SECTION 1. IDENTIFICATION

Product name : Gentamicin Cream Formulation

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 : EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
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/ face protection.

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

Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ 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>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.
SAFETY DATA SHEET

Gentamicin Cream Formulation

Version 3.2  Revision Date: 09/13/2019  SDS Number: 1844915-00006  Date of last issue: 04/24/2019
Date of first issue: 07/21/2017

Unsuitable extinguishing media : None known.
Specific hazards during fire fighting : 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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.
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.
Methods and materials for containment and cleaning up : 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.

SECTION 7. HANDLING AND STORAGE

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 vapors or spray mist.
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 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>Polyethylene Glycol Sorbitan</td>
<td>9005-67-8</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Monostearate</td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</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 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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air
supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>cream</td>
</tr>
<tr>
<td>Color</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor 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>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</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>
</tbody>
</table>
SAFETY DATA SHEET

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Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : No data available
Solubility(ies) : No data available
   Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
   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.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

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:
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:**
**Stearic acid:**
Species: Rabbit
Gentamicin Cream Formulation

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)  
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
IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.
NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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
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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
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.

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.

Toxicity to microorganisms:
   EC10 (Pseudomonas putida): 883 mg/l
   Exposure time: 18 h

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms:
NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

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

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-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
49 CFR
UN/ID/NA number: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes(Gentamicin)
Remarks: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity
Specifc target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
Water 7732-18-5
Propylene glycol monostearate 1323-39-3
Isopropyl myristate 110-27-0
Polyethylene Glycol Sorbitan Monostearate 9005-67-8
Stearic acid 57-11-4
Propylene glycol 57-55-6

California Prop. 65
WARNING: This product can expose you to chemicals including Gentamicin, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

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

AICS : not determined

DSL : not determined

IECSC : not determined
SAFETY DATA SHEET

Gentamicin Cream Formulation

SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

- **Health:** 0
- **Flammability:** 1
- **Special hazard:** 0
- **Instability:** 0

**HMIS® IV:**

- **HEALTH:** *
- **FLAMMABILITY:** 1
- **PHYSICAL HAZARD:** 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "\" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
- ACGIH / TWA: 8-hour, time-weighted average
- US WEEL / TWA: 8-hr TWA

- AICS: Australian Inventory of Chemical Substances
- ASTM: American Society for the Testing of Materials
- bw: Body weight
- CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act
- CMR: Carcinogen, Mutagen or Reproductive Toxicant
- DIN: Standard of the German Institute for Standardisation
- DOT: Department of Transportation
- DSL: Domestic Substances List (Canada)
- ECx: Concentration associated with x% response
- EHS: Extremely Hazardous Substance
- ELx: Loading rate associated with x% response
- EmS: Emergency Schedule
- ENCS: Existing and New Chemical Substances (Japanese)
- ErCx: Concentration associated with x% growth rate response
- ERG: Emergency Response Guide
- GHS: Globally Harmonized System
- GLP: Good Laboratory Practice
- HMIS: Hazardous Materials Identification System
- 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
- ICSC: 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
- MSHA: Mine Safety and Health Administration
- n.o.s.: Not Otherwise Specified
- NFPA: National Fire Protection Association
- NO(A)EC: No Observed (Adverse) Effect Concentration
- NO(A)EL: No Observed (Adverse) Effect Level
- NT: 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
- RCRA: Resource Conservation and Recovery Act
SAFETY DATA SHEET

Gentamicin Cream Formulation

Version 3.2 Revision Date: 09/13/2019 SDS Number: 1844915-00006 Date of last issue: 04/24/2019 Date of first issue: 07/21/2017

Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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


Revision Date: 09/13/2019

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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