SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadiazine / Trimethoprim Solid Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Sulfadiazine / Trimethoprim Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

   Classification (REGULATION (EC) No 1272/2008)
   Skin irritation, Category 2 : H315: Causes skin irritation.
   Eye irritation, Category 2 : H319: Causes serious eye irritation.
   Respiratory sensitisation, Category 1 : H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
   Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child.
   Specific target organ toxicity - single exposure, Category 3 : H335: May cause respiratory irritation.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Sulfadiazine / Trimethoprim Solid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.3</td>
<td>23.03.2020</td>
<td>1738927-00009</td>
<td>13.09.2019</td>
<td>08.06.2017</td>
</tr>
</tbody>
</table>

Hazard pictograms:

Signal word: Danger

Hazard statements:

H315 Causes skin irritation.
H319 Causes serious 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 through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**

P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Sulfadiazine
trimethoprim

2.3 **Other hazards**

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

**SECTION 3: Composition/information on ingredients**

3.2 **Mixtures**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9 200-685-8</td>
<td>Acute Tox.4; H302 Skin Irrit.2; H315 Eye Irrit.2; H319 Resp. Sens.1; H334 STOT SE3; H335</td>
<td>33,34</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadiazine / Trimethoprim Solid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 13.09.2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.3</td>
<td>23.03.2020</td>
<td>1738927-00009</td>
<td>Date of first issue: 08.06.2017</td>
</tr>
</tbody>
</table>

Aquatic Acute1; H400
Aquatic Chronic1; H410
M-Factor (Acute aquatic toxicity): 1
M-Factor (Chronic aquatic toxicity): 1

trimethoprim 738-70-5 212-006-2 Acute Tox.4; H302 Repr.2; H361d STOT RE1; H372 Aquatic Chronic2; H411 6,66

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes skin irritation. Causes serious 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 other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

4.3 Indication of any immediate medical attention and special treatment needed  
Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media  
Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture  
Specific hazards during firefighting : 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  
Metal oxides

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures  
Personal precautions : Use personal protective equipment.  
Follow safe handling advice and personal protective equip-
6.2 Environmental precautions

Environmental precautions:
- Discharge into the environment must be avoided.
- 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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- 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.
- 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
- 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 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.
- Take care to prevent spills, waste and minimize release to the...
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: 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.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9</td>
<td>TWA</td>
<td>2 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>trimethoprim</td>
<td>738-70-5</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6,36 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>6,1 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1,06 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>6,1 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

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

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.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143
Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder
Colour: light yellow
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
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
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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.

9.2 Other information
Flammability (liquids) : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.
11.1 Information on toxicological effects

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
    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
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Serious eye damage/eye irritation
Causes serious 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.

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
Sulfadiazine / Trimethoprim Solid Formulation

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

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.
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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.

STOT - repeated exposure
May cause damage to organs 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

SECTION 12: Ecological information

12.1 Toxicity

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
M-Factor (Acute aquatic toxicity): 1

Toxicity to microorganisms:
- EC50: > 1,000 mg/l
- NOEC: 1,000 mg/l

M-Factor (Chronic aquatic toxicity): 1

**trimethoprim:**

Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): 100 mg/l
- NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna Straus): 92 mg/l
- EC50 (Anabaena flos-aquae): 253 mg/l
- EC10 (Anabaena flos-aquae): 26 mg/l

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l
- NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l

Toxicity to fish (Chronic toxicity):
- NOEC: 0.157 mg/l
- Species: Zebrafish
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 6 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)

12.2 Persistence and degradability

**Components:**

**Sulfadiazine:**
- Biodegradability: Result: Not readily biodegradable.
- Biodegradation: 0 %
- Exposure time: 28 d
- Method: OECD Test Guideline 314

12.3 Bioaccumulative potential

**Components:**

**Sulfadiazine:**
- Partition coefficient: n-octanol/water: log Pow: 0.12

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- **Product:** Dispose of in accordance with local regulations.
  According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
  Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **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.

SECTION 14: Transport information

14.1 UN number

- **ADN:** UN 3077
- **ADR:** UN 3077
Sulfadiazine / Trimethoprim Solid Formulation

RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Sulfadiazine)
IATA : Environmentally hazardous substance, solid, n.o.s. (Sulfadiazine)

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9 (ENVIRONM.)

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9 (ENVIRONM.)
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9 (ENVIRONM.)

IMDG
Packing group : III
Sulfadiazine / Trimethoprim Solid Formulation

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that de-
Sulfadiazine / Trimethoprim Solid Formulation

Complete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

**Other regulations:**
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

**The components of this product are reported in the following inventories:**
- AICS : not determined
- DSL : not determined
- IECSC : not determined

**15.2 Chemical safety assessment**
A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of H-Statements**
- H302 : Harmful if swallowed.
- H315 : Causes skin irritation.
- H319 : Causes serious 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.
- H372 : Causes damage to organs through prolonged or repeated exposure.
- H400 : Very toxic to aquatic life.
- H410 : Very toxic to aquatic life with long lasting effects.
- H411 : Toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**
- Acute Tox. : Acute toxicity
- Aquatic Acute : Short-term (acute) aquatic hazard
- Aquatic Chronic : Long-term (chronic) aquatic hazard
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sulfadiazine / Trimethoprim Solid Formulation

Version: 5.3
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Eye Irrit.: Eye irritation
Repr.: Reproductive toxicity
Resp. Sens.: Respiratory sensitisation
Skin Irrit.: Skin irritation
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSGA - 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

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Skin Irrit.</th>
<th>Eye Irrit. 2</th>
<th>Resp. Sens. 1</th>
<th>Repr. 2</th>
<th>STOT SE 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>H315</td>
<td>H319</td>
<td>H334</td>
<td>H361d</td>
<td>H335</td>
</tr>
</tbody>
</table>

Classification procedure:
Calculation method
Sulfadiazine / Trimethoprim Solid Formulation

STOT RE 2  H373  Calculation method
Aquatic Acute 1  H400  Calculation method
Aquatic Chronic 1  H410  Calculation method

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.

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