

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 7.0     | 17.06.2025     | 9792586-00014 | Date of first issue: 08.10.2021 |

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

#### 1.1 Product identifier

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

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

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.                      |

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### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

|                          |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | : |                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Signal word              | : | Danger                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Hazard statements        | : | <div><div>H315</div><div>Causes skin irritation.</div></div> <div><div>H319</div><div>Causes serious eye irritation.</div></div> <div><div>H334</div><div>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</div></div> <div><div>H335</div><div>May cause respiratory irritation.</div></div> <div><div>H361d</div><div>Suspected of damaging the unborn child.</div></div> <div><div>H373</div><div>May cause damage to organs through prolonged or repeated exposure.</div></div> <div><div>H410</div><div>Very toxic to aquatic life with long lasting effects.</div></div>                                                                            |
| Precautionary statements | : | <div><div><b>Prevention:</b></div><div><div>P260</div><div>Do not breathe dust.</div></div><div><div>P273</div><div>Avoid release to the environment.</div></div><div><div>P280</div><div>Wear protective gloves/ protective clothing/ eye protection/ face protection.</div></div></div> <div><div><b>Response:</b></div><div><div>P304 + P340 + P312</div><div>IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.</div></div><div><div>P342 + P311</div><div>If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.</div></div><div><div>P391</div><div>Collect spillage.</div></div></div> |

#### Hazardous components which must be listed on the label:

sulfadiazine  
Trimethoprim

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                                                                                                                                                                                                                                                                                 | Concentration<br>(% w/w) |
|---------------|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| sulfadiazine  | 68-35-9<br>200-685-8                                  | Acute Tox. 4; H302<br>Skin Irrit. 2; H315<br>Eye Irrit. 2; H319<br>Resp. Sens. 1; H334<br>STOT SE 3; H335<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><br>M-Factor (Acute<br>aquatic toxicity): 1<br>M-Factor (Chronic<br>aquatic toxicity): 1<br><br>Acute toxicity esti-<br>mate<br><br>Acute oral toxicity:<br>1,500 mg/kg | >= 30 - < 50             |
| Trimethoprim  | 738-70-5<br>212-006-2                                 | Acute Tox. 4; H302<br>Repr. 2; H361d<br>STOT RE 1; H372<br>(Bone marrow)<br>Aquatic Chronic 2;<br>H411                                                                                                                                                                                                                                         | >= 3 - < 10              |

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.<br>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                                    |

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when the potential for exposure exists (see section 8).

- |                         |   |                                                                                                                                                                                                                                          |
|-------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If inhaled              | : | If inhaled, remove to fresh air.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>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.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.                                                                       |
| If swallowed            | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                                                    |

### 4.2 Most important symptoms and effects, both acute and delayed

- |       |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Risks | : | Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).<br><br>Causes skin irritation.<br>Causes serious eye irritation.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>May cause respiratory irritation.<br>Suspected of damaging the unborn child.<br>May cause damage to organs through prolonged or repeated exposure. |
|-------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
|------------------------------|---|--------------------------------------------------------------------------------------------|

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Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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

### 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 (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for 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.  
Clean up remaining materials from spill with suitable absor-

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bent.

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

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>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.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| 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.<br>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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### 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  
Self-reactive substances and mixtures  
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

dusts non-specific 4 mg/m<sup>3</sup>  
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)  
Basis: IE OEL

10 mg/m<sup>3</sup>  
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)  
Basis: IE OEL

| Components   | CAS-No.  | Value type (Form of exposure) | Control parameters            | Basis    |
|--------------|----------|-------------------------------|-------------------------------|----------|
| sulfadiazine | 68-35-9  | TWA                           | 2 mg/m <sup>3</sup> (OEB 1)   | Internal |
| Trimethoprim | 738-70-5 | TWA                           | 400 µg/m <sup>3</sup> (OEB 2) | Internal |

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

| Substance name | Environmental Compartment | Value     |
|----------------|---------------------------|-----------|
| sulfadiazine   | Water                     | 0.01 mg/l |
| Trimethoprim   | Water                     | 0.9 mg/l  |

### 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/face protection : Wear safety glasses with side shields or goggles.

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|                          |   |                                                                                                                                                                                                                                                        |
|--------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          |   | 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 I.S. EN 143                                           |
| Filter type              | : | Particulates type (P)                                                                                                                                                                                                                                  |

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Physical state                                   | : | powder                                                                          |
| Colour                                           | : | white                                                                           |
| Odour                                            | : | No data available                                                               |
| Odour Threshold                                  | : | No data available                                                               |
| Melting point/freezing point                     | : | No data available                                                               |
| Initial boiling point and boiling range          | : | No data available                                                               |
| 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                                                               |
| Flash point                                      | : | Not applicable                                                                  |
| Auto-ignition temperature                        | : | No data available                                                               |
| Decomposition temperature                        | : | No data available                                                               |
| pH                                               | : | 6.5 - 8.5                                                                       |

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|                                        |   |                   |
|----------------------------------------|---|-------------------|
| Viscosity                              |   |                   |
| Viscosity, kinematic                   | : | Not applicable    |
| Solubility(ies)                        |   |                   |
| Water solubility                       | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable    |
| Vapour pressure                        | : | Not applicable    |
| Relative density                       | : | No data available |
| Density                                | : | No data available |
| Relative vapour density                | : | Not applicable    |
| Particle characteristics               |   |                   |
| Particle size                          | : | No data available |

### 9.2 Other information

|                      |   |                                                          |
|----------------------|---|----------------------------------------------------------|
| Explosives           | : | Not explosive                                            |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate     | : | Not applicable                                           |
| Molecular weight     | : | 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.<br>Can react with strong oxidizing agents. |
|---------------------|---|----------------------------------------------------------------------------------------------------------------------------|

### 10.4 Conditions to avoid

|                     |   |                                                   |
|---------------------|---|---------------------------------------------------|
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |
|---------------------|---|---------------------------------------------------|

### 10.5 Incompatible materials

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Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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<br>Remarks: Based on data from similar materials                                               |
| Acute toxicity (other routes of administration) | : LD50 (Rat): 880 mg/kg<br>Application Route: Intravenous<br><br>LD50 (Mouse): 180 mg/kg<br>Application Route: Intravenous |

##### **Trimethoprim:**

|                                                 |                                                                                                                                                                                                    |
|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity                             | : LD50 (Rat): 1,500 - 5,300 mg/kg<br><br>LD50 (Mouse): 1,910 - 7,000 mg/kg                                                                                                                         |
| Acute toxicity (other routes of administration) | : LD50 (Rat): 400 - 500 mg/kg<br>Application Route: Intraperitoneal<br><br>LD50 (Dog): 90 mg/kg<br>Application Route: Intravenous<br><br>LD50 (Mouse): 132 mg/kg<br>Application Route: Intravenous |

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### Skin corrosion/irritation

Causes skin irritation.

#### Components:

##### sulfadiazine:

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

### 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)<br>Result: negative<br>Remarks: Based on data from similar materials |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------|

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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)<br>Result: negative                                        |
|                       |   | Test Type: Chromosomal aberration<br>Result: negative                                                         |
|                       |   | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative                                     |
|                       |   | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: negative |
| Genotoxicity in vivo  | : | Test Type: Micronucleus test<br>Species: Rat<br>Result: negative                                              |
|                       |   | Test Type: Chromosomal aberration<br>Species: Humans<br>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<br>Species: Mouse<br>Application Route: Oral<br>General Toxicity Maternal: NOAEL: 1,000 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses |
|-------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### Trimethoprim:

|                      |   |                                                                                                                                              |
|----------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 70 mg/kg body weight<br>Result: No effects on fertility |
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## Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

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

### 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.

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### Repeated dose toxicity

#### Components:

##### Trimethoprim:

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

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

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

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not classified based on available information.

#### Product:

|            |                                                                                                                                                                                                                                                               |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment | : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Experience with human exposure

#### Components:

##### sulfadiazine:

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

##### Trimethoprim:

|           |                                                                                        |
|-----------|----------------------------------------------------------------------------------------|
| Ingestion | : Target Organs: Bone marrow<br>Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, |
|-----------|----------------------------------------------------------------------------------------|

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II

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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Toxicity to algae/aquatic plants                    | : EC50 (Anabaena flos-aquae): 17 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Anabaena flos-aquae): 3.9 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Microcystis aeruginosa (blue-green algae)): 0.135 mg/l<br>Exposure time: 7 Days<br>Method: ISO 8692 |
| M-Factor (Acute aquatic toxicity)                   | : 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Toxicity to microorganisms                          | : EC50 : > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC : 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                                                                                                                                                                                                                                                                                                                                              |

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 6.2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1

### 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 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

Toxicity to fish (Chronic toxicity) : NOEC: 0.157 mg/l  
Exposure time: 21 d  
Species: Zebrafish

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

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### 12.2 Persistence and degradability

#### Components:

##### **sulfadiazine:**

|                  |   |                                                                                                                     |
|------------------|---|---------------------------------------------------------------------------------------------------------------------|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314 |
|------------------|---|---------------------------------------------------------------------------------------------------------------------|

##### **Trimethoprim:**

|                  |   |                                                                                                                         |
|------------------|---|-------------------------------------------------------------------------------------------------------------------------|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 4 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301D    |
|                  | : | Result: Not inherently biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 302B |

### 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

#### Product:

|            |   |                                                                                                                                                                                                    |
|------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment | : | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. |
|------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 12.6 Endocrine disrupting properties

#### Product:

|            |   |                                                                                                                                                                                                                                   |
|------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment | : | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at |
|------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |                                                                                                                                                                                                                                                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.                                                                                                                                                        |

## SECTION 14: Transport information

### 14.1 UN number or ID number

|      |           |
|------|-----------|
| ADN  | : UN 3077 |
| ADR  | : UN 3077 |
| RID  | : UN 3077 |
| IMDG | : UN 3077 |
| IATA | : UN 3077 |

### 14.2 UN proper shipping name

|      |                                                                        |
|------|------------------------------------------------------------------------|
| ADN  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(sulfadiazine) |
| ADR  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(sulfadiazine) |
| RID  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(sulfadiazine) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(sulfadiazine) |
| IATA | : Environmentally hazardous substance, solid, n.o.s.<br>(sulfadiazine) |

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### 14.3 Transport hazard class(es)

|      | Class | Subsidiary risks |
|------|-------|------------------|
| ADN  | : 9   |                  |
| ADR  | : 9   |                  |
| RID  | : 9   |                  |
| IMDG | : 9   |                  |
| IATA | : 9   |                  |

### 14.4 Packing group

|                                          |                 |
|------------------------------------------|-----------------|
| <b>ADN</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M7            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| <b>ADR</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M7            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| Tunnel restriction code                  | : (-)           |
| <b>RID</b>                               |                 |
| Packing group                            | : III           |
| Classification Code                      | : M7            |
| Hazard Identification Number             | : 90            |
| Labels                                   | : 9             |
| <b>IMDG</b>                              |                 |
| Packing group                            | : III           |
| Labels                                   | : 9             |
| EmS Code                                 | : F-A, S-F      |
| <b>IATA (Cargo)</b>                      |                 |
| Packing instruction (cargo aircraft)     | : 956           |
| Packing instruction (LQ)                 | : Y956          |
| Packing group                            | : III           |
| Labels                                   | : Miscellaneous |
| <b>IATA (Passenger)</b>                  |                 |
| Packing instruction (passenger aircraft) | : 956           |
| Packing instruction (LQ)                 | : Y956          |
| Packing group                            | : III           |
| Labels                                   | : Miscellaneous |

### 14.5 Environmental hazards

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### 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 Maritime transport in bulk according to IMO instruments

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, mixtures and articles (Annex XVII) : Not applicable

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

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

|    |                       |                     |                     |
|----|-----------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|-----------------------|---------------------|---------------------|

Other regulations:

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Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

### 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                                                                                            |
| 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                                                                              |
| IE OEL                      | : | Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2 |
| IE OEL / OELV - 8 hrs (TWA) | : | Occupational exposure limit value (8-hour reference period)                                                                   |

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; 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; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

|                   |       |
|-------------------|-------|
| Skin Irrit. 2     | H315  |
| Eye Irrit. 2      | H319  |
| Resp. Sens. 1     | H334  |
| Repr. 2           | H361d |
| STOT SE 3         | H335  |
| STOT RE 2         | H373  |
| Aquatic Acute 1   | H400  |
| Aquatic Chronic 1 | H410  |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

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IE / EN