# SAFETY DATA SHEET

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

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
|---|---|---|---|
| 9.0 | 30.09.2023 | 1737558-00019 | Date of first issue: 08.06.2017 |

## Section 1: Identification

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

**Manufacturer or supplier's details**

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product
Restrictions on use : Not applicable

## Section 2: Hazard identification

**GHS Classification**

Skin corrosion/irritation : Category 1B

Serious eye damage/eye irritation : Category 1

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure : Category 3

Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow)

Hazardous to the aquatic environment - chronic hazard : Category 2

**GHS label elements**

| | | |
|---|---|---|
| Hazard pictograms | : |  |
| Signal word | : | Danger |
| Hazard statements | : | H314 Causes severe skin burns and eye damage.<br>H317 May cause an allergic skin reaction.<br>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>H335 May cause respiratory irritation.<br>H361 Suspected of damaging fertility or the unborn child.<br>H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.<br>H411 Toxic to aquatic life with long lasting effects. |
| Precautionary statements | : | **Prevention:**<br>P201 Obtain special instructions before use.<br>P202 Do not handle until all safety precautions have been read and understood.<br>P260 Do not breathe mist or vapours.<br>P264 Wash skin thoroughly after handling.<br>P271 Use only outdoors or in a well-ventilated area.<br>P272 Contaminated work clothing should not be allowed out of the workplace.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.<br>P284 Wear respiratory protection.<br><br>**Response:**<br>P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.<br>P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.<br>P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.<br>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/ doctor.<br>P308 + P313 IF exposed or concerned: Get medical advice/ attention.<br>P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.<br>P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor. |

P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| sulfadiazine | 68-35-9 | 20 |
| Trimethoprim | 738-70-5 | 4 |
| Sodium hydroxide | 1310-73-2 | 3 |
| 2,2'-Iminodiethanol | 111-42-2 | 0.6 |
| Sodium metabisulphite | 7681-57-4 | 0.1 |

## 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 centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

| | | |
|---|---|---|
| Most important symptoms and effects, both acute and delayed | : | May cause an allergic skin reaction.<br>Causes serious eye damage.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>May cause respiratory irritation.<br>Suspected of damaging fertility or the unborn child.<br>May cause damage to organs through prolonged or repeated exposure.<br>Causes severe burns.<br>Causes digestive tract burns.<br>Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). |
| 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Metal oxides<br>Nitrogen oxides (NOx) |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| Hazchem Code | : | 2R |

## Section 6: Accidental release measures

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>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.<br>For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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.<br>Do not breathe mist or vapours.<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>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.<br>When using do not eat, drink or smoke.<br>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. |

| | | |
|---|---|---|
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Oxidizing agents<br>Explosives |

## Section 8: Exposure controls/personal protection

**Components with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| sulfadiazine | 68-35-9 | TWA | 2 mg/m3 (OEB 1) | Internal |
| Trimethoprim | 738-70-5 | TWA | 400 µg/m3 (OEB 2) | Internal |
| Sodium hydroxide | 1310-73-2 | WES-Ceiling | 2 mg/m3 | NZ OEL |
| | | C | 2 mg/m3 | ACGIH |
| 2,2'-Iminodiethanol | 111-42-2 | WES-TWA | 3 ppm<br>13 mg/m3 | NZ OEL |
| | Further information: Skin absorption | | | |
| | | TWA (Inhalable fraction and vapor) | 1 mg/m3 | ACGIH |
| Sodium metabisulphite | 7681-57-4 | WES-TWA | 5 mg/m3 | NZ OEL |
| | Further information: Skin sensitiser, Respiratory sensitiser | | | |
| | | TWA | 5 mg/m3 | ACGIH |

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

**Personal protective equipment**

| | | |
|---|---|---|
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : | Particulates type |
| Hand protection | | |
| Material | : | Chemical-resistant gloves |

| | | |
|---|---|---|
| Eye protection | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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. |

## Section 9: Physical and chemical properties

| | | |
|---|---|---|
| Appearance | : | liquid |
| Colour | : | off-white to beige |
| Odour | : | No data available |
| Odour 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 |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n- | : | Not applicable |

| | | |
|---|---|---|
| octanol/water | | |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Particle size | : | Not applicable |

## 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<br>Acids |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## Section 11: Toxicological information

Exposure routes : 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

Acute dermal 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 |

**Sodium hydroxide:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: 500 mg/kg<br>Method: Expert judgement<br>Remarks: Based on national or regional regulation. |
| Acute inhalation toxicity | : | Assessment: Corrosive to the respiratory tract. |
| Acute dermal toxicity | : | Acute toxicity estimate: 1,100 mg/kg<br>Method: Expert judgement<br>Remarks: Based on national or regional regulation. |

**2,2'-Iminodiethanol:**

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

**Sodium metabisulphite:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 1,540 mg/kg<br>Method: OECD Test Guideline 401 |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.5 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Causes severe burns.

**Components:**

**sulfadiazine:**

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

**Sodium hydroxide:**

Result : Corrosive after 3 minutes or less of exposure

**2,2'-Iminodiethanol:**

Species : Rabbit
Result : Skin irritation

**Sodium metabisulphite:**

Result : Skin irritation
Remarks : Based on national or regional regulation.

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:**

**sulfadiazine:**

Species : Rabbit
Result : Irritation to eyes, reversing within 7 days
Remarks : Based on data from similar materials

**Sodium hydroxide:**

Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

**2,2'-Iminodiethanol:**

Species : Rabbit
Result : Irreversible effects on the eye

**Sodium metabisulphite:**

Species : Rabbit

| | | |
|---|---|---|
| Result | : | Irreversible effects on the eye |
| Method | : | OECD Test Guideline 405 |

**Respiratory or skin sensitisation**

**Skin sensitisation**

May cause an allergic skin reaction.

**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. |

**Sodium hydroxide:**

| | | |
|---|---|---|
| Test Type | : | Human repeat insult patch test (HRIPT) |
| Exposure routes | : | Skin contact |
| Result | : | negative |

**2,2'-Iminodiethanol:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Method | : | OECD Test Guideline 406 |
| Result | : | negative |

**Sodium metabisulphite:**

| | | |
|---|---|---|
| Assessment | : | Probability or evidence of skin sensitisation in humans |
| Remarks | : | Based on national or regional regulation. |

| | | |
|---|---|---|
| Assessment | : | May cause sensitisation by inhalation. |
| Remarks | : | Based on national or regional regulation. |

**Chronic toxicity**

**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<br><br>Test Type: Chromosomal aberration<br>Test system: Chinese hamster ovary cells<br>Result: negative<br>Remarks: Based on data from similar materials |

**Trimethoprim:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>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<br><br>Test Type: Chromosomal aberration<br>Species: Humans<br>Result: negative |

**2,2'-Iminodiethanol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative<br><br>Test Type: In vitro sister chromatid exchange assay in mam- |

malian cells
Result: negative

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

**Sodium metabisulphite:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Subcutaneous
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:**

**2,2'-Iminodiethanol:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Skin contact |
| Exposure time | : | 103 weeks |
| Result | : | positive |
| Remarks | : | The mechanism or mode of action may not be relevant in humans. |

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Skin contact |
| Exposure time | : | 103 weeks |
| Result | : | negative |

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

**Sodium metabisulphite:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Ingestion |

| | | |
|---|---|---|
| Exposure time | : | 24 Months |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

**Reproductive toxicity**

Suspected of damaging fertility or 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 |
| Effects on foetal development | : | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 70 mg/kg body weight<br>Result: Effects on newborn<br>Remarks: Maternal toxicity observed.<br><br>Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 70 mg/kg body weight<br>Result: Embryotoxic effects.<br>Remarks: Maternal toxicity observed.<br><br>Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 15 mg/kg body weight<br>Result: Embryotoxic effects., Teratogenic effects<br><br>Test Type: Development<br>Species: Hamster<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 1.7 mg/kg body weight<br>Result: Embryotoxic effects., No teratogenic effects |

| | | |
|---|---|---|
| | | Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 100 mg/kg body weight<br>Result: Embryotoxic effects., No teratogenic effects |
| Reproductive toxicity - Assessment | : | Suspected of damaging the unborn child. |

**2,2'-Iminodiethanol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 443<br>Result: positive |
| Effects on foetal development | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 443<br>Result: positive |
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments. |

**Sodium metabisulphite:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Three-generation study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Ingestion<br>Result: negative |

**STOT - single exposure**

May cause respiratory irritation.

**Components:**

**sulfadiazine:**

| | | |
|---|---|---|
| Assessment | : | May cause respiratory irritation. |

**STOT - repeated exposure**

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

**Components:**

**Trimethoprim:**

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

**2,2'-Iminodiethanol:**

| | | |
|---|---|---|
| Exposure routes | : | 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. |

| | | |
|---|---|---|
| Exposure routes | : | 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. |

| | | |
|---|---|---|
| Exposure routes | : | 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:**

| | | |
|---|---|---|
| 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 |

**2,2'-Iminodiethanol:**

| | | |
|---|---|---|
| Species | : | Rat, female |
| LOAEL | : | 14 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 13 Weeks |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 0.015 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 90 Days |
| Method | : | OECD Test Guideline 413 |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 32 mg/kg |
| Application Route | : | Skin contact |
| Exposure time | : | 13 Weeks |

**Sodium metabisulphite:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 110 mg/kg |
| LOAEL | : | 220 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 104 Weeks |

**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<br>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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l |

| | | |
|---|---|---|
| aquatic invertebrates | | 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 daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 6.2 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |
| M-Factor (Chronic 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 |

**Trimethoprim:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 100 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna Straus): 92 mg/l<br>Exposure time: 48 h |

| | | |
|---|---|---|
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l<br>Exposure time: 72 h<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l<br>Exposure time: 72 h<br><br>EC50 (Anabaena flos-aquae): 253 mg/l<br>Exposure time: 72 h<br><br>EC10 (Anabaena flos-aquae): 26 mg/l<br>Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Zebrafish): 0.157 mg/l<br>Exposure time: 21 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 6 mg/l<br>Exposure time: 21 d |
| Toxicity to microorganisms | : | EC10: 16.7 mg/l<br>Exposure time: 3 hrs<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>EC50: > 1,000 mg/l<br>Exposure time: 3 hrs<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

**2,2'-Iminodiethanol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 460 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 30.1 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l<br>Exposure time: 72 h<br><br>EC10 (Pseudokirchneriella subcapitata (green algae)): 1.1 mg/l<br>Exposure time: 72 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | EC10 (Daphnia magna (Water flea)): 1.05 mg/l<br>Exposure time: 21 d |
| Toxicity to microorganisms | : | EC10 (activated sludge): > 1,000 mg/l<br>Exposure time: 30 min |

Method: OECD Test Guideline 209

**Sodium metabisulphite:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 178 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 89 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Desmodesmus subspicatus (green algae)): 43.8 mg/l<br>Exposure time: 72 h<br><br>EC10 (Desmodesmus subspicatus (green algae)): 33.3 mg/l<br>Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Danio rerio (zebra fish)): >= 316 mg/l<br>Exposure time: 34 d<br>Method: OECD Test Guideline 210<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): >= 10 mg/l<br>Exposure time: 21 d |
| Toxicity to microorganisms | : | EC10 (Pseudomonas putida): 30.8 mg/l<br>Exposure time: 17 h |

**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<br><br>Result: Not inherently biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 302B |

**2,2'-Iminodiethanol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 93 %<br>Exposure time: 28 d<br>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<br>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 | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| 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

**International Regulations**

**UNRTDG**

| | | |
|---|---|---|
| UN number | : | UN 1824 |
| Proper shipping name | : | SODIUM HYDROXIDE SOLUTION |
| Class | : | 8 |
| Packing group | : | II |
| Labels | : | 8 |
| Environmentally hazardous | : | yes |

**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.

**National Regulations**

**NZS 5433**

| | | |
|---|---|---|
| UN number | : | UN 1824 |
| Proper shipping name | : | SODIUM HYDROXIDE SOLUTION |
| Class | : | 8 |
| Packing group | : | II |
| Labels | : | 8 |
| Hazchem Code | : | 2R |
| Marine pollutant | : | yes |

**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

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

**HSNO Approval Number**

not allocated

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

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |

| | | |
|---|---|---|
| IECSC | : | not determined |

## Section 16: Other information

| | | |
|---|---|---|
| Revision Date | : | 30.09.2023 |

**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/ |

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

| | | |
|---|---|---|
| Date format | : | dd.mm.yyyy |

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NZ OEL | : | New Zealand. Workplace Exposure Standards for Atmospheric Contaminants |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| ACGIH / C | : | Ceiling limit |
| NZ OEL / WES-TWA | : | Workplace Exposure Standard - Time Weighted average |
| NZ OEL / WES-Ceiling | : | Workplace Exposure Standard - Ceiling |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evalua-

tion, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN