

## Gentamicin Cream Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 1844917-00009      Date of last issue: 10.10.2020  
Date of first issue: 21.07.2017

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : Gentamicin Cream Formulation

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Use of the Sub-stance/Mixture : Pharmaceutical

**1.3 Details of the supplier of the safety data sheet**

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

**1.4 Emergency telephone number**


215-631-6999

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**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Reproductive toxicity, Category 1A	H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :  

Signal word : Danger

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

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Precautionary statements :

**Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

**Storage:**  
P405 Store locked up.

Hazardous components which must be listed on the label:  
Gentamicin

**2.3 Other hazards**

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

**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

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

For explanation of abbreviations see section 16.

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**SECTION 4: First aid measures****4.1 Description of first aid measures**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

**4.2 Most important symptoms and effects, both acute and delayed**

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

**4.3 Indication of any immediate medical attention and special treatment needed**

- Treatment : Treat symptomatically and supportively.
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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

- Specific hazards during fire- : Exposure to combustion products may be a hazard to health.
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fighting

Hazardous combustion products : Carbon oxides

**5.3 Advice for firefighters**

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

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

**6.2 Environmental precautions**

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

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**6.4 Reference to other sections**

See sections: 7, 8, 11, 12 and 13.

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe vapours.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**7.2 Conditions for safe storage, including any incompatibilities**

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

**7.3 Specific end use(s)**

- Specific use(s) : No data available

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propylene glycol	57-55-6	TWA OEL-RL (particulate)	10 mg/m <sup>3</sup>	ZA OEL

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Further information: Recommended Limit				
		TWA OEL-RL (Vapour + particulates)	150 ppm 470 mg/m <sup>3</sup>	ZA OEL
Further information: Recommended Limit				
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (OEB 2)	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Isopropyl myristate	Workers	Inhalation	Long-term systemic effects	23,5 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	33 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,79 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	16 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1,6 mg/kg bw/day
	Stearic acid	Workers	Inhalation	Long-term systemic effects
Workers		Skin contact	Long-term systemic effects	10 mg/kg bw/day
Consumers		Inhalation	Long-term systemic effects	4,348 mg/m <sup>3</sup>
Consumers		Skin contact	Long-term systemic effects	5 mg/kg bw/day
Consumers		Ingestion	Long-term systemic effects	2,5 mg/kg bw/day
Propylene glycol		Workers	Inhalation	Long-term local effects
	Workers	Inhalation	Long-term systemic effects	168 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>

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

Substance name	Environmental Compartment	Value
Isopropyl myristate	Fresh water sediment	1,44 mg/kg
	Marine sediment	1,44 mg/kg
	Soil	20 mg/kg
Propylene glycol	Fresh water	260 mg/l
	Marine water	26 mg/l
	Intermittent use/release	183 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg
	Marine sediment	57,2 mg/kg
	Soil	50 mg/kg

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**8.2 Exposure controls****Engineering measures**

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

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

**Personal protective equipment**

Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Combined particulates and organic vapour type (A-P)

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**SECTION 9: Physical and chemical properties****9.1 Information on basic 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
Flammability (solid, gas)	:	Not applicable
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

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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.

### 9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions	:	Can react with strong oxidizing agents.
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### 10.4 Conditions to avoid

Conditions to avoid	:	None known.
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### 10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of	:	Inhalation
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exposure

Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Polyethylene Glycol Sorbitan Monostearate:**

Acute oral toxicity : LD50 (Mouse): > 15.000 mg/kg

**Gentamicin:**

Acute oral toxicity : LD50 (Rat): 8.000 - 10.000 mg/kg

LD50 (Mouse): 10.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg  
Application Route: Intravenous

LD50 (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Gentamicin:**

Species : Rabbit  
Result : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Gentamicin:**

Species : Rabbit  
Result : Mild eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

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**Respiratory sensitisation**

Not classified based on available information.

**Components:****Gentamicin:**

Remarks : No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Gentamicin:**Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negativeTest Type: Chromosome aberration test in vitro  
Result: equivocalGenotoxicity 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:****Gentamicin:**

Carcinogenicity - Assessment : No data available

**Reproductive toxicity**

May damage the unborn child.

**Components:****Gentamicin:**Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Fertility: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reportedEffects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3,6 mg/kg body weight  
Result: No embryo-foetal toxicityTest Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 75 mg/kg body weight

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Result: Embryo-foetal toxicity

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

Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Intraperitoneal  
 Developmental Toxicity: LOAEL: 50 mg/kg body weight  
 Result: foetal mortality, No malformations were observed.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

**Components:****Gentamicin:**

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

**Repeated dose toxicity****Components:****Gentamicin:**

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

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

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

Species : Rat

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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

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**SECTION 12: Ecological information****12.1 Toxicity****Components:****Polyethylene Glycol Sorbitan Monostearate:**

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

**Gentamicin:**

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

LC50 (Americamysis): 30 mg/l  
 Exposure time: 96 h  
 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

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EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100

Toxicity to microorganisms : EC50 : 288,7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity) : 1

## 12.2 Persistence and degradability

### Components:

#### **Polyethylene Glycol Sorbitan Monostearate:**

Biodegradability : Result: Not readily biodegradable.  
Remarks: Based on data from similar materials

#### **Gentamicin:**

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

## 12.3 Bioaccumulative potential

### Components:

#### **Gentamicin:**

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

## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

### Product:

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

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**12.6 Other adverse effects****Product:**

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

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

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

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

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**SECTION 14: Transport information****14.1 UN number**

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

**14.2 UN proper shipping name**

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Gentamicin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Gentamicin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Gentamicin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Gentamicin)

IATA : Environmentally hazardous substance, liquid, n.o.s.  
(Gentamicin)

**14.3 Transport hazard class(es)**

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**ADN** : 9  
**ADR** : 9  
**RID** : 9  
**IMDG** : 9  
**IATA** : 9

**14.4 Packing group**

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

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

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

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

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

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

**14.5 Environmental hazards**

**ADN**  
 Environmentally hazardous : yes

**ADR**  
 Environmentally hazardous : yes

**RID**  
 Environmentally hazardous : yes

**IMDG**

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Marine pollutant : yes

**IATA (Passenger)**

Environmentally hazardous : yes

**IATA (Cargo)**

Environmentally hazardous : yes

**14.6 Special precautions for user**

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

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

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**SECTION 16: Other information**

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of H-Statements**

H360D : May damage the unborn child.

H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

H412 : Harmful to aquatic life with long lasting effects.

**Full text of other abbreviations**

Aquatic Acute : Short-term (acute) aquatic hazard

Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits

ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit



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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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); 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

### 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/>

### Classification of the mixture:

Repr. 1A	H360D
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 3	H412

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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

# SAFETY DATA SHEET



## Gentamicin Cream Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	1844917-00009	Date of first issue: 21.07.2017

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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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