SAFETY DATA SHEET

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

SECTION 1. IDENTIFICATION

Product name : Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin corrosion : Category 1B
Serious eye damage : Category 1
Respiratory sensitization : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - single exposure : Category 3
Specific target organ toxicity - repeated exposure : Category 1 (Bone marrow)

GHS label elements
Hazard pictograms

Signal Word : Danger
Hazard Statements : H314 Causes severe skin burns and eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (Bone marrow) through prolonged or repeated exposure.
Precautionary Statements:

**Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
P285 In case of inadequate ventilation wear respiratory protection.

**Response:**
P301 + P330 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Immediately call a POISON CENTER.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.
P308 + P313 IF exposed or concerned: Get medical attention.
P342 + P311 If experiencing respiratory symptoms: Call a doctor.
P363 Wash contaminated clothing before reuse.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards:
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>sulfadiazine</td>
<td>68-35-9</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
</tr>
<tr>
<td>2,2'-Iminodiethanol</td>
<td>111-42-2</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

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 immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.

If swallowed: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

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

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-:

Carbon oxides
## SECTION 6. ACCIDENTAL RELEASE MEASURES

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

### Environmental precautions
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

### Methods and materials for containment and cleaning up
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- 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.

## SECTION 7. HANDLING AND STORAGE

### Technical measures
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

### Local/Total ventilation
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

### Advice on safe handling
- Do not get on skin or clothing.
- Do not breathe mist or vapors.
- 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.
SAFETY DATA SHEET

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<table>
<thead>
<tr>
<th>Version</th>
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<tbody>
<tr>
<td>8.0</td>
<td>04/04/2023</td>
<td>1737586-00020</td>
<td>10/01/2022</td>
</tr>
</tbody>
</table>

assessment

Keep container tightly closed.

Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:

- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.

Materials to avoid:

- Do not store with the following product types:
  - Strong oxidizing agents
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9</td>
<td>TWA</td>
<td>2 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>TWA</td>
<td>400 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>C</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>2,2'-Iminodiethanol</td>
<td>111-42-2</td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>1 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>3 ppm 15 mg/m³</td>
<td>NIOSH REL</td>
</tr>
</tbody>
</table>

Engineering measures:

- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection:

- General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are
unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material: Chemical-resistant gloves

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: off-white to beige

Odor: No data available

Odor Threshold: No data available

pH: 10.0 - 10.5

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available
### SAFETY DATA SHEET

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<tr>
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<tr>
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<td>10/01/2022</td>
<td>06/08/2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### SECTION 10. STABILITY AND REACTIVITY

- **Reactivity**: Not classified as a reactivity hazard.
- **Chemical stability**: Stable under normal conditions.
- **Possibility of hazardous reactions**: Can react with strong oxidizing agents.
- **Conditions to avoid**: None known.
- **Incompatible materials**: Oxidizing agents, Acids
- **Hazardous decomposition products**: No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

- **Information on likely routes of exposure**
  - Inhalation
  - Skin contact
Ingestion
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity:

- Acute toxicity estimate: 4,687 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

**Sodium hydroxide:**

- Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.

**2,2'-Iminodiethanol:**

- Acute oral toxicity: LD50 (Rat): 1,600 mg/kg
- Acute inhalation toxicity: LC50 (Rat, male): > 3.35 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist

**Skin corrosion/irritation**

Causes severe burns.
Components:
sulfadiazine:

<table>
<thead>
<tr>
<th>Result</th>
<th>Skin irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Sodium hydroxide:

| Result                              | Corrosive after 3 minutes or less of exposure |

2,2’-Iminodiethanol:

<table>
<thead>
<tr>
<th>Result</th>
<th>Skin irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Serious eye damage/eye irritation

Species: Rabbit

Result: Skin irritation

Components:
sulfadiazine:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irritation to eyes, reversing within 7 days</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Sodium hydroxide:

<table>
<thead>
<tr>
<th>Result</th>
<th>Irreversible effects on the eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Based on skin corrosivity.</td>
</tr>
</tbody>
</table>

2,2’-Iminodiethanol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irreversible effects on the eye</td>
</tr>
</tbody>
</table>

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:
sulfadiazine:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Trimethoprim:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Dermal</td>
</tr>
</tbody>
</table>

Date of last issue: 10/01/2022
Date of first issue: 06/08/2017
Species: Guinea pig
Result: Not a skin sensitizer.

**Sodium hydroxide:**
- **Test Type:** Human repeat insult patch test (HRIPT)
- **Routes of exposure:** Skin contact
- **Result:** negative

**2,2'-Iminodiethanol:**
- **Test Type:** Maximization Test
- **Routes of exposure:** Skin contact
- **Species:** Guinea pig
- **Method:** OECD Test Guideline 406
- **Result:** negative

**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 synthesis in mammalian cells (in vitro)
  - **Result:** negative

- **Genotoxicity in vivo:**
  - **Test Type:** Micronucleus test
  - **Species:** Rat
  - **Result:** negative
  - **Test Type:** Chromosomal aberration
  - **Species:** Humans
  - **Result:** negative
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---

2,2'-Iminodiethanol:

**Genotoxicity in vitro**

- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

- Test Type: Chromosome aberration test in vitro
  - Result: negative

- Test Type: In vitro sister chromatid exchange assay in mammalian cells
  - Result: negative

**Genotoxicity in vivo**

- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Skin contact
  - Result: negative

---

**Carcinogenicity**

Not classified based on available information.

**Components:**

2,2'-Iminodiethanol:

**Species**

- Species: Mouse

**Application Route**

- Application Route: Skin contact

**Exposure time**

- Exposure time: 103 weeks

**Result**

- Result: positive

**Remarks**

- Remarks: The mechanism or mode of action may not be relevant in humans.

**Species**

- Species: Rat

**Application Route**

- Application Route: Skin contact

**Exposure time**

- Exposure time: 103 weeks

**Result**

- Result: negative

**Carcinogenicity - Assessment**

- Weight of evidence does not support classification as a carcinogen

**IARC**

- Group 2B: Possibly carcinogenic to humans

**OSHA**

- No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**

- No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:

**Sulfadiazine:**

Effects on fetal 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 fetal development: 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 - As-

Suspected of damaging the unborn child.
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Assessment

2,2'-Iminodiethanol:

Effects on fertility: Test Type: One-generation reproduction toxicity study; Species: Rat; Application Route: Ingestion; Method: OECD Test Guideline 443; Result: positive

Effects on fetal development: Test Type: One-generation reproduction toxicity study; Species: Rat; Application Route: Ingestion; Method: OECD Test Guideline 443; Result: positive

Reproductive toxicity - Assessment: Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

STOT-single exposure

May cause respiratory irritation.

Components:

sulfadiazine:

Assessment: May cause respiratory irritation.

STOT-repeated exposure

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

Components:

Trimethoprim:

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

2,2'-Iminodiethanol:

Routes of exposure: Ingestion
Target Organs: Kidney, Blood, Liver, Nervous system
Assessment: Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

Routes of exposure: Inhalation (dust/mist/fume)
Target Organs: Kidney, Blood
Assessment: Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d.

Routes of exposure: Skin contact
Target Organs: Blood, Liver, Kidney
Assessment: Shown to produce significant health effects in animals at concentrations of >20 to 200 mg/kg bw.
Repeated dose toxicity

**Components:**

**Trimethoprim:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>300 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone marrow, Liver, Pituitary gland, Thyroid</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>300 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone marrow</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>2.5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>45 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Thyroid</td>
</tr>
</tbody>
</table>

**2,2’-Iminodiethanol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>14 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.015 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 413</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>32 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
</tbody>
</table>

**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

Ecotoxicity

Components:
sulfadiazine:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
EC50 (Anabaena flos-aquae): 17 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 3.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Microcystis aeruginosa (blue-green algae)): 0.135 mg/l
Exposure time: 7 Days
Method: ISO 8692

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

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
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimethoprim:</td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 100 mg/l Exposure time: 96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna Straus (Water flea)): 92 mg/l Exposure time: 48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l Exposure time: 72 h</td>
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<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>EC50 (Anabaena flos-aquae): 253 mg/l Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>EC10 (Anabaena flos-aquae): 26 mg/l Exposure time: 72 h</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Zebrafish): 0.157 mg/l Exposure time: 21 d</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 6 mg/l Exposure time: 21 d</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC10: 16.7 mg/l Exposure time: 3 hrs Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

| 2,2'-Iminodiethanol: |                         |
| Toxicity to fish     | LC50 (Oncorhynchus mykiss (rainbow trout)): 460 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | EC50 (Ceriodaphnia dubia (water flea)): 30.1 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | ErC50 (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l Exposure time: 72 h |
|                       | EC10 (Pseudokirchneriella subcapitata (green algae)): 1.1 mg/l Exposure time: 72 h |
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- EC10 (Daphnia magna (Water flea)): 1.05 mg/l
- Exposure time: 21 d

Toxicity to microorganisms:
- EC10 (activated sludge): > 1,000 mg/l
- Exposure time: 30 min
- Method: OECD Test Guideline 209

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

**2,2'-Iminodiethanol:**
- Biodegradability: Result: Readily biodegradable.
- Biodegradation: 93 %
- Exposure time: 28 d
- Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

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

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

**2,2'-Iminodiethanol:**
- Partition coefficient: n-octanol/water: log Pow: -2.46
  - Method: OECD Test Guideline 107
Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 1824
Proper shipping name: SODIUM HYDROXIDE SOLUTION
Class: 8
Packing group: II
Labels: 8

IATA-DGR
UN/ID No.: UN 1824
Proper shipping name: Sodium hydroxide solution
Class: 8
Packing group: II
Labels: Corrosive
Packing instruction (cargo aircraft): 855
Packing instruction (passenger aircraft): 851

IMDG-Code
UN number: UN 1824
Proper shipping name: SODIUM HYDROXIDE SOLUTION (sulfadiazine, Trimethoprim)
Class: 8
Packing group: II
Labels: 8
EmS Code: F-A, S-B
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
UN/ID/NA number: UN 1824
Proper shipping name: Sodium hydroxide solution
SAFETY DATA SHEET
Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 8.0  Revision Date: 04/04/2023  SDS Number: 1737586-00020  Date of last issue: 10/01/2022

Class: 8
Packing group: II
Labels: CORROSIVE
ERG Code: 154
Marine pollutant: yes (sulfadiazine, Trimethoprim)

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.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,2'-Iminodiethanol</td>
<td>111-42-2</td>
<td>100</td>
<td>16666</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>1000</td>
<td>33333</td>
</tr>
</tbody>
</table>

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Respiratory or skin sensitization
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)
- Skin corrosion or irritation
- Serious eye damage or eye irritation

SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Water: 7732-18-5
- Sulfadiazine: 68-35-9
- Trimethoprim: 738-70-5
- Sodium hydroxide: 1310-73-2
- 2,2'-Iminodiethanol: 111-42-2

California Prop. 65
WARNING: This product can expose you to chemicals including 2,2'-Iminodiethanol, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
- Sodium hydroxide: 1310-73-2
- Polyvinyl pyrrolidone: 9003-39-8
SAFETY DATA SHEET

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 8.0  Revision Date: 04/04/2023  SDS Number: 1737586-00020  Date of last issue: 10/01/2022
Date of first issue: 06/08/2017

California Permissible Exposure Limits for Chemical Contaminants
Sodium hydroxide  1310-73-2

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

HMIS® IV:

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / C : Ceiling limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / C : Ceiling value not be exceeded at any time.
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Haz-

Revision Date: 04/04/2023

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 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.