1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Oxytetracycline (10%) 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 : Category 2
Serious eye damage/eye irritation : Category 2
Skin sensitisation : Category 1
Reproductive toxicity : Category 1A
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : [Image]
Signal word : Danger
Hazard statements : H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360D May damage the unborn child.
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.
P261 Avoid breathing mist or vapours.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it 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
None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 10 - &lt; 20</td>
<td>9-271</td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>2</td>
<td>2-301</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphinate</td>
<td>6035-47-8</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>2-1633</td>
</tr>
</tbody>
</table>

### 4. FIRST AID MEASURES

**General advice:**
In the case of accident or if you feel unwell, seek medical ad-
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

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Date of first issue: 2020/03/10

If inhaled
If inhaled, remove to fresh air. Get medical attention.

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. 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.

If swallowed
If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed
Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May damage the unborn child.

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)

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.

Special protective equipment for firefighters
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

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

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

### Methods and materials for containment and cleaning up

- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If 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

#### Handling

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>If sufficient ventilation is unavailable, use with local exhaust ventilation.</td>
</tr>
<tr>
<td>Advice on safe handling</td>
<td>Do not get on skin or clothing. Avoid breathing 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. Take care to prevent spills, waste and minimize release to the environment.</td>
</tr>
<tr>
<td>Avoidance of contact</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td>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. Contaminated work clothing should not be allowed out of the workplace. 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.</td>
</tr>
</tbody>
</table>
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>Oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Ethanolamine</td>
<td>141-43-5</td>
<td>OEL-M</td>
<td>3 ppm 7.5 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>3 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>6 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: DSEN

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>Wipe limit</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 µg/100 cm²</td>
<td>Internal</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: Combined particulates and organic vapour 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.

9. PHYSICAL AND CHEMICAL PROPERTIES
Physical state : suspension

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity
  Viscosity, kinematic : Not applicable

Solubility(ies)
  Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density
  Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

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 reactions: Can react with strong oxidizing agents.
- Conditions to avoid: None known.
- Incompatible materials: Oxidizing agents
- 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

- **Acute inhalation toxicity:**
  - Acute toxicity estimate: > 20 mg/l
  - Exposure time: 4 h
  - Test atmosphere: vapour
  - Method: Calculation method

- **Acute dermal toxicity:**
  - Acute toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

**Components:**

**oxytetracycline:**

- **Acute oral toxicity:**
  - LD50 (Rat): 4,800 mg/kg
  - LD50 (Mouse): 2,240 mg/kg
  - Remarks: Evidence of phototoxicity was observed

- **Acute inhalation toxicity:**
  - Remarks: No data available

- **Acute dermal toxicity:**
  - Remarks: No data available

- **Acute toxicity (other routes of):**
  - LD50 (Rat): 4,840 mg/kg
SAFETY DATA SHEET
Oxytetracycline (10%) Formulation

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Date of first issue: 2020/03/10

administration)  Application Route: Intramuscular
LD50 (Mouse): 3,500 mg/kg
Application Route: Subcutaneous

Ethanolamine:
Acute oral toxicity  :  LD50 (Rat): 1,089 mg/kg
Acute inhalation toxicity  :
  Acute toxicity estimate: 11 mg/l
  Exposure time: 4 h
  Test atmosphere: vapour
  Method: Expert judgement
  Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI
Acute dermal toxicity  :  LD50 (Rabbit, female): 1,018 mg/kg

Sodium hydroxymethanesulphinate:
Acute oral toxicity  :  LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 423
  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 skin irritation.

Components:
oxytetracycline:
Remarks  :  No data available

Ethanolamine:
Species  :  Rabbit
Result  :  Corrosive after 3 minutes to 1 hour of exposure

Sodium hydroxymethanesulphinate:
Species  :  Rat
Result  :  No skin irritation
Remarks  :  Based on data from similar materials

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:
oxytetracycline:
Remarks  :  No data available
Ethanolamine:
Species: Rabbit
Result: Irreversible effects on the eye

Sodium hydroxymethanesulphinate:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

Respiratory or skin sensitisation
Skin sensitisation
May cause an allergic skin reaction.
Respiratory sensitisation
Not classified based on available information.

Components:

oxytetracycline:
Test Type: Human repeat insult patch test (HRIPT)
Result: Sensitiser

Ethanolamine:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Sodium hydroxymethanesulphinate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

oxytetracycline:
Genotoxicity in vitro:
Test Type: Microbial mutagenesis assay (Ames test)
Result: negative
Test Type: Mouse Lymphoma
Metabolic activation: Metabolic activation
Result: positive
Test Type: sister chromatid exchange assay
## Genotoxicity in vivo

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Cell type</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micronucleus test</td>
<td>equivocal</td>
<td>Mouse</td>
<td>Bone marrow</td>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>in vivo assay</td>
<td>equivocal</td>
<td>Mouse</td>
<td>Intraperitoneal injection</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity - Assessment

- Weight of evidence does not support classification as a germ cell mutagen.

### Ethanolamine

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td></td>
<td></td>
<td>OECD Test Guideline 476</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Sodium hydroxymethanesulphinate

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
<td>Mouse</td>
<td>Ingestion</td>
<td>OECD Test Guideline 474</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity - Assessment

- Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.
Carcinogenicity
Not classified based on available information.

Components:
oxylactone:
Species: Mouse
Application Route: Oral
Exposure time: 104 weeks
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 103 weeks
Result: equivocal
Target Organs: Adrenal gland, Pituitary gland
Remarks: The mechanism or mode of action may not be relevant in humans.

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

Reproductive toxicity
May damage the unborn child.

Components:
oxylactone:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 18 mg/kg body weight
Result: No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight
Result: Postimplantation loss., Skeletal malformations

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 1,500 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
General Toxicity Maternal: LOAEL: 1,325 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 2,100 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 41.5 mg/kg body weight
Result: Postimplantation loss., No foetal abnormalities

Test Type: Embryo-foetal development
Species: Dog
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 20.75 mg/kg body weight
Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.

Ethanolamine:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

Sodium hydroxymethanesulphinate:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment: Some evidence of adverse effects on development, based on animal experiments.
STOT - single exposure
Not classified based on available information.

Components:
Ethanolamine:
Assessment : May cause respiratory irritation.

STOT - repeated exposure
Not classified based on available information.

Components:
Ethanolamine:
Assessment : No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

Repeated dose toxicity

Components:
oxytetracycline:
Species : Rat
LOAEL : 198 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Bone
Remarks : No significant adverse effects were reported

Species : Mouse
LOAEL : 7,990 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Bone
Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 125 mg/kg
LOAEL : 250 mg/kg
Application Route : Oral
Exposure time : 12 Months
Target Organs : Testis
Remarks : Significant toxicity observed in testing

Species : Rat
NOAEL : 40 mg/kg
LOAEL : 100 mg/kg
Application Route : Intraperitoneal
Exposure time : 14 Days
Target Organs : Kidney

Ethanolamine:
Species : Rat
NOAEL : > 120 mg/kg
Application Route: Ingestion
Exposure time: > 75 Days
Remarks: Based on data from similar materials

Species: Rat
NOAEL: >= 0.15 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

Sodium hydroxymethanesulphinate:
Species: Rat
NOAEL: 600 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
oxytetracycline:
Ingestion: Symptoms: Gastrointestinal disturbance, tooth discoloration
Remarks: May cause birth defects.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
oxytetracycline:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 621 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 669 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Anabaena): 0.032 mg/l
Exposure time: 72 h
NOEC (Anabaena): 0.0031 mg/l
Exposure time: 72 h

M-Factor (Acute aquatic toxicity) : 10
M-Factor (Chronic aquatic toxicity) : 10
Toxicity to microorganisms : EC50: 17.9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 0.2 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Ethanolamine:
Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 349 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 65 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Orange-red killifish)): 1.24 mg/l
Exposure time: 41 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.85 mg/l
Exposure time: 21 d

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

Sodium hydroxymethanesulphinate:
Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity): NOEC (Danio rerio (zebra fish)): 13.5 mg/l
Exposure time: 35 d
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 5.6 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 4 h
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Ethanolamine:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 90%
Exposure time: 21 d
Method: OECD Test Guideline 301A

Sodium hydroxymethanesulphinate:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 77%
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Ethanolamine:
Partition coefficient: n-octanol/water: log Pow: -2.3
Method: OECD Test Guideline 107

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

<table>
<thead>
<tr>
<th>UNRTDG</th>
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<tbody>
<tr>
<td>UN number</td>
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<td>Marine pollutant</td>
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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
15. REGULATORY INFORMATION

Related Regulations

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

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
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<tr>
<td>2-Aminoethanol</td>
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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)

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

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

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances

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High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet
SAFETY DATA SHEET

Oxytetracycline (10%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
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<th>SDS Number:</th>
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Date format: yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIIC - 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, Evaluation, 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.

JP / EN