

## Sulfadiazine / Trimethoprim Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 10.0 2023/09/30 1737632-00019 Date of first issue: 2017/06/08

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Sulfadiazine / Trimethoprim Solid 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 : Category 2

Serious eye damage/eye irri-

tation

Category 2B

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 1

Long-term (chronic) aquatic

hazard

Category 1

#### **GHS** label elements



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Hazard pictograms :







Signal word : Danger

Hazard statements : H315 + H320 Causes skin and eye irritation.

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.

H410 Very 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 dust.

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:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P332 + P313 If skin irritation occurs: Get medical advice/ atten-

P337 + P313 If eye irritation persists: Get medical advice/ attention.

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

P362 + P364 Take off contaminated clothing and wash it before

P391 Collect spillage.

#### Storage:

reuse.

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

Important symptoms and out: : lines of the emergency as-

sumed

May form explosive dust-air mixture during processing, han-

dling or other means.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Calcium carbonate	471-34-1	60	1-122
1			
sulfadiazine	68-35-9	33.34	
Trimethoprim	738-70-5	6.66	

#### 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.

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. 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.

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 skin and eye irritation.

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.

Excessive exposure may aggravate preexisting asthma and



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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

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides Metal oxides

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-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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

Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air.

Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.



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Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## 7. HANDLING AND STORAGE

## Handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

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 dust. 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.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. 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 Hygiene measures

Oxidizing agents

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.



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**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 / Reference concentration / Permissible concentration	Basis
Calcium carbonate	471-34-1	OEL-M (Respirable dust)	2 mg/m3	JP OEL JSOH
		OEL-M (Total dust)	8 mg/m3	JP OEL JSOH
sulfadiazine	68-35-9	TWA	2 mg/m3 (OEB 1)	Internal
Trimethoprim	738-70-5	TWA	400 μg/m3 (OEB 2)	Internal

**Engineering measures** : Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

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

: 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.



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#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state powder

Colour light yellow

Odour No data available

Odour Threshold No data available

No data available Melting point/freezing point

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

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

pН No data available

Not applicable Evaporation rate

Auto-ignition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Solubility(ies)

No data available Water solubility

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure Not applicable

Density and / or relative density

Relative density No data available

Density No data available



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Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Particle characteristics

Particle size : No data available

## 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

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:**

Calcium carbonate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 420

Assessment: The substance or mixture has no acute oral tox-

icity

Acute inhalation toxicity : LC50 (Rat): > 3 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist



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Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

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

Skin corrosion/irritation

Causes skin irritation.

**Components:** 

Calcium carbonate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

sulfadiazine:

Result : Skin irritation

Remarks : Based on data from similar materials



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#### Serious eye damage/eye irritation

Causes eye irritation.

#### Components:

#### Calcium carbonate:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

## sulfadiazine:

Species : Rabbit

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

## 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:**

#### Calcium carbonate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

Species : Mouse

Method : OECD Test Guideline 429

Result : negative

## 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.

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

## Calcium carbonate:



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

Method: OECD Test Guideline 471

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

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

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Suspected of damaging the unborn child.



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#### **Components:**

#### Calcium carbonate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

#### sulfadiazine:

Effects on foetal develop-

ment

Test Type: Development

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

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

Tresuit. Embryotoxic effects., Teratogenic effects



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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.

## 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.

## Repeated dose toxicity

## **Components:**

## Calcium carbonate:

Species : Rat

NOAEL : > 1,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Method : OECD Test Guideline 422

## 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



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Species : Rat
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Bone marrow

Species: DogNOAEL: 2.5 mg/kgLOAEL: 45 mg/kgApplication Route: OralExposure time: 3 MonthsTarget Organs: Blood, Thyroid

## **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

## 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

## **Components:**

## Calcium carbonate:

Toxicity to fish : LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

NOELR (Pseudokirchneriella subcapitata (green algae)): 50

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201



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EL50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC: 1,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

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

Method: OECD Test Guideline 209

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-

citv'

: 1

Toxicity to daphnia and other : aquatic invertebrates (Chron-

Exposure time: 21 d

ic toxicity)

Method: OECD Test Guideline 211

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



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: 1

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M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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/

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)

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



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## 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

## Bioaccumulative potential

#### Components:

sulfadiazine:

Partition coefficient: n- : log Pow: 0.12

octanol/water

Trimethoprim:

Partition coefficient: n-

octanol/water

log Pow: 0.91

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(sulfadiazine)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(sulfadiazine)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen- : 956

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(sulfadiazine)

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



# **Sulfadiazine / Trimethoprim Solid Formulation**

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#### 15. REGULATORY INFORMATION

## **Related Regulations**

## Fire Service Law

Not applicable to dangerous materials / designated flammables.

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

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

## **Industrial Safety and Health Law**

#### **Harmful Substances Prohibited from Manufacture**

Not applicable

## **Harmful Substances Required Permission for Manufacture**

Not applicable

## **Substances Prevented From Impairment of Health**

Not applicable

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

Not applicable

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

Not applicable

#### **Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

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

## 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

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

Not applicable

## **Ordinance on Prevention of Lead Poisoning**

Not applicable

## Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

#### Ordinance on Prevention of Organic Solvent Poisoning

Not applicable



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

Not applicable

#### Poisonous and Deleterious Substances Control Law

Not applicable

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

## 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

## 16. OTHER INFORMATION

#### **Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD



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compile the Safety Data eChem Portal search results and European Chemicals Agen-

Sheet 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

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

mendation of Occupational Exposure Limits

JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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



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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