1. PRODUCT AND COMPANY IDENTIFICATION

**Product name:** Gentamicin Ointment Formulation

**Manufacturer or supplier’s details**

**Company name of supplier:** MSD

**Address:** Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory

**Telephone:** 048-588-8411

**E-mail address:** EHSDATASTEWARD@msd.com

**Emergency telephone number:** 1-908-423-6000

**Recommended use of the chemical and restrictions on use**

**Recommended use:** Pharmaceutical

2. HAZARDS IDENTIFICATION

**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:**

- ![](image1)
- ![](image2)

**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:**


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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.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Petrolatum</td>
</tr>
<tr>
<td></td>
<td>White mineral oil (petroleum)</td>
</tr>
<tr>
<td></td>
<td>Propyl p-hydroxybenzoate</td>
</tr>
<tr>
<td></td>
<td>Methyl p-Hydroxybenzoate</td>
</tr>
<tr>
<td></td>
<td>Gentamicin</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).
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.

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
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.

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/PERSICAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>OEL-M (Mist)</td>
<td>3 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>OEL-M (Mist)</td>
<td>3 mg/m3</td>
<td>JP OEL JSOH</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>

Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans
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
Hand protection: 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: Work uniform or laboratory coat.

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
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

Information on likely routes of exposure: 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
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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

**Propyl p-hydroxybenzoate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

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

**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

Propyl p-hydroxybenzoate:
Species: Rabbit
Result: No skin irritation

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:

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

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

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:**

**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

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

**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:**

**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)
White mineral oil (petroleum):
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo:
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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:
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:
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 478
Result: negative

Gentamicin:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: equivocal
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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:
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

**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

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

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

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

Methyl p-Hydroxybenzoate:
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Species: Rat
NOAEL: 250 mg/kg
LOAEL: 1,000 mg/kg
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
## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

**Components:**

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

- **Toxicity to daphnia and other aquatic invertebrates**
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 202
  - Remarks: Based on data from similar materials
  - EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
  - Exposure time: 48 h

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

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

**White mineral oil (petroleum):**
- **Toxicity to fish**
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 203
  - LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h

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

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

- **Toxicity to fish (Chronic toxicity)**
  - Test substance: Water Accommodated Fraction
  - NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
  - Exposure time: 28 d

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - Test substance: Water Accommodated Fraction
  - NOEC (Daphnia magna (Water flea)): 1,000 mg/l
  - Exposure time: 21 d
Propyl p-hydroxybenzoate:

Toxicity to fish

: 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

: EC50 (Daphnia magna (Water flea)): 15.4 mg/l
   Exposure time: 48 h
   Method: ISO 6341

Toxicity to algae/aquatic plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): 16.0 mg/l
   Exposure time: 72 h
   Method: OECD Test Guideline 201

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

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

: 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)

: NOEC (Daphnia magna (Water flea)): 0.2 mg/l
   Exposure time: 21 d
   Method: OECD Test Guideline 211

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

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

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

Bioaccumulative potential

Components:

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

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

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

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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
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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
Refer to section 15 for specific national regulation.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Designated Flammable Substances, Flammable solid, (3000 kilogram)

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
<td>&gt;=100 - &lt;=100</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic acid, 4-hydroxy-, methyl ester</td>
<td>334</td>
<td>1.0</td>
</tr>
</tbody>
</table>

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance(Category Y)
Pack transportation : Classified as marine pollutant
SAFETY DATA SHEET

Gentamicin Ointment Formulation

Version 2.4
Revision Date: 09/13/2019
SDS Number: 2050360-00006
Date of last issue: 2019/04/24
Date of first issue: 2017/10/09

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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
Sources of key data used to compile the Safety Data Sheet:
- Date format: yyyy/mm/dd

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

ACGIH / TWA : 8-hour, time-weighted average
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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 Develop-
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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