SECTION 1. IDENTIFICATION

Product name : Gentamicin Cream Formulation
Other means of identification : No data available

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATA STEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Kidney, inner ear)

GHS label elements
Hazard pictograms :

Signal Word : Danger
Hazard Statements :
H360D May damage the unborn child.
H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Precautionary Statements :
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol monostearate</td>
</tr>
<tr>
<td></td>
<td>Polyethylene Glycol Sorbitan Monostearate</td>
</tr>
<tr>
<td></td>
<td>Stearic acid</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
<tr>
<td></td>
<td>Gentamicin</td>
</tr>
</tbody>
</table>

SECTION 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.
Causes 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.

SECTION 5. FIRE-FIGHTING MEASURES

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

None known.

Exposure to combustion products may be a hazard to health.

Carbon oxides

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.

In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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 certain local or national requirements.

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

If sufficient ventilation is unavailable, use with local exhaust ventilation.

Do not get on skin or clothing. Do not breathe mist or vapors. 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.

Conditions for safe storage:
Keep in properly labeled 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 
Organic peroxides 
Explosives 
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Polyethylene Glycol Sorbitan Monostearate</td>
<td>9005-67-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Propylene glycol | 57-55-6 | TWA (aerosol) | 10 mg/m³ | CA ON OEL
| | | TWA (Vapour and aerosols) | 50 ppm | 155 mg/m³ | CA ON OEL
| Gentamicin | 1403-66-3 | TWA | 0.1 mg/m³ (OEL 2) | Internal

**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**

**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 vapor type

**Hand protection Material**: 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.

**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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: cream

**Color**: white to off-white

**Odor**: No data available

**Odor Threshold**: No data available

**pH**: No data available
SAFETY DATA SHEET

Gentamicin Cream Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>10/10/2020</td>
<td>1844921-00008</td>
<td>03/23/2020</td>
<td>07/21/2017</td>
</tr>
</tbody>
</table>

Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : No data available
Evaporation rate : 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
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition 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.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
SECTION 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: vapor
  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

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 sensitization**

**Skin sensitization**  
Not classified based on available information.

**Respiratory sensitization**  
Not classified based on available information.

**Components:**

**Stearic acid:**  
Test Type: Maximization Test  
Routes of exposure: Skin contact  
Species: Guinea pig  
Result: negative  
Remarks: Based on data from similar materials

**Propylene glycol:**  
Test Type: Maximization Test  
Routes of exposure: 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

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

**Propylene glycol:**  
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
SAFETY DATA SHEET

Gentamicin Cream Formulation

Result: negative

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
Result: negative
Remarks: Based on data from similar materials

Effects on fetal 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
Remarks: Based on data from similar materials

**Propylene glycol:**
- **Effects on fertility**: Test Type: Three-generation reproduction toxicity study
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

- **Effects on fetal development**: Test Type: Embryo-fetal 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 fetal development**: Test Type: Embryo-fetal development
  - Species: Rabbit
  - Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
  - Result: No embryo-fetal toxicity.

  Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Intraperitoneal
  - Developmental Toxicity: LOAEL: 75 mg/kg body weight
  - Result: Embryo-fetal toxicity.

  Test Type: Embryo-fetal development
  - Species: Mouse
  - Application Route: Intraperitoneal
  - Developmental Toxicity: LOAEL: 10 mg/kg body weight
  - Result: Fetal mortality., No malformations were observed.

  Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Intraperitoneal
  - Developmental Toxicity: LOAEL: 50 mg/kg body weight
  - Result: Fetal 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**
Causes 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 y

Gentamicin:
Species: Dog
LOAEL: 3 mg/kg
Application Route: Intramuscular
Exposure time: 12 Months
Target Organs: Kidney
Symptoms: Vomiting, Salivation

Species: Monkey
LOAEL: 50 mg/kg
Application Route: Subcutaneous
Exposure time: 3 Weeks
Target Organs: Kidney, inner ear

Species: Monkey
LOAEL: 6 mg/kg
Application Route: Intramuscular
Exposure time: 3 Weeks
Target Organs: Blood, Kidney, inner ear, Liver

Species: Rat
NOAEL: 5 mg/kg
LOAEL: 10 mg/kg
Application Route: Intramuscular
Exposure time: 52 Weeks
Target Organs: Kidney, Blood

Species: Rat
SAFETY DATA SHEET
Gentamicin Cream Formulation

Version: 3.1
Revision Date: 10/10/2020
SDS Number: 1844921-00008
Date of last issue: 03/23/2020
Date of first issue: 07/21/2017

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.

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

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.
## Gentamicin Cream Formulation

<table>
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<tr>
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<td>07/21/2017</td>
</tr>
</tbody>
</table>

### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOELR (Daphnia magna (Water flea)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 211</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>&gt; 0.5 mg/l</td>
<td>21 d</td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
<td></td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

### Toxicity to Microorganisms

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC10 (Pseudomonas putida):</th>
<th>Exposure time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>883 mg/l</td>
<td>18 h</td>
</tr>
</tbody>
</table>

### Toxicity to Fish

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)):</th>
<th>Exposure time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>40,613 mg/l</td>
<td>96 h</td>
</tr>
</tbody>
</table>

### Toxicity to Daphnia and Other Aquatic Invertebrates

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Ceriodaphnia dubia (water flea)):</th>
<th>Exposure time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>18,340 mg/l</td>
<td>48 h</td>
</tr>
</tbody>
</table>

### Toxicity to Algae/Aquatic Plants

<table>
<thead>
<tr>
<th>Compound</th>
<th>ErC50 (Skeletonema costatum (marine diatom)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>19,300 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC (Ceriodaphnia dubia (water flea)):</th>
<th>Exposure time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>13,020 mg/l</td>
<td>7 d</td>
</tr>
</tbody>
</table>

### Toxicity to Microorganisms

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC (Pseudomonas putida):</th>
<th>Exposure time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>&gt; 20,000 mg/l</td>
<td>18 h</td>
</tr>
</tbody>
</table>

### Gentamicin

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Daphnia magna (Water flea)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 202</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>86 mg/l</td>
<td>48 h</td>
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<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>30 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>10 µg/l</td>
<td>72 h</td>
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</table>

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50: 288.7 mg/l</th>
</tr>
</thead>
</table>
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-octanol/water : log Pow: -1.07

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

Mobility in soil
No data available

Other adverse effects
No data available
SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(Gentamicin)

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.

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>CA AB OEL</td>
<td>Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)</td>
</tr>
<tr>
<td>CA BC OEL</td>
<td>Canada. British Columbia OEL</td>
</tr>
<tr>
<td>CA ON OEL</td>
<td>Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>CA AB OEL / TWA</td>
<td>8-hour Occupational exposure limit</td>
</tr>
<tr>
<td>CA BC OEL / TWA</td>
<td>8-hour time weighted average</td>
</tr>
<tr>
<td>CA ON OEL / TWA</td>
<td>Time-Weighted Average Limit (TWA)</td>
</tr>
</tbody>
</table>

AICL - 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; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); 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...
SAFETY DATA SHEET

Gentamicin Cream Formulation

Version: 3.1
Revision Date: 10/10/2020
SDS Number: 1844921-00008
Date of last issue: 03/23/2020
Date of first issue: 07/21/2017

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

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

Revision Date: 10/10/2020
Date format: mm/dd/yyyy

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.

CA / Z8