

## Gentamicin Cream Formulation

Version 2.2      Revision Date: 09.04.2021      SDS Number: 1844944-00009      Date of last issue: 10.10.2020  
Date of first issue: 21.07.2017

---

**Section 1: Identification**

Product name : Gentamicin Cream Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

---

**Section 2: Hazard identification****GHS Classification**

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, inner ear)

**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.

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 vapours.  
P281 Use personal protective equipment as required.

**Response:**

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

**Storage:**

## Gentamicin Cream Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 10.10.2020  
2.2                    09.04.2021                1844944-00009            Date of first issue: 21.07.2017

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.

**Section 3: Composition/information on ingredients**

Substance / Mixture            :    Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Propylene glycol monostearate	1323-39-3	10
Polyethylene Glycol Sorbitan Monostearate	9005-67-8	6
Stearic acid	57-11-4	6
Propylene glycol	57-55-6	3
Gentamicin	1403-66-3	1

**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.  
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.

**Section 5: Fire-fighting measures**

- Suitable extinguishing media    :    Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

Unsuitable extinguishing media	:	Dry chemical 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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Hazchem Code	:	3Z

---

**Section 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 spillages 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 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 vapours. Do not swallow.

## Gentamicin Cream Formulation

Version 2.2      Revision Date: 09.04.2021      SDS Number: 1844944-00009      Date of last issue: 10.10.2020  
Date of first issue: 21.07.2017

- 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.
- 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

## Section 8: Exposure controls/personal protection

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylene glycol monostearate	1323-39-3	WES-TWA	10 mg/m <sup>3</sup>	NZ OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Polyethylene Glycol Sorbitan Monostearate	9005-67-8	WES-TWA	10 mg/m <sup>3</sup>	NZ OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Stearic acid	57-11-4	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Res-	3 mg/m <sup>3</sup>	ACGIH

# SAFETY DATA SHEET



## Gentamicin Cream Formulation



Version 2.2      Revision Date: 09.04.2021      SDS Number: 1844944-00009      Date of last issue: 10.10.2020  
Date of first issue: 21.07.2017

		pirable particulate matter)		
Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m <sup>3</sup>	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m <sup>3</sup>	NZ OEL
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (OEB 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 vapour 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.

### Section 9: Physical and chemical properties

Appearance : cream  
Colour : white to off-white  
Odour : No data available  
Odour Threshold : No data available  
pH : No data available  
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

# SAFETY DATA SHEET



## Gentamicin Cream Formulation



Version 2.2      Revision Date: 09.04.2021      SDS Number: 1844944-00009      Date of last issue: 10.10.2020  
Date of first issue: 21.07.2017

---

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

Vapour pressure : No data available

Relative vapour 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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

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

Exposure routes : Inhalation

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

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

**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

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

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.



## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

**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
---------	---	-------------------

**Chronic toxicity****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 Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

**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 foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

**Propylene glycol:**

Effects on fertility : Test Type: Three-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

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.

**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.

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

**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
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

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

**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

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

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

Toxicity to algae/aquatic : ErC50 (*Skeletonema costatum* (marine diatom)): 19,300 mg/l  
plants Exposure time: 72 h  
Method: OECD Test Guideline 201

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

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

**Gentamicin:**

Toxicity to daphnia and other : EC50 (*Daphnia magna* (Water flea)): 86 mg/l  
aquatic invertebrates Exposure time: 48 h  
Method: OECD Test Guideline 202

LC50 (*Americamysis*): 30 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic : EC50 (*Pseudokirchneriella subcapitata* (green algae)): 10 µg/l  
plants 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

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

**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 han-

---

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

ding 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.

**National Regulations****NZS 5433**

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)  
 Class : 9  
 Packing group : III  
 Labels : 9  
 Hazchem Code : 3Z



## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

**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****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

---

**Section 16: Other information****Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AllC - 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 Sys-

## Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.2	09.04.2021	1844944-00009	Date of first issue: 21.07.2017

---

tem; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN