

Gentamicin Cream Formulation

Version 7.0 Revision Date: 2024/04/06 SDS Number: 1844940-00016 Date of last issue: 2023/09/30
Date of first issue: 2017/07/21

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Gentamicin Cream Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

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

Telephone : +1-551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : +1-215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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.

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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.
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.

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)	ENCS No.
Propylene glycol monostearate	1323-39-3	10	2-772, 2-2523
Polyethylene Glycol Sorbitan Monostearate	9005-67-8	6	8-55, 7-110
Stearic acid	57-11-4	6	2-608
Propylene glycol	57-55-6	3	2-234
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.

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		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.

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.

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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.

7. HANDLING AND STORAGE
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.

Avoidance of contact : Oxidizing agents

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.

Storage

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:

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Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / 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 particulate matter)	3 mg/m ³	ACGIH
Gentamicin	1403-66-3	TWA	0.1 mg/m ³ (OEB 2)	Internal
Further information: OTO				

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

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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: cream
Colour	: white to off-white
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Lower explosion limit and upper explosion limit / flammability limit	
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: No data available
Decomposition temperature	: No data available
pH	: No data available
Evaporation rate	: No data available
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Solubility(ies)	
Water solubility	: No data available

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Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
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.

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 (Rat): > 20,000 mg/kg

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Acute dermal toxicity : LD50 (Rat): > 2,000 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): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 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

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Components:**Propylene glycol monostearate:**

|| Result : No skin irritation

Polyethylene Glycol Sorbitan Monostearate:

|| Species : Rabbit
|| 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:**Polyethylene Glycol Sorbitan Monostearate:**

|| Species : Rabbit
|| Result : No eye irritation

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

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Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Polyethylene Glycol Sorbitan Monostearate:**

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

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
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Germ cell mutagenicity

Not classified based on available information.

Components:**Polyethylene Glycol Sorbitan Monostearate:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	:	Test Type: Chromosome aberration test in vitro Result: negative
	:	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative

Stearic acid:

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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

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
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

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Carcinogenicity - Assessment : No data available

Reproductive toxicity

May damage the unborn child.

Components:**Polyethylene Glycol Sorbitan Monostearate:**

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

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

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: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Gentamicin:

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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.

Repeated dose toxicity**Components:****Polyethylene Glycol Sorbitan Monostearate:**

Species	:	Rat
NOAEL	:	1,355 mg/kg

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Application Route	: Ingestion
Exposure time	: 13 Weeks

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

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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

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Polyethylene Glycol Sorbitan Monostearate:**

Toxicity to fish	:	LC50 : > 10 - 100 mg/l
		Exposure time: 96 h

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

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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

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M-Factor (Acute aquatic toxicity)	:	100
M-Factor (Chronic aquatic toxicity)	:	1
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.
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Stearic acid:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 71 % Exposure time: 28 d Method: OECD Test Guideline 301B
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Propylene glycol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F
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Gentamicin:

Biodegradability	:	Result: rapidly degradable Biodegradation: 100 % Exposure time: 28 d Method: OECD Test Guideline 314
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Bioaccumulative potential**Components:****Stearic acid:**

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

Partition coefficient: n-octanol/water	:	log Pow: -1.07 Method: Regulation (EC) No. 440/2008, Annex, A.8
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Gentamicin:

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

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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
Environmentally hazardous	:	yes

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

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Version 7.0 Revision Date: 2024/04/06 SDS Number: 1844940-00016 Date of last issue: 2023/09/30
Date of first issue: 2017/07/21

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

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
propane-1,2-diol	>0 - <10	From April 1st, 2025

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Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
propane-1,2-diol	From April 1st, 2025

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

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Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); 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

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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; TECL - Thailand Existing Chemicals 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; 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.

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