

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Sulfadiazine / Trimethoprim Solid Formulation

Version 9.0 Revision Date: 14.04.2025 SDS Number: 2456148-00015 Date of last issue: 28.09.2024
Date of first issue: 13.02.2018

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

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A
Çubuk Yolu 2. Km
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848 and subsequent amendments

| | |
|--|--|
| 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 T.R. SEA No 28848 and subsequent amendments

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

Components

| Chemical name | CAS-No. EC-No. Index-No. KKDIK Registration No. | SEA Classification | Concentration (% w/w) |
|---------------|--|--------------------|--------------------------|
| | | | |

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| | | | |
|--------------|-----------------------|---|-------|
| sulfadiazine | 68-35-9 200-685-8 | Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Resp. Sens. 1; H334 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 | 33,34 |
| Trimethoprim | 738-70-5 212-006-2 | Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow) Aquatic Chronic 2; 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

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

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 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
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.

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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 absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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

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| | |
|-------------------------|--|
| Advice on safe handling | <p>ventilation.</p> <p>: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.</p> |
| Hygiene measures | <p>: 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.</p> |

7.2 Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Requirements for storage areas and containers | <p>: 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.</p> |
| Advice on common storage | <p>: Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases</p> |

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

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| | |
|------|--|
| Dust | 15 mg/m3 Value type (Form of exposure): ZOAD/TWA (Total dust) Basis: TR OEL DU Further information: Allowable occupational exposure limit values of mineral dusts |
| | 5 mg/m3 Value type (Form of exposure): ZOAD/TWA (Respirable part) Basis: TR OEL DU Further information: Allowable occupational exposure limit values of mineral dusts |

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--------------|----------|-------------------------------|--------------------|----------|
| sulfadiazine | 68-35-9 | TWA | 2 mg/m3 (OEB 1) | Internal |
| Trimethoprim | 738-70-5 | TWA | 400 µg/m3 (OEB 2) | Internal |

Derived No Effect Level (DNEL)

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|-------------------|-----------|-----------------|----------------------------|------------------|
| Calcium carbonate | Workers | Inhalation | Long-term systemic effects | 6,36 mg/m3 |
| | Consumers | Ingestion | Acute systemic effects | 6,1 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 1,06 mg/m3 |
| | Consumers | Ingestion | Long-term systemic effects | 6,1 mg/kg bw/day |
| Calcium carbonate | Workers | Inhalation | Long-term systemic effects | 6,36 mg/m3 |
| | Consumers | Ingestion | Acute systemic effects | 6,1 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 1,06 mg/m3 |
| | Consumers | Ingestion | Long-term systemic effects | 6,1 mg/kg bw/day |

Predicted No Effect Concentration (PNEC):

| Substance name | Environmental Compartment | Value |
|-------------------|---------------------------|-----------|
| sulfadiazine | Water | 0,01 mg/l |
| Trimethoprim | Water | 0,9 mg/l |
| Calcium carbonate | Sewage treatment plant | 100 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 TS 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. |
| Flammability (liquids) | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Vapour pressure | : Not applicable |
| Relative vapour density | : Not applicable |
| Relative density | : No data available |
| Density | : No data available |

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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

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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

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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 |

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

sulfadiazine:

| | |
|---------|----------|
| Species | : Rabbit |
|---------|----------|

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| | |
|---------|---|
| 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 |
| | : Test Type: In vitro mammalian cell gene mutation test Result: negative |
| | : Test Type: DNA damage and repair, unscheduled DNA syn- |

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| | | |
|----------------------|---|--|
| | | thesis in mammalian cells (in vitro) Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test Species: Rat Result: negative |
| | | Test Type: Chromosomal aberration Species: Humans Result: negative |

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Suspected of damaging the unborn child.

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. |
| | | Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 15 mg/kg body weight |

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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

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| | | |
|-------------------|---|----------------|
| 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 mg/l Exposure time: 72 h |
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| | | Method: OECD Test Guideline 201 |
| | | EC50 (Microcystis aeruginosa (blue-green algae)): 0,135 mg/l Exposure time: 7 Days Method: ISO 8692 |
| M-Factor (Acute aquatic toxicity) | : | 1 |
| Toxicity to microorganisms | : | EC50 : > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| | | NOEC : 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| 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 |

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| | |
|--|---|
| | 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) |

12.2 Persistence and degradability

Components:

sulfadiazine:

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

Trimethoprim:

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

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

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12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

| | |
|------------------------|--|
| Product | : Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Waste management needs to comply with provisions laid down in Waste Management Regulation (TR Official Gazette, 2015, Number: 29314) and with the respective national provisions legally enforced 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. Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. 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 |
| 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. |

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(sulfadiazine)

IATA : Environmentally hazardous substance, solid, n.o.s.
(sulfadiazine)

14.3 Transport hazard class(es)

| | Class | Subsidiary risks |
|-------------|-------|------------------|
| 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

ADR

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

RID

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

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| | | | |
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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 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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published)

Regulation on prevention of major industrial accidents. Reg number 30702

| | Quantity 1 | Quantity 2 | |
|----|--------------------------|------------|-------|
| E1 | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.

Regulation on Import and Export of Certain Hazardous Chemicals, No. 32087, 2023

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

AICS : not determined

DSL : not determined

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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.
The SDS has been prepared by: Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

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.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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
- TR OEL DU : Türkiye. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1)
- TR OEL DU / ZOAD/TWA : Time Weighted Average Value

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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

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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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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 |

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

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

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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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