SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin Ointment Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Gentamicin Ointment Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             Shotton Lane
             NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Reproductive toxicity, Category 1A
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 3
   H360D: May damage the unborn child.
   H400: Very toxic to aquatic life.
   H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements :
   Prevention:
Gentamicin Ointment Formulation

Hazardous components which must be listed on the label:
Gentamicin

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>99-76-3 202-785-7</td>
<td>Aquatic Chronic 2; H411</td>
<td>&lt;= 1</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3 215-765-8</td>
<td>Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1</td>
<td>&gt;= 0.1 - &lt;= 0.3</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
### 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).

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

### In case of skin contact
In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

### In case of eye contact
Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

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

### 4.2 Most important symptoms and effects, both acute and delayed
**Risks**
May damage the unborn child.

### 4.3 Indication of any immediate medical attention and special treatment needed
**Treatment**
Treat symptomatically and supportively.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media
**Suitable extinguishing media**
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

**Unsuitable extinguishing media**
None known.

#### 5.2 Special hazards arising from the substance or mixture
**Specific hazards during firefighting**
- Vapours may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

**Hazardous combustion products**
Carbon oxides

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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 swallow. Avoid contact with eyes. 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
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>58.76 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>9.8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>14.49 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4.2 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4.16 mg/kg bw/day</td>
</tr>
<tr>
<td>Propyl p-hydroxybenzoate</td>
<td>Workers</td>
<td>Inhalation</td>
<td></td>
<td>57.6 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td></td>
<td>20.42 mg/kg bw/day</td>
</tr>
</tbody>
</table>
Gentamicin Ointment Formulation

<table>
<thead>
<tr>
<th>Consumers</th>
<th>Inhalation</th>
<th>Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Petrolatum: Oral (Secondary Poisoning) 9.33 mg/kg food&lt;br&gt;Methyl p-Hydroxybenzoate: Fresh water 2.4 µg/l&lt;br&gt;Marine water 0.24 µg/l&lt;br&gt;Sewage treatment plant 2 mg/l&lt;br&gt;Freshwater - intermittent 0.112 mg/l&lt;br&gt;Fresh water sediment 0.0632 mg/kg dry weight (d.w.)&lt;br&gt;Marine sediment 0.00632 mg/kg dry weight (d.w.)&lt;br&gt;Soil 0.0115 mg/kg dry weight (d.w.)&lt;br&gt;Propyl p-hydroxybenzoate: Fresh water 0.0064 mg/l&lt;br&gt;Marine water 0.00064 mg/l&lt;br&gt;Intermittent use/release 0.064 mg/l&lt;br&gt;Sewage treatment plant 2 mg/l&lt;br&gt;Fresh water sediment 0.2065 mg/kg&lt;br&gt;Marine sediment 0.0206 mg/kg&lt;br&gt;Soil 0.0375 mg/kg</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>14.2 mg/m3&lt;br&gt;10.21 mg/kg bw/day&lt;br&gt;4.08 mg/kg bw/day</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

**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**

- **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.
- **Hand protection**: Chemical-resistant gloves
- **Skin and body protection**: Work uniform or laboratory coat.
- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387

**Filter type**: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Gentamicin Ointment Formulation

Appearance : ointment
Colour : colourless
Odour : No data available
Odour Threshold : No data available

pH : No data available
Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available
Flash point : > 93.3 °C
Evaporation rate : No data available

Flammability (solid, gas) : Not classified as a flammability hazard
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
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 : No data available

Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : Not applicable
Particle size : Not applicable
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions:
- Vapours may form explosive mixture with air.
- Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

Methyl p-Hydroxybenzoate:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Gentamicin:
Acute oral toxicity: LD50 (Rat): 8,000 - 10,000 mg/kg
LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 0.2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration): LD50 (Rat): 67 - 96 mg/kg
Application Route: Intravenous
LD50 (Rat): 371 - 384 mg/kg
Gentamicin Ointment Formulation

Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg
Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.

Components:

Methyl p-Hydroxybenzoate:
Species: Rabbit
Result: No skin irritation

Gentamicin:
Species: Rabbit
Result: Mild skin irritation

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

Components:

Methyl p-Hydroxybenzoate:
Species: Rabbit
Result: No eye irritation

Gentamicin:
Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Methyl p-Hydroxybenzoate:
Test Type: Maurer optimisation test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Gentamicin:
Remarks: No data available
## Germ cell mutagenicity
Not classified based on available information.

### Components:

#### Methyl p-Hydroxybenzoate:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 471</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 473</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
</tr>
</tbody>
</table>

#### Gentamicin:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cyto genetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous injection</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

## Carcinogenicity
Not classified based on available information.

### Components:

#### Gentamicin:

Carcinogenicity - Assessment: No data available

## Reproductive toxicity
May damage the unborn child.

### Components:

#### Methyl p-Hydroxybenzoate:

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>
Gentamicin Ointment Formulation

Gentamicin:
Effects on fertility:
- Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Fertility: NOAEL: 20 mg/kg body weight
  - Result: No significant adverse effects were reported

Effects on foetal development:
- Test Type: Embryo-foetal development
  - Species: Rabbit
  - Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
  - Result: No embryo-foetal toxicity

  - Test Type: Embryo-foetal development
    - Species: Rat
    - Application Route: Intraperitoneal
    - Developmental Toxicity: LOAEL: 75 mg/kg body weight
    - Result: Embryo-foetal toxicity

  - Test Type: Embryo-foetal development
    - Species: Mouse
    - Application Route: Intraperitoneal
    - Developmental Toxicity: LOAEL: 10 mg/kg body weight
    - Result: foetal mortality, No malformations were observed.

  - Test Type: Embryo-foetal development
    - Species: Rat
    - Application Route: Intraperitoneal
    - Developmental Toxicity: LOAEL: 50 mg/kg body weight
    - Result: foetal mortality, No malformations were observed.

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

STOT - single exposure
- Not classified based on available information.

STOT - repeated exposure
- Not classified based on available information.

Components:

Gentamicin:
Target Organs: Kidney, inner ear
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Methyl p-Hydroxybenzoate:
- Species: Rat
- NOAEL: 250 mg/kg
- LOAEL: 1,000 mg/kg
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Application Route: Ingestion  
Exposure time: 28 Days  
Method: OECD Test Guideline 407

Gentamicin:
Species: Dog  
LOAEL: 3 mg/kg  
Application Route: Intramuscular  
Exposure time: 12 Months  
Target Organs: Kidney  
Symptoms: Vomiting, Salivation

Species: Monkey  
LOAEL: 50 mg/kg  
Application Route: Subcutaneous  
Exposure time: 3 Weeks  
Target Organs: Kidney, inner ear

Species: Monkey  
LOAEL: 6 mg/kg  
Application Route: Intramuscular  
Exposure time: 3 Weeks  
Target Organs: Blood, Kidney, inner ear, Liver

Species: Rat  
NOAEL: 5 mg/kg  
LOAEL: 10 mg/kg  
Application Route: Intramuscular  
Exposure time: 52 Weeks  
Target Organs: Kidney, Blood

Species: Rat  
NOAEL: 12.5 mg/kg  
LOAEL: 50 mg/kg  
Application Route: Intramuscular  
Exposure time: 13 Weeks  
Target Organs: Kidney

Aspiration toxicity
Not classified based on available information.

Product:
No aspiration toxicity classification

Experience with human exposure

Components:

Gentamicin:
Ingestion: Target Organs: Kidney  
Target Organs: inner ear  
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal
Gentamicin Ointment Formulation

SECTION 12: Ecological information

12.1 Toxicity

Components:

Methyl p-Hydroxybenzoate:

- Toxicity to fish
  - LC50 (Oryzias latipes (Japanese medaka)): 59.5 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

- Toxicity to daphnia and other aquatic invertebrates
  - EC50 (Daphnia magna (Water flea)): 11.2 mg/l
  - Exposure time: 48 h
  - Method: ISO 6341

- Toxicity to algae/aquatic plants
  - EC50 (Pseudokirchneriella subcapitata (green algae)): 91 mg/l
  - Exposure time: 72 h
  - Method: ISO 8692

  - EC10 (Pseudokirchneriella subcapitata (green algae)): 31 mg/l
  - Exposure time: 72 h
  - Method: ISO 8692

Gentamicin:

- Toxicity to fish (Chronic toxicity)
  - NOEC: 0.024 mg/l
  - Exposure time: 70 d
  - Species: Danio rerio (zebra fish)

- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
  - NOEC: 0.2 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211

- Toxicity to daphnia and other aquatic invertebrates
  - EC50 (Daphnia magna (Water flea)): 86 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

  - LC50 (Americamysis): 30 mg/l
  - Exposure time: 96 h

- Toxicity to algae/aquatic plants
  - EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  - NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 100

Toxicity to microorganisms:  
EC50 : 288.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity): 1

12.2 Persistence and degradability

Components:

Methyl p-Hydroxybenzoate:  
Biodegradability: Result: Readily biodegradable.  
Biodegradation: 89 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

Gentamicin:  
Biodegradability: Result: rapidly degradable  
Biodegradation: 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

12.3 Bioaccumulative potential

Components:

Methyl p-Hydroxybenzoate:  
Partition coefficient: n-octanol/water: log Pow: 1.98

Gentamicin:  
Partition coefficient: n-octanol/water: log Pow: < -2

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available
SECTION 13: Disposal considerations

13.1 Waste treatment methods

- **Product**: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **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

14.1 UN number

- **ADN**: UN 3077
- **ADR**: UN 3077
- **RID**: UN 3077
- **IMDG**: UN 3077
- **IATA**: UN 3077

14.2 UN proper shipping name

- **ADN**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Gentamicin)
- **ADR**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Gentamicin)
- **RID**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Gentamicin)
- **IMDG**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Gentamicin)
- **IATA**: Environmentally hazardous substance, solid, n.o.s. (Gentamicin)

14.3 Transport hazard class(es)

- **ADN**: 9
- **ADR**: 9
- **RID**: 9
- **IMDG**: 9
- **IATA**: 9

14.4 Packing group
ADN
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9

ADR
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9

RID
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9

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

IATA (Cargo)
Packing instruction (cargo aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous

14.5 Environmental hazards
ADN
Environmentally hazardous: yes
ADR
Environmentally hazardous: yes
RID
Environmentally hazardous: yes
IMDG
Marine pollutant: yes
IATA (Passenger)
Environmentally hazardous: yes
IATA (Cargo)
Environmentally hazardous: yes
14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

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SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin Ointment Formulation

Version 2.4 Revision Date: 28.09.2020 SDS Number: 2054107-00008 Date of last issue: 23.03.2020 Date of first issue: 09.10.2017

Full text of H-Statements
H360D : May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin Ointment Formulation

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Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification of the mixture</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1A</td>
<td>H360D</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 3</td>
<td>H412</td>
</tr>
</tbody>
</table>

Classification procedure:

- Calculation method

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