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

1.1 Product identifier
Trade name : Gentamicin Cream Formulation

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

1.3 Details of the supplier of the safety data sheet
Company : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A
Telephone : 551-430-6000
E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 1A
Specific target organ toxicity - repeated exposure, Category 2
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 3

H360D: May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements :

Prevention:
P201 Obtain special instructions before use.
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.

Hazardous components which must be listed on the label:
Gentamicin

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Polyethylene Glycol Sorbitan Monostearate</td>
<td>9005-67-8</td>
<td>Aquatic Chronic 3; H412</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Gentamicin</td>
<td>1403-66-3 215-765-8</td>
<td>Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100</td>
<td>1</td>
</tr>
</tbody>
</table>
Gentamicin Cream Formulation

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

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

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

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

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

4.2 Most important symptoms and effects, both acute and delayed

Risks: May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

M-Factor (Chronic aquatic toxicity): 1

For explanation of abbreviations see section 16.
Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting : Exposure to combustion products may be a hazard to health.
Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters
Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

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

6.2 Environmental precautions
Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. 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 spillages cannot be contained.

6.3 Methods and material for containment and cleaning up
Methods for 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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding
6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling:
- Do not get on skin or clothing.
- Do not 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.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

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

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

7.3 Specific end use(s)

Specific use(s):
- No data available
## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m3</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Polyethylene Glycol Sorbitan Monostearate</td>
<td>9005-67-8</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m3</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>OELV - 8 hrs (TWA) (particles)</td>
<td>10 mg/m3</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

<table>
<thead>
<tr>
<th>Components</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OELV - 8 hrs (TWA) (total (vapour and particles))</td>
<td>150 ppm 470 mg/m3</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl myristate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>23.5 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>33 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5.79 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>16 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1.6 mg/kg bw/day</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17.63 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4.348 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>2.5 mg/kg bw/day</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m3</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Gentamicin Cream Formulation**

**Version**: 3.2  
**Revision Date**: 09.04.2021  
**SDS Number**: 1845426-00009  
**Date of last issue**: 10.10.2020  
**Date of first issue**: 21.07.2017

<table>
<thead>
<tr>
<th>Consumers</th>
<th>Inhalation</th>
<th>Long-term local effects</th>
<th>10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl myristate</td>
<td>Fresh water sediment</td>
<td>1.44 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.44 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>20 mg/kg</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg</td>
</tr>
</tbody>
</table>

**8.2 Exposure controls**

**Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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**

**Eye protection**: Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**: Chemical-resistant gloves

**Skin and body protection**: Work uniform or laboratory coat.

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to I.S. EN 14387  
Filter type: Combined particulates and organic vapour type (A-P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

**Physical state**: cream  
**Colour**: white to off-white  
**Odour**: No data available  
**Odour Threshold**: No data available  
**Melting point/freezing point**: No data available
Initial boiling point and boiling range: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Flash point: No data available

Auto-ignition temperature: No data available

Decomposition temperature
Decomposition temperature: No data available

pH: No data available

Viscosity
Viscosity, kinematic: No data available

Solubility(ies)
Water solubility: No data available

Partition coefficient: n-octanol/water
Vapour pressure: No data available

Relative density: No data available

Density: No data available

Relative vapour density: No data available

Particle characteristics
Particle size: No data available

9.2 Other information

Explosives: Not explosive

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

Evaporation rate: No data available

Molecular weight: No data available
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity
Not classified based on available information.

Components:

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

**Gentamicin:**
Species: Rabbit
Result: Mild skin irritation

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

**Components:**

**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:**

**Gentamicin:**
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

**Components:**

**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
SAFETY DATA SHEET
generated by Regulation (EC) No. 1907/2006

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Carcinogenicity
Not classified based on available information.

Components:

Gentamicin:
Carcinogenicity - Assessment: No data available

Reproductive toxicity
May damage the unborn child.

Components:

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:
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
May cause damage to organs through prolonged or repeated exposure.
Components:

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

Repeated dose toxicity

Components:

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: 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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
- Assessment: The substance/mixture does not contain components consid-
Gentamicin Cream Formulation

Experience with human exposure

**Components:**

**Gentamicin:**

Ingestion:
- Target Organs: Kidney
- Target Organs: inner ear
- Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

**SECTION 12: Ecological information**

**12.1 Toxicity**

**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

**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

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 tox-):
- 100
icity)

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

M-Factor (Chronic aquatic toxicity) : 1

12.2 Persistence and degradability

Components:

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

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

12.3 Bioaccumulative potential

Components:

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Date of last issue: 10.10.2020
Date of first issue: 21.07.2017

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN: UN 3082
ADR: UN 3082
RID: UN 3082
IMDG: UN 3082
IATA: UN 3082

14.2 UN proper shipping name

ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
IATA: Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)

14.3 Transport hazard class(es)

ADN: 9
ADR: 9
RID: 9
IMDG: 9
14.4 Packing group

**ADN**
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**ADR**
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID**
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

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

**IATA (Cargo)**
Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

**IATA (Passenger)**
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

**ADN**
Environmentally hazardous : yes

**ADR**
Environmentally hazardous : yes

**RID**
Environmentally hazardous : yes

**IMDG**
Marine pollutant : yes

**IATA (Passenger)**
Environmentally hazardous : yes

**IATA (Cargo)**
SAFETY DATA SHEET
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3  Date of first issue: 21.07.2017

Environmentally hazardous : yes

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

14.7 Maritime transport in bulk according to IMO instruments
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals
Quantity 1 Quantity 2
E1 ENVIRONMENTAL HAZARDS 100 t 200 t

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

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

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

SECTION 16: Other information

Other information : Items where changes have been made to the previous version
Full text of H-statements

H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)

Further information
Gentamicin Cream Formulation

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Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
- **Classification procedure:**
  - Repr. 1A: H360D - Calculation method
  - STOT RE 2: H373 - Calculation method
  - Aquatic Acute 1: H400 - Calculation method
  - Aquatic Chronic 3: H412 - Calculation method

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.

IE / EN