1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin Ointment Formulation

Manufacturer or supplier’s details

Company : MSD
Address : Briahnager - Off Pune Nagar Road
           Wagholi - Pune - India  412 207
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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.

**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.

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

Technical measures: See Engineering measures under EXPOSURE.
SAFETY DATA SHEET
Gentamicin Ointment Formulation

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.

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

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 (Mist)</td>
<td>5 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 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

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.

Hygiene measures:

- Work uniform or laboratory coat.
- 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>ointment</td>
</tr>
<tr>
<td>Colour</td>
<td>colourless</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>&gt; 93.3 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Gentamicin Ointment Formulation

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

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
  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
SAFETY DATA SHEET

Gentamicin Ointment Formulation

Version: 2.2  Revision Date: 09/13/2019  SDS Number: 2054105-00006  Date of last issue: 24.04.2019  Date of first issue: 09.10.2017

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
      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
**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
Method: OECD Test Guideline 405
Result: No eye irritation
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
Method: OECD Test Guideline 405
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

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

Gentamicin:
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:**
- Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - 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: Skin contact
  - Result: negative

- Remarks: Based on data from similar materials
Gentamicin Ointment Formulation

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

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
### Gentamicin Ointment Formulation

<table>
<thead>
<tr>
<th>Method</th>
<th>OECD Test Guideline 422</th>
</tr>
</thead>
</table>

**Gentamicin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
<th>LOAEL</th>
<th>3 mg/kg</th>
<th>Application Route</th>
<th>Intramuscular</th>
<th>Exposure time</th>
<th>12 Months</th>
<th>Target Organs</th>
<th>Kidney</th>
<th>Symptoms</th>
<th>Vomiting, Salivation</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
<th>LOAEL</th>
<th>50 mg/kg</th>
<th>Application Route</th>
<th>Subcutaneous</th>
<th>Exposure time</th>
<th>3 Weeks</th>
<th>Target Organs</th>
<th>Kidney, inner ear</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
<th>LOAEL</th>
<th>6 mg/kg</th>
<th>Application Route</th>
<th>Intramuscular</th>
<th>Exposure time</th>
<th>3 Weeks</th>
<th>Target Organs</th>
<th>Blood, Kidney, inner ear, Liver</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>NOAEL</th>
<th>5 mg/kg</th>
<th>LOAEL</th>
<th>10 mg/kg</th>
<th>Application Route</th>
<th>Intramuscular</th>
<th>Exposure time</th>
<th>52 Weeks</th>
<th>Target Organs</th>
<th>Kidney, Blood</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>NOAEL</th>
<th>12.5 mg/kg</th>
<th>LOAEL</th>
<th>50 mg/kg</th>
<th>Application Route</th>
<th>Intramuscular</th>
<th>Exposure time</th>
<th>13 Weeks</th>
<th>Target Organs</th>
<th>Kidney</th>
</tr>
</thead>
</table>

**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: 10 mg/l
   Exposure time: 21 d
   Species: Daphnia magna (Water flea)
   Test substance: Water Accommodated Fraction
   Remarks: Based on data from similar materials

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

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

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
: NOEC: 1,000 mg/l
   Exposure time: 21 d
   Species: Daphnia magna (Water flea)
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: 0.2 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

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

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**: EC50 (Pseudokirchneriella subcapitata (green algae)): 10
plants

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td>1.5 µg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>EC50 (Anabaena flos-aquae (cyanobacterium))</td>
<td>4.7 µg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Anabaena flos-aquae (cyanobacterium))</td>
<td>1.6 µg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**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

### 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
15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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 : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
SAFETY DATA SHEET

Gentamicin Ointment Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 2054105-00006  Date of last issue: 24.04.2019  Date of first issue: 09.10.2017


Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
IN OEL : India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA : 8-hour, time-weighted average
IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL : Short-term exposure Limit STEL (15 min)

AIICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN