SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Sulfamethoxazole / Trimethoprim Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Skin corrosion/irritation : Sub-category 1A
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.
SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Formulation

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.
P361 + P330 + 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.
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>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>&gt;= 30 - &lt; 40</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td></td>
<td>5.0891</td>
<td>1-410</td>
</tr>
</tbody>
</table>
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 : 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)

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.
### 4. 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.

#### Avoidance of contact

- Oxidizing agents
## Acids

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 decontamination and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### Storage

**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:
  - Strong oxidizing agents

**Packaging material:**
- Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / 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>OEL-C</td>
<td>2 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

### Engineering measures

- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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

- 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

- Chemical-resistant gloves
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>suspension</td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit flammability limit</td>
<td>No data available</td>
</tr>
<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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>9.5 - 12.5</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</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>Vapour pressure</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Density and / or relative density
Relative density : No data available
Density : 1.179 g/cm³
Relative vapour density : No data available

Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle characteristics
Particle size : Not applicable

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac-
tions : 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):

- **Sulfamethoxazole**:
  - Application Route: Intraperitoneal
  - **LD50 (Rat)**: 400 - 500 mg/kg

- **Sodium hydroxide**:
  - Application Route: Intravenous
  - **LD50 (Dog)**: 90 mg/kg
  - **LD50 (Mouse)**: 132 mg/kg

**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:**

- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: Chromosome aberration test in vitro
  Result: negative

- Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Humans
  Result: negative

**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

**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
  - **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.
SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Formulation

Version 4.0
Revision Date: 2021/08/27
SDS Number: 6289826-00006
Date of last issue: 2021/04/09
Date of first issue: 2020/08/25

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:

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Bone marrow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

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>

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Trimethoprim:

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Target Organs: Bone marrow</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion</td>
</tr>
</tbody>
</table>
## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Sulfamethoxazole:

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity</th>
<th>Concentration</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Oryzias latipes (Japanese medaka))</td>
<td>562.5 mg/l</td>
<td>96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Ceriodaphnia dubia (water flea))</td>
<td>0.21 mg/l</td>
<td>48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Synechococcus leopoliensis (blue-green algae))</td>
<td>0.0268 mg/l</td>
<td>96 h</td>
</tr>
<tr>
<td>NOEC (Synechococcus leopoliensis (blue-green algae))</td>
<td></td>
<td>0.0059 mg/l</td>
<td>96 h</td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Danio rerio (zebra fish))</td>
<td>0.533 mg/l</td>
<td>21 d</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea))</td>
<td>0.01 mg/l</td>
<td>30 d</td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>NOEC (activated sludge)</td>
<td>3.76 mg/l</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 301D</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Trimethoprim:

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity</th>
<th>Concentration</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow))</td>
<td>100 mg/l</td>
<td>96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna Straus):</td>
<td>92 mg/l</td>
<td>48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (microalgae)):</td>
<td>80.3 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td></td>
<td>16 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td>EC50 (Anabaena flos-aquae):</td>
<td></td>
<td>253 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td>EC10 (Anabaena flos-aquae):</td>
<td></td>
<td>26 mg/l</td>
<td>72 h</td>
</tr>
</tbody>
</table>
Toxicity to fish (Chronic toxicity): NOEC (Zebrafish): 0.157 mg/l
Exposure time: 21 d

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

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

Hazardous to the ozone layer: Not applicable

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
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**
Refer to section 15 for specific national regulation.

**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**

**Related Regulations**

**Fire Service Law**
Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**
Not applicable

**Harmful Substances Required Permission for Manufacture**
Not applicable
Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>319</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>319</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Deleterious substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Cabinet Order Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparations containing sodium hydroxide</td>
<td>68</td>
</tr>
</tbody>
</table>

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Corrosive substances (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)
SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Formulation

Version 4.0
Revision Date: 2021/08/27
SDS Number: 6289826-00006
Date of last issue: 2021/04/09
Date of first issue: 2020/08/25

16. OTHER INFORMATION

Further information

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

Date format: yyyy/mm/dd

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

AICL - 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
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