Enramycin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Enramycin Formulation

Manufacturer or supplier's details
Company : MSD
Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone : +1-908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>light brown</td>
</tr>
<tr>
<td>Odour</td>
<td>characteristic</td>
</tr>
</tbody>
</table>

Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

GHS Classification

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

GHS label elements
Hazard pictograms :

Signal word : Warning

Hazard statements : H400 Very toxic to aquatic life.
                   H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :
Prevention: P273 Avoid release to the environment.
Response:
Enramycin Formulation

Physical and chemical hazards
Not classified based on available information.

Health hazards
Not classified based on available information.

Environmental hazards
Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosible dust-air mixture if dispersed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
</tr>
<tr>
<td>ENRAMYCIN B</td>
<td>34304-21-7</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.
Get medical attention if symptoms occur.

In case of skin contact: Wash with water and soap.
Get medical attention if symptoms occur.

In case of eye contact: If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

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

Most important symptoms and effects, both acute and delayed: Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Notes to physician: No special precautions are necessary for first aid responders.
Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Enramycin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 2020/10/16</th>
<th>Date of first issue: 2014/10/22</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.6</td>
<td>2021/08/27</td>
<td>24582-00016</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Unsuitable extinguishing media: High volume water jet

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.
- Do not use a solid water stream as it may scatter and spread fire.
- 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:
- Wear self-contained breathing apparatus for firefighting if necessary.
- Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- 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

Handling
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: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: None.

Storage
Conditions for safe storage: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Materials to avoid: No special restrictions on storage with other products.

Packaging material: Unsuitable material: None known.

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>Talc</td>
<td>14807-96-6</td>
<td>PC-TWA (Total dust)</td>
<td>3 mg/m3</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-TWA (Respirable dust)</td>
<td>1 mg/m3</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>ENRAMYCIN B</td>
<td>34304-21-7</td>
<td>TWA</td>
<td>5 mg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: 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.

Personal protective equipment
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-
Filter type: Recommended guidelines, use respiratory protection.

Particulates type: 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.

Eye/face 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.

Hand protection:
- Material: Chemical-resistant gloves

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Colour: light brown

Odour: characteristic

Odour Threshold: No data available

pH: 5 - 8.5

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): No data available

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available
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Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Solubility(ies)
Water solubility: practically insoluble
Partition coefficient: n-octanol/water: No data available
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
Particle size: No data available

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Dust can form an explosive mixture in air.
Conditions to avoid: Avoid dust formation.
Incompatible materials: None.
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Talc:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials
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ENRAMYCIN B:
Acute oral toxicity: LD50 (Mouse): > 5,000 mg/kg
LD50 (Rat): > 10,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Talc:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Talc:
Species: Rabbit
Result: No eye irritation

ENRAMYCIN B:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Talc:
Exposure routes: Skin contact
Species: Humans
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Talc:
Genotoxicity in vitro: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative
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Genotoxicity in vivo: Test Type: Chromosome aberration test in vitro  
Species: Rat  
Application Route: Ingestion  
Result: negative

ENRAMYCIN B:  
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Carcinogenicity  
Not classified based on available information.

Components:  
Talc:  
Species: Mouse  
Application Route: Inhalation (dust/mist/fume)  
Exposure time: 2 Years  
Result: negative

Reproductive toxicity  
Not classified based on available information.

Components:  
Talc:  
Effects on foetal development: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

STOT - single exposure  
Not classified based on available information.

STOT - repeated exposure  
Not classified based on available information.

Repeated dose toxicity

Components:  
ENRAMYCIN B:  
Species: Rat  
NOAEL: 1,000 mg/kg  
Application Route: Ingestion  
Exposure time: 6 Months

Aspiration toxicity  
Not classified based on available information.
12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Talc:**
- Toxicity to fish: LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l
  Exposure time: 24 h

**ENRAMYCIN B:**
- Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 1 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
  Remarks: No toxicity at the limit of solubility

  Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
  Remarks: No toxicity at the limit of solubility

  Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 18 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 0.96 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

  EC50 (Anabaena flos-aquae (cyanobacterium)): 0.083 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

  NOEC (Anabaena flos-aquae (cyanobacterium)): 0.045 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

**M-Factor (Acute aquatic toxicity):** 10

**M-Factor (Chronic aquatic toxicity):** 1

**Toxicity to microorganisms:**
- EC50: 438.5 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209

- EC10: 0.045 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209
10. PERSISTENCE AND DEGRADABILITY

**Components:**

**ENRAMYCIN B:**

**Biodegradability:**

Result: Not readily biodegradable.

Method: OECD Test Guideline 301B

**Bioaccumulative potential**

No data available

**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. (ENRAMYCIN B)
- **Class:** 9
- **Packing group:** III
- **Labels:** 9

**IATA-DGR**

- **UN/ID No.:** UN 3077
- **Proper shipping name:** Environmentally hazardous substance, solid, n.o.s. (ENRAMYCIN B)
- **Class:** 9
- **Packing group:** III
- **Labels:** Miscellaneous
- **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,
Enramycin Formulation

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.

National Regulations

GB 6944/12268
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ENRAMYCIN B)
Class: 9
Packing group: III
Labels: 9

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

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

Date format: yyyy/mm/dd

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

CN OEL: Occupational exposure limits for hazardous agents in the
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workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

AllC - 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 Standardisation; 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

Disclaimer

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.

CN / EN