SAFETY DATA SHEET

Enramycin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Enramycin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 50 Tuas West Drive
          Singapore - Singapore 638408
Telephone : 908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

2. HAZARDS IDENTIFICATION

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:
                           P391 Collect spillage.
                           Disposal:
                           P501 Dispose of contents/ container to an approved waste disposal plant.
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Version 2.4  Revision Date: 23.03.2020  SDS Number: 24603-00014  Date of last issue: 13.09.2019  Date of first issue: 22.10.2014

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 exploisible dust-air mixture if dispersed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td></td>
<td>&gt;= 90 -&lt; 100</td>
</tr>
<tr>
<td>ENRAMYCIN B</td>
<td>34304-21-7</td>
<td></td>
<td>&gt;= 2.5 -&lt; 10</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical 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
Protection of first-aiders : 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
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

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)
3. 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.

4. 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 and personal protective equipment recommendations.
   - Environmental precautions:
     - Discharge into the environment must be avoided.
     - 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
   - Advice on safe handling:
     - Use only with adequate ventilation.
     - 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.
   - 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.

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>PEL (long term)</td>
<td>2 mg/m3</td>
<td>SG 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 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 face shield 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.
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

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

Information on likely routes of exposure:
- 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

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

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

Exposure time: 3 h

Method: OECD Test Guideline 209

EC50: 438.5 mg/l
EC10: 0.045 mg/l

Method: OECD Test Guideline 209

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
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
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16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
SG OEL: Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / TWA: 8-hour, time-weighted average
SG OEL / PEL (long term): Permissible Exposure Level (PEL) Long Term

AICS - Australian Inventory of Chemical Substances; 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; 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
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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