight
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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

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.

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-

: Test Type: One-generation reproduction toxicity study

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ment	Species: Rat Application Route: Ingestion Method: OECD Test Guideline 443 Result: positive
Reproductive toxicity - Assessment	: Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

Polyethylene glycol sorbitan monolaurate:

Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative
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STOT - single exposure

May cause respiratory irritation.

Components:

sulfadiazine:

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
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 concentrations 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 concentrations 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 concentrations of >20 to 200 mg/kg bw.

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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

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:

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

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 toxicity) : 1

Toxicity to daphnia and other aquatic invertebrates (Chronic 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 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

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

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l

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

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	Exposure time: 72 h
	EC10 (Pseudokirchneriella subcapitata (green algae)): 1.1 mg/l
	Exposure time: 72 h
Toxicity to daphnia and other aquatic invertebrates (Chronic 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 (Chronic 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
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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. Biodegradation: 93 % Exposure time: 28 d Method: OECD Test Guideline 301F
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Polyethylene glycol sorbitan monolaurate:

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

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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 handling site for recycling or disposal.
 If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 1824
 Proper shipping name : SODIUM HYDROXIDE SOLUTION
 Class : 8
 Packing group : II
 Labels : 8

IATA-DGR

UN/ID No. : UN 1824
 Proper shipping name : Sodium hydroxide solution
 Class : 8

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

Version 10.0 Revision Date: 2023/04/04 SDS Number: 1737572-00019 Date of last issue: 2022/10/01
Date of first issue: 2017/06/08

Packing group : II
Labels : Corrosive
Packing instruction (cargo aircraft) : 855
Packing instruction (passenger aircraft) : 851

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
Mono(or poly)ether of (mono ester of anhydro(or dianhydro)glucitol and dodecanoic acid) and alpha-hydro-omega-hydroxypoly(oxyethylene)	222

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

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

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Date of first issue: 2017/06/08

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	$\geq 1 - < 10$	From April 1st, 2024
Sodium hydroxide	$\geq 1 - < 10$	-
Diethanolamine	$\geq 0.1 - < 1$	-

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	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

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

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

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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

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

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

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

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ACGIH / TWA	:	8-hour, time-weighted average
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 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