

Gentamicin Cream Formulation

Version 3.2 Revision Date: 09.04.2021 SDS Number: 1845427-00009 Date of last issue: 10.10.2020
Date of first issue: 21.07.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin Cream Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd 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

2. HAZARDS IDENTIFICATION**Manufacture, Storage and Import of Hazardous Chemicals Rules 1989****Classification**

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Reproductive toxicity : Category 1A

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

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 3

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.
H400 Very toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.

Gentamicin Cream Formulation

Version 3.2 Revision Date: 09.04.2021 SDS Number: 1845427-00009 Date of last issue: 10.10.2020
 Date of first issue: 21.07.2017

Precautionary statements : **Prevention:**
 P203 Obtain, read and follow all safety instructions before use.
 P260 Do not breathe vapours.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
 P318 IF exposed or concerned, get medical advice.
 P391 Collect spillage.

Storage:
 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.

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
Gentamicin	1403-66-3	1

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.

Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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

Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

certain local or national requirements.

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.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly 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

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	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Polyethylene Glycol Sorbitan Monostearate	9005-67-8	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Stearic acid	57-11-4	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable par-	3 mg/m ³	ACGIH

SAFETY DATA SHEET



Gentamicin Cream Formulation



Version 3.2 Revision Date: 09.04.2021 SDS Number: 1845427-00009 Date of last issue: 10.10.2020
Date of first issue: 21.07.2017

		ticulate matter)		
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (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.

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.

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

SAFETY DATA SHEET



Gentamicin Cream Formulation



Version 3.2 Revision Date: 09.04.2021 SDS Number: 1845427-00009 Date of last issue: 10.10.2020
Date of first issue: 21.07.2017

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

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

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.

Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Components:**Propylene glycol monostearate:**

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg

Polyethylene Glycol Sorbitan Monostearate:

Acute oral toxicity : LD50 (Mouse): > 15,000 mg/kg

Stearic acid:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2 mg/l
Exposure time: 1 h
Test atmosphere: 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

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.

Gentamicin Cream Formulation

Version 3.2 Revision Date: 09.04.2021 SDS Number: 1845427-00009 Date of last issue: 10.10.2020
Date of first issue: 21.07.2017

Components:

Propylene glycol monostearate:

Result : No skin irritation

Stearic acid:

Species : Rabbit
Method : Patch Test 24 Hrs.
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

Gentamicin:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Stearic acid:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

Gentamicin:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Gentamicin Cream Formulation

Version 3.2 Revision Date: 09.04.2021 SDS Number: 1845427-00009 Date of last issue: 10.10.2020
Date of first issue: 21.07.2017

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

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:**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

Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 422
 Result: negative
 Remarks: Based on data from similar materials

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
3.2 09.04.2021 1845427-00009 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

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:**

Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOELR: > 0.5 mg/l
 Exposure time: 21 d
 Species: Daphnia magna (Water flea)
 Method: OECD Test Guideline 211
 Remarks: Based on data from similar materials
 No toxicity at the limit of solubility

Gentamicin:

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 86 mg/l

Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

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 plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic 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

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
------------------	---	---

Gentamicin:

Biodegradability	:	Result: rapidly degradable Biodegradation: 100 %
------------------	---	---

Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

Exposure time: 28 d
Method: OECD Test Guideline 314

Bioaccumulative potential**Components:****Stearic acid:**

Partition coefficient: n-octanol/water : log Pow: 8.23

Gentamicin:

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

Mobility in soil

No data available

Other adverse effects

No data available

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.

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

Gentamicin Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

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 IMO instruments

Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION**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

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)

ACGIH / TWA : 8-hour, 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;

SAFETY DATA SHEET



Gentamicin Cream Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.2	09.04.2021	1845427-00009	Date of first issue: 21.07.2017

ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - 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.

IN / EN