1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Gentamicin Ointment Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 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: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>ointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>colourless</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

May damage the unborn child. Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

GHS Classification

Reproductive toxicity: Category 1A
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 3

GHS label elements

Hazard pictograms: 

Signal word: Danger
Hazard statements: 
H360D May damage the unborn child.
H400 Very toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

**Physical and chemical hazards**
Not classified based on available information.

**Health hazards**
May damage the unborn child.

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

**Other hazards which do not result in classification**
None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 90 -&lt; 100</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>99-76-3</td>
<td>&lt;= 1</td>
</tr>
<tr>
<td>Propyl p-hydroxybenzoate</td>
<td>94-13-3</td>
<td>&lt;= 1</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&gt;= 0.1 -&lt; 0.3</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.
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.

Most important symptoms and effects, both acute and delayed: May damage the unborn child.

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: Vapours may form explosive mixtures with air. 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 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.
SAFETY DATA SHEET  
according to GB/T 16483 and GB/T 17519

Gentamicin Ointment Formulation

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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 environment.
Avoidance of contact: Oxidizing agents

Storage
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: Strong oxidizing agents
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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<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>

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**: Combined particulates and organic vapour type

**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**: 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
Flammability (liquids) : Not applicable
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.
Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Skin contact
   Ingestion
   Eye contact
Acute toxicity
Not classified based on available information.

Components:

Petrolatum:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

White mineral oil (petroleum):
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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

Propyl p-hydroxybenzoate:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

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
Application Route: Intramuscular
Skin corrosion/irritation
Not classified based on available information.

Components:

Petrolatum:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

White mineral oil (petroleum):
Species: Rabbit
Result: No skin irritation

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

Propyl 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:

Petrolatum:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

White mineral oil (petroleum):
Species: Rabbit
Result: No eye irritation

Methyl p-Hydroxybenzoate:
Species: Rabbit
Result: No eye irritation
Propyl p-hydroxybenzoate:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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:
Petrolatum:
Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

White mineral oil (petroleum):
Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

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

Propyl p-hydroxybenzoate:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

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

Components:

Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

White mineral oil (petroleum):
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Methyl p-Hydroxybenzoate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive

Genotoxicity in vivo: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 478
Result: negative

Propyl p-hydroxybenzoate:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Genotoxicity in vitro
Test Type: In vitro mammalian cell gene mutation test
Result: negative
Test Type: Chromosome aberration test in vitro
Result: equivocal

Genotoxicity in vivo
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intravenous injection
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Petrolatum:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

White mineral oil (petroleum):
Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
Result: negative

Propyl p-hydroxybenzoate:
Species: Rat
Application Route: Ingestion
Exposure time: 96 weeks
Result: negative

Gentamicin:
Carcinogenicity - Assessment: No data available

Reproductive toxicity
May damage the unborn child.

Components:
Petrolatum:
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin Ointment Formulation

Effects on fertility:
- Test Type: Reproduction/Developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Skin contact
- Result: negative
- Remarks: Based on data from similar materials

White mineral oil (petroleum):
Effects on fertility:
- Test Type: One-generation reproduction toxicity study
- Species: Rat
- Application Route: Skin contact
- Result: negative

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

Methyl p-Hydroxybenzoate:
Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Rabbit
- Application Route: Ingestion
- Result: negative

Propyl p-hydroxybenzoate:
Effects on fertility:
- Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 422
- Result: negative

Effects on foetal development:
- Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 422
- Result: negative

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
Gentamicin Ointment Formulation

**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:**

**Petrolatum:**

- Species: Rat
- NOAEL: 5,000 mg/kg
- Application Route: Ingestion
- Exposure time: 2 yr

**White mineral oil (petroleum):**

- Species: Rat
- LOAEL: 160 mg/kg
- Application Route: Ingestion
Exposure time : 90 Days
Species : Rat
LOAEL : >= 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Method : OECD Test Guideline 412

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

Propyl p-hydroxybenzoate:
Species : Rat
NOAEL : 1,076 mg/kg
Application Route : Ingestion
Exposure time : 7 Weeks
Method : OECD Test Guideline 422

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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin Ointment Formulation

Version 2.4  Revision Date: 09/13/2019  SDS Number: 2050366-00006  Date of last issue: 2019/04/24  Date of first issue: 2017/10/09

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 deafness

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

White mineral oil (petroleum):
### Gentamicin Ointment Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4</td>
<td>09/13/2019</td>
<td>2050366-00006</td>
<td>2019/04/24</td>
<td>2017/10/09</td>
</tr>
</tbody>
</table>

#### Toxicity to fish
- **Gentamicin**
  - LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

#### Toxicity to daphnia and other aquatic invertebrates
- **Gentamicin**
  - EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

#### Toxicity to algae/aquatic plants
- **Gentamicin**
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

#### Toxicity to fish (Chronic toxicity)
- **Gentamicin**
  - NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
  - Exposure time: 28 d

#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **Gentamicin**
  - NOEC (Daphnia magna (Water flea)): 1,000 mg/l
  - Exposure time: 21 d

### Methyl p-Hydroxybenzoate:

#### Toxicity to fish
- **Methyl p-Hydroxybenzoate**
  - 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
- **Methyl p-Hydroxybenzoate**
  - EC50 (Daphnia magna (Water flea)): 11.2 mg/l
  - Exposure time: 48 h
  - Method: ISO 6341

#### Toxicity to algae/aquatic plants
- **Methyl p-Hydroxybenzoate**
  - ErC50 (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

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

### Propyl p-hydroxybenzoate:

#### Toxicity to fish
- **Propyl p-hydroxybenzoate**
  - LC50 (Danio rerio (zebra fish)): 6.4 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

#### Toxicity to daphnia and other aquatic invertebrates
- **Propyl p-hydroxybenzoate**
  - EC50 (Daphnia magna (Water flea)): 15.4 mg/l
  - Exposure time: 48 h
  - Method: ISO 6341

#### Toxicity to algae/aquatic plants
- **Propyl p-hydroxybenzoate**
  - EC50 (Pseudokirchneriella subcapitata (green algae)): 16.0 mg/l
  - Exposure time: 72 h
Gentamicin Ointment Formulation

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 2.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Gentamicin:

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
  Method: US-EPA OPPTS 850.1035

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
M-Factor (Chronic aquatic toxicity): 1

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

Persistence and degradability

Components:

Petrolatum:

Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials
White mineral oil (petroleum):
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

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

Propyl p-hydroxybenzoate:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 91.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

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

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

Propyl p-hydroxybenzoate:
Partition coefficient: n-octanol/water : log Pow: 2.34

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

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. (Gentamicin)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Gentamicin)
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, N.O.S. (Gentamicin)
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. (Gentamicin)
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.
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)
- **ACGIH / TWA**: 8-hour, time-weighted average

Abbreviations:
- **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, Bioaccumu-
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Gentamicin Ointment Formulation

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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.

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