SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Formulation

Version 2.4  Revision Date: 27.08.2021  SDS Number: 6289830-00006  Date of last issue: 09.04.2021
Date of first issue: 25.08.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sulfamethoxazole / Trimethoprim Formulation

Manufacturer or supplier's details
Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Skin corrosion/irritation: Category 1
Serious eye damage/eye irritation: Category 1
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure: Category 2 (Bone marrow)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements:
H314 Causes severe skin burns and eye damage.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
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 vapours.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. Immediately call a POISON CENTER/ doctor.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.
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:
Corrosive to the respiratory tract.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical ad-
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: Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Causes severe burns. Causes digestive tract burns. Corrosive to respiratory system.

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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides
Metal oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

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 vapours.
- 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.
- 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 labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Formulation

Version 2.4  Revision Date: 27.08.2021  SDS Number: 6289830-00006  Date of last issue: 09.04.2021  Date of first issue: 25.08.2020

Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Explosives

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<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>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1000 µg/m³)</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>PEL (short term)</td>
<td>2 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>ACGIH</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

Filter type: Particulates type
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.
9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension
Colour : white to off-white
Odour : No data available
Odour Threshold : No data available
pH : 9.5 - 12.5
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 : 1.179 g/cm³
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 : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
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.

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: > 2,000 mg/kg
Method: Calculation method

Components:

Sulfamethoxazole:
Acute oral toxicity: LD50 (Mouse): 2,300 mg/kg

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.
**Skin corrosion/irritation**
Causes severe burns.

**Components:**

**Sulfamethoxazole:**
- **Species:** Rabbit
- **Result:** No skin irritation

**Sodium hydroxide:**
- **Result:** Corrosive after 3 minutes or less of exposure

**Serious eye damage/eye irritation**
Causes serious eye damage.

**Components:**

**Sodium hydroxide:**
- **Result:** Irreversible effects on the eye
- **Remarks:** Based on skin corrosivity.

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Sulfamethoxazole:**
- **Test Type:** Magnusson-Kligman-Test
- **Exposure routes:** Skin contact
- **Species:** Guinea pig
- **Result:** negative

**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

**Germ cell mutagenicity**
Not classified based on available information.
## Components:

### Sulfamethoxazole:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Humans</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

### Trimethoprim:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

### Carcinogenicity

Not classified based on available information.

### Components:

#### Sulfamethoxazole:

- **Species**: Mouse
- **Application Route**: Ingestion
- **Exposure time**: 26 weeks
- **Result**: negative

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### Trimethoprim:

- **Effects on fertility**: Test Type: Fertility
**SAFETY DATA SHEET**

**Sulfamethoxazole / Trimethoprim Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4</td>
<td>27.08.2021</td>
<td>6289830-00006</td>
<td>09.04.2021</td>
<td>25.08.2020</td>
</tr>
</tbody>
</table>

- **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
- **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**

Not classified based on available information.

**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.
Repeated dose toxicity

**Components:**

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

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

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

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Trimethoprim:**
- **Ingestion**
  - **Target Organs:** Bone marrow
  - **Symptoms:** Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Sulfamethoxazole:**
- **Toxicity to fish**
  - **LC50** (Oryzias latipes (Japanese medaka)): 562.5 mg/l
  - **Exposure time:** 96 h

- **Toxicity to daphnia and other aquatic invertebrates**
  - **EC50** (Ceriodaphnia dubia (water flea)): 0.21 mg/l
  - **Exposure time:** 48 h

- **Toxicity to algae/aquatic plants**
  - **EC50** (Synechococcus leopoliensis (blue-green algae)): 0.0268 mg/l
  - **Exposure time:** 96 h

  **NOEC** (Synechococcus leopoliensis (blue-green algae)):...
M-Factor (Acute aquatic toxicity) : 10
Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 0.533 mg/l
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
M-Factor (Chronic aquatic toxicity) : 10
Toxicity to microorganisms : NOEC (activated sludge): 3.76 mg/l
Method: OECD Test Guideline 301D

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

Persistence and degradability

Components:

Sulfamethoxazole:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
Bioaccumulative potential

Components:

Sulfamethoxazole:
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): < 120
Partition coefficient: n-octanol/water: log Pow: 0.89

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

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
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.

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
(Sulfamethoxazole)
Class: 8
SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Formulation

Version 2.4  Revision Date: 27.08.2021  SDS Number: 6289830-00006  Date of last issue: 09.04.2021
Date of first issue: 25.08.2020

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.

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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

DSL: not determined
AICS: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / C: Ceiling limit
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.