Enramycin Formulation

SECTION 1. IDENTIFICATION

Product name: Enramycin Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Combustible dust: Category 1

GHS label elements
Signal Word: Warning
Hazard Statements: May form combustible dust concentrations in air.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc</td>
<td>Talc (Mg3H2(SiO3)4)</td>
<td>14807-96-6</td>
<td>&gt;= 80 - &lt;= 100 *</td>
</tr>
<tr>
<td>ENRAMYCIN B</td>
<td>No data available</td>
<td>34304-21-7</td>
<td>&gt;= 5 - &lt; 10 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

SECTION 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
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.

Protection of first-aiders: No special precautions are necessary for first aid responders.

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING 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)

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 fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 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
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.

SECTION 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:
- 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.

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>TWAEV (respirable dust)</td>
<td>2 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulates)</td>
<td>2 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 fibres per cubic centimeter</td>
<td>CA ON OEL</td>
</tr>
</tbody>
</table>
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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 faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

Hygiene measures:
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: light brown
Odor: characteristic
Odor Threshold: No data available
pH: 5 - 8.5
Melting point/freezing point: No data available
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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
Vapor pressure: No data available
Relative vapor density: No data available
Relative density: No data available
Solubility(ies)
   Water solubility: practically insoluble
Partition coefficient: n-octanol/water: No data available
Autoignition 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

SECTION 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.
SECTION 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

ENRAMYCIN B:
- Species: Rabbit
  Result: No eye 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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.
Components:

Talc:
- Routes of exposure: 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 fetal development: Test Type: Embryo-fetal 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.

### SECTION 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

- **Toxicity to microorganisms:** EC50: 438.5 mg/l
  - **Exposure time:** 3 h
  - **Method:** OECD Test Guideline 209
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Date of first issue: 10/22/2014

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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

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.

SECTION 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): 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(ENRAMYCIN B)

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.

Domestic regulation

TDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(ENRAMYCIN B)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(ENRAMYCIN B)

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.

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA ON OEL : Ontario Table of Occupational Exposure Limits made under
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the Occupational Health and Safety Act.

CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
CA QC OEL / TWA EV : Time-weighted average exposure value


Revision Date: 03/20/2023
Date format: mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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

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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.