SAFETY DATA SHEET

Doxycycline Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Doxycycline 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
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 2

GHS label elements
Hazard pictograms: 
Signal word: Danger
Hazard statements: H314 Causes severe skin burns and eye damage.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements: 
Prevention:
P260 Do not breathe dust.
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.
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
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxycycline Hyclate</td>
<td>24390-14-5</td>
<td>&gt;= 50 -&lt; 70</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 while keeping eyelids open.
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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.
- Causes severe burns.
- Causes digestive tract burns.

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:
- Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon 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.

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.
- 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:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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: Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 dust.
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.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
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>Doxycycline Hyclate</td>
<td>24390-14-5</td>
<td>TWA</td>
<td>OEL = 100</td>
<td>Internal</td>
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</table>
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<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Personal protective equipment</th>
<th>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</th>
</tr>
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<table>
<thead>
<tr>
<th>Hand protection Material: Chemical-resistant gloves</th>
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<tr>
<th>Eye protection</th>
<th>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.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Skin and body protection</th>
<th>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.</th>
</tr>
</thead>
</table>

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<thead>
<tr>
<th>9. PHYSICAL AND CHEMICAL PROPERTIES</th>
<th>Appearance: powder</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Colour</th>
<th>light yellow</th>
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<table>
<thead>
<tr>
<th>Odour</th>
<th>No data available</th>
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</table>

<table>
<thead>
<tr>
<th>Odour Threshold</th>
<th>No data available</th>
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<table>
<thead>
<tr>
<th>pH</th>
<th>1.5 - 3.5</th>
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<table>
<thead>
<tr>
<th>Melting point/freezing point</th>
<th>No data available</th>
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</table>

<table>
<thead>
<tr>
<th>Initial boiling point and boiling range</th>
<th>No data available</th>
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</table>

<table>
<thead>
<tr>
<th>Flash point</th>
<th>Not applicable</th>
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</table>

<table>
<thead>
<tr>
<th>Evaporation rate</th>
<th>Not applicable</th>
</tr>
</thead>
</table>
### Flammability (solid, gas)
May form explosive dust-air mixture during processing, handling or other means.

### Flammability (liquids)
Not applicable

### Upper explosion limit / Upper flammability limit
No data available

### Lower explosion limit / Lower flammability limit
No data available

### Vapour pressure
Not applicable

### Relative vapour density
Not applicable

### Relative density
No data available

### Density
No data available

### 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
  Not applicable

### Explosive properties
Not explosive

### Oxidizing properties
The substance or mixture is not classified as oxidizing.

### Molecular weight
No data available

### Particle size
No data available

### Stability and Reactivity

#### Reactivity
Not classified as a reactivity hazard.

#### Chemical stability
Stable under normal conditions.

#### Possibility of hazardous reactions
May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

#### Conditions to avoid
Heat, flames and sparks.

#### Incompatible materials
Avoid dust formation.

#### Hazardous decomposition products
Oxidizing agents

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:
Doxycycline Hyclate:
Acute oral toxicity:
- LD50 (Rat): 2,000 mg/kg
- LD50 (Mouse): 1,870 mg/kg
- LD50 (Dog): 500 mg/kg

Skin corrosion/irritation
Causes severe burns.

Components:
Doxycycline Hyclate:
Remarks:
- No data available
- May irritate skin.

Serious eye damage/eye irritation
Causes serious eye damage.

Components:
Doxycycline Hyclate:
Remarks:
- No data available
- May irritate eyes.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.
Components:

Doxycycline Hyclate:
Remarks: No data available
May cause sensitisation by skin contact.
May cause sensitisation of susceptible persons by skin contact or by inhalation of dust.

Germ cell mutagenicity
Not classified based on available information.

Components:

Doxycycline Hyclate:
Genotoxicity in vitro:
Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster cells
Result: Weakly positive
Remarks: Based on data from similar materials
Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster cells
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo:
Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Oral
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:

Doxycycline Hyclate:
Species: Rat
Application Route: Oral
Exposure time: 2 Years: 200 mg/kg body weight
Symptoms: females
Target Organs: Uterus (including cervix)
Remarks: Benign tumor(s)

Reproductive toxicity
Not classified based on available information.

Components:

Doxycycline Hyclate:
Effects on foetal development:
Test Type: Fertility/early embryonic development
Species: Rat, females
Application Route: Oral
General Toxicity Maternal: NOAEL: 250 mg/kg body weight
Result: No adverse effects

Test Type: Fertility/early embryonic development
Species: Rat, male
Application Route: Oral
General Toxicity Maternal: NOAEL: 50 mg/kg body weight
Symptoms: male reproductive effects

Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Doxycycline Hyclate:
Species: Rat
NOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 28 d
Symptoms: Thyroid effects

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Doxycycline Hyclate:
General Information: May cause
Target Organs: Teeth
Symptoms: Gastrointestinal disturbance
Skin contact: Remarks: May cause photosensitisation

Further information

Components:

Doxycycline Hyclate:
Remarks: Well tolerated in clinical use

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Doxycycline Hyclate:
Toxicity to algae/aquatic plants: EC10 (Anabaena flos-aquae): 0.251 mg/l
End point: Growth rate
Exposure time: 72 h

Ecotoxicology Assessment
Acute aquatic toxicity: Very toxic to aquatic life.
Chronic aquatic toxicity: Toxic to aquatic life with long lasting effects.

Persistence and degradability
No data available

Bioaccumulative potential

Components:
Doxycycline Hyclate:
Partition coefficient: n-octanol/water
log Pow: 0.02

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 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Doxycycline Hyclate)
Class: 9
Packing group: III
Labels: Miscellaneous
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- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

**IMDG-Code**

- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Doxycycline Hyclate)

- Class: 9
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F
- 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:**

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

### 16. OTHER INFORMATION

**Further information**

Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
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Date format: dd.mm.yyyy

Full text of other abbreviations

ALLIC - 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 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.

SG / EN