1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfamethoxazole / Trimethoprim Formulation

Manufacturer or supplier's details
Company : MSD
Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
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 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.
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

Components

<table>
<thead>
<tr>
<th>Chemical name</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; 60</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-
vice 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)
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.
### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:**
- Evacuate area.
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

**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:
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>KTD</td>
<td>2 mg/m3</td>
<td>ID OEL</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 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

Hygiene measures:
Work uniform or laboratory coat.
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.
Molecular weight : No data available
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:
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: 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: Bone marrow, 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)): 
0.0059 mg/l
Exposure time: 96 h

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) : NOEC (Daphnia magna (Water flea)): 0.01 mg/l
Exposure time: 30 d

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) : 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

**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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Sodium hydroxide
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : 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
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.

ID / EN