SAFETY DATA SHEET

Gentamicin Cream Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Gentamicin Cream Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33rd floor
          Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, inner ear)
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.
                   H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.
                   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.
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P260 Do not breathe vapours.  
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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>10</td>
<td>2-772, 2-2523</td>
</tr>
<tr>
<td>Polyethylene Glycol Sorbitan Monostearate</td>
<td>9005-67-8</td>
<td>6</td>
<td>8-55</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>6</td>
<td>2-608</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>3</td>
<td>2-234</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>1</td>
<td></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.
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Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
- May damage the unborn child.
- May cause damage to organs through prolonged or repeated exposure if swallowed.

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:
- 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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- 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 deter-
mine 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 breathe vapours.
                          : Do not swallow.
                          : Avoid contact with eyes.
                          : Wash skin thoroughly after handling.
                          : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
                          : Keep container tightly closed.
                          : Do not eat, drink or smoke when using this product.
                          : 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/PERSONAL 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>
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<tbody>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>TWA (Inhal-)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
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</table>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure Limit (TWA)</th>
<th>Source</th>
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</thead>
<tbody>
<tr>
<td>Polyethylene Glycol Sorbitan Monostearate 9005-67-8</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Stearic acid 57-11-4</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Gentamicin 1403-66-3</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Engineering measures**: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

**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**

- **Physical state**: cream
- **Colour**: white to off-white
- **Odour**: No data available
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<th>Property</th>
<th>Value</th>
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<td>Melting point/freezing point</td>
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<td>Boiling point, initial boiling point and boiling range</td>
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<td>Flammability (solid, gas)</td>
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<td>Flammability (liquids)</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<td>Flash point</td>
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<td>Vapour pressure</td>
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<td>Density and/or relative density</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Density</td>
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</tr>
<tr>
<td>Relative vapour density</td>
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<td>Explosive properties</td>
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<td>Oxidizing properties</td>
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<td>Particle characteristics</td>
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10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
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<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
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<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
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<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

**Propylene glycol monostearate:**
- Acute oral toxicity: LD50 (Mouse): > 5,000 mg/kg

**Polyethylene Glycol Sorbitan Monostearate:**
- Acute oral toxicity: LD50 (Mouse): > 15,000 mg/kg

**Stearic acid:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 401
- Acute inhalation toxicity: LC50 (Rat): > 2 mg/l
  Exposure time: 1 h
  Test atmosphere: vapour
  Remarks: Based on data from similar materials
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

**Propylene glycol:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rabbit): > 159 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity
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toxicity

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:

Propylene glycol monostearate:
Result : No skin irritation

Stearic acid:
Species : Rabbit
Method : Patch Test 24 Hrs.
Result : No skin irritation

Propylene glycol:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Gentamicin:
Species : Rabbit
Result : Mild skin irritation

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

Components:

Stearic acid:
Species : Rabbit
Result : No eye irritation
Propylene glycol:
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:
Stearic acid:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Gentamicin:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:
Stearic acid:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials
Propylene glycol:

Genotoxicity in vitro

Test Type: Bacterial reverse mutation assay (AMES)
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
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:

Propylene glycol:

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

Gentamicin:

Carcinogenicity - Assessment: No data available

Reproductive toxicity

May damage the unborn child.

Components:

Stearic acid:

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
Effects on foetal development:

Propylene glycol:
- Effects on fertility:
  - Test Type: Three-generation reproduction toxicity study
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative
- Effects on foetal development:
  - Test Type: Embryo-foetal development
  - Species: Mouse
  - 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 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.
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STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

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

Repeated dose toxicity

Components:
Stearic acid:
Species: Rat
NOAEL: 1,000 mg/kg
Application Route: Ingestion
Exposure time: 42 Days
Method: OECD Test Guideline 422
Remarks: Based on data from similar materials

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

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
Aspiration toxicity
Not classified based on available information.

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:

Polyethylene Glycol Sorbitan Monostearate:
Toxicity to algae/aquatic plants:
EC50: > 10 - 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Stearic acid:
Toxicity to fish:
LL50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 48 h
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates:
EL50 (Daphnia magna (Water flea)): > 10 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
NOELR (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

**EL50** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

: NOELR (Daphnia magna (Water flea)): > 0.5 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Propylene glycol:

Toxicity to fish:

: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates

: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants

: ErC50 (Skeletonema costatum (marine diatom)): 19,300 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:

Polyethylene Glycol Sorbitan Monostearate:
Biodegradability : Result: Not readily biodegradable.
Remarks: Based on data from similar materials

Stearic acid:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 71 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Propylene glycol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
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:

Stearic acid:
Partition coefficient: n-octanol/water : log Pow: 8.23

Propylene glycol:
Partition coefficient: n- : log Pow: -1.07
octanol/water

**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**

<table>
<thead>
<tr>
<th>UNRTDG</th>
<th></th>
<th>IATA-DGR</th>
<th>IMDG-Code</th>
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</thead>
<tbody>
<tr>
<td>UN number</td>
<td>UN 3082</td>
<td>UN 3082</td>
<td>UN 3082</td>
</tr>
<tr>
<td>Proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)</td>
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<tr>
<td>Packing group</td>
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<td>Labels</td>
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<td>Packing instruction (passenger aircraft)</td>
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<td>Environmentally hazardous</td>
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<td></td>
</tr>
</tbody>
</table>


15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
</tbody>
</table>

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
Not applicable

Substances Subject to be Indicated Names
Not applicable

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

Ordinance on Prevention of Lead Poisoning
Not applicable
Ordnance 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
Not applicable

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 Z)
Pack transportation : Classified as marine pollutant

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
SAFETY DATA SHEET

Gentamicin Cream Formulation

Version 3.2  Revision Date: 2021/04/09  SDS Number: 1844940-00009  Date of last issue: 2020/10/10  Date of first issue: 2017/07/21

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)

**AIC** - Australian Inventory of Industrial Chemicals; **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; **IC50** - Half maximal inhibitory concentration; **ICD** - 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.

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