

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
Date of first issue: 2021/10/08

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : 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

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
Date of first issue: 2021/10/08

- 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 protection/ 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/ attention.
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 reuse.
P391 Collect spillage.
- Storage:**
P405 Store locked up.
- Disposal:**

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
Date of first issue: 2021/10/08

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
sulfadiazine	68-35-9	41.67
Trimethoprim	738-70-5	8.33

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.
- 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 difficulties 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 other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
-

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

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 products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
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.

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
 Date of first issue: 2021/10/08

Components	CAS-No.	Value type (Form of exposure)	Control parameters / 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

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 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

pH : 6.5 - 8.5

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
Date of first issue: 2021/10/08

Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
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

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
Date of first issue: 2021/10/08

LD50 (Dog): 90 mg/kg
Application Route: Intravenous

LD50 (Mouse): 132 mg/kg
Application Route: Intravenous

Skin corrosion/irritation

Causes skin irritation.

Components:**sulfadiazine:**

Result : Skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes eye irritation.

Components:**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:**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.

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
Date of first issue: 2021/10/08

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 synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Result: negative

Test Type: Chromosomal aberration
Species: Humans
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:**sulfadiazine:**

Effects on foetal development : 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

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

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.

STOT - single exposure

May cause respiratory irritation.

Components:

sulfadiazine:

Assessment : May cause respiratory irritation.

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
Date of first issue: 2021/10/08

STOT - repeated exposure

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

Components:

Trimethoprim:

Target Organs : Bone marrow
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Trimethoprim:

Species : Rat
NOAEL : 100 mg/kg
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Bone marrow, Liver, Pituitary gland, Thyroid

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

Species : Dog
NOAEL : 2.5 mg/kg
LOAEL : 45 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Blood, Thyroid

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

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

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

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 |

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

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

Persistence and degradability

Components:

sulfadiazine:

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 0 %
 Exposure time: 28 d

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 4.1 Revision Date: 2023/09/30 SDS Number: 9791122-00010 Date of last issue: 2023/04/04
Date of first issue: 2021/10/08

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-octanol/water : log Pow: 0.12

Trimethoprim:

Partition coefficient: n-octanol/water : log Pow: 0.91

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

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 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(sulfadiazine)
Class : 9

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

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 aircraft) : 956
 Packing instruction (passenger aircraft) : 956
 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.

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2023/09/30

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/>

Date format : yyyy/mm/dd

Full text of other abbreviations

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 Or-

Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
4.1	2023/09/30	9791122-00010	Date of first issue: 2021/10/08

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.

ID / EN