

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

SECTION 1. IDENTIFICATION

Product name : Gentamicin / Cloxacillin Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 37 McCarville Street
Charlottetown, PE C1E 2A7
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Respiratory sensitization : Category 1
Skin sensitization : Category 1
Reproductive toxicity : Category 1A

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360D May damage the unborn child.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing mist or vapors.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
P284 Wear respiratory protection.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P342 + P311 If experiencing respiratory symptoms: Call a doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Peanut oil	No data available	8002-03-7	$\geq 80 - < 100$ *
1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)	Octadecanoic acid, 12-hydroxy-, 1,1',1''-(1,2,3-propanetriyl) ester	139-44-6	$\geq 1 - < 5$ *
cloxacillin	No data available	61-72-3	$\geq 1 - < 5$ *
Gentamicin	No data available	1403-66-3	$\geq 0.1 - < 1$ *

* Actual concentration or concentration range is withheld as a trade secret

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.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

- In case of skin contact : Get medical attention.
: 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 cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage the unborn child.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
No information available.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.
-

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- 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
Chlorine compounds
Nitrogen oxides (NO_x)
Sulfur compounds
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/17/2025
5.1	12/06/2025	1936034-00021	Date of first issue: 09/11/2017

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

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Peanut oil	8002-03-7	TWAEV (Mist)	10 mg/m ³	CA QC OEL
1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)	139-44-6	TWA	10 mg/m ³	CA AB OEL
		TWA (Inhalable)	10 mg/m ³	CA BC OEL
		TWA (Respirable)	3 mg/m ³	CA BC OEL
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
cloxacillin	61-72-3	TWA	100 µg/m ³ (OEB 2)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 µg/100 cm ²	Internal
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 vapor type
Hand protection

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

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 Hygiene measures	: Work uniform or laboratory coat. : 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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: suspension
Color	: white
Odor	: No data available
Odor 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
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: No data available

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/17/2025
5.1	12/06/2025	1936034-00021	Date of first issue: 09/11/2017

Relative vapor 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	:	Not applicable
Autoignition 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.
Particle characteristics	:	
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute dermal toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
-----------------------	---	--

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

Components:

Peanut oil:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

cloxacillin:

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

Acute toxicity (other routes of administration) : LD50 (Mouse): 1,117 mg/kg
Application Route: Intramuscular

LD50 (Mouse): 916 mg/kg
Application Route: Intravenous

LD50 (Mouse): 1,500 mg/kg
Application Route: Subcutaneous

LD50 (Rat): 1,660 mg/kg
Application Route: Intravenous

LD50 (Rat): 4,200 mg/kg
Application Route: Subcutaneous

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

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:

Peanut oil:

Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):

Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

cloxacillin:

Remarks : Not classified due to lack of data.

Gentamicin:

Species : Rabbit
Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Peanut oil:

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

cloxacillin:

Remarks : Not classified due to lack of data.

Gentamicin:

Species : Rabbit
Result : Mild eye irritation

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

cloxacillin:

Routes of exposure : Dermal
Assessment : Probability or evidence of skin sensitization in humans
Result : positive

Assessment : Probability of respiratory sensitization in humans based on animal testing
Result : positive

Gentamicin:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Peanut oil:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

cloxacillin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Information given is based on data obtained from similar substances.

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Result: negative
Remarks: Information given is based on data obtained from similar substances.

Gentamicin:

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

- 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:

cloxacillin:

Remarks : Not classified due to lack of data.

Gentamicin:

Carcinogenicity - Assessment : No data available

Reproductive toxicity

May damage the unborn child.

Components:

cloxacillin:

Effects on fertility : Test Type: Multi-generation study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 500 mg/kg body weight
Result: No effects on fertility., No effects on reproduction parameters.

Effects on fetal development : Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: No malformations were observed.

Test Type: Development
Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Result: No effects on fetal development.

Gentamicin:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Fertility: NOAEL: 20 mg/kg body weight

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

Result: No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-fetal toxicity.

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

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

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

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:

Gentamicin:

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

Repeated dose toxicity

Components:

cloxacillin:

Species : Rat
LOAEL : 7,000 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks
Symptoms : Hypoglycemia

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

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:

cloxacillin:

Inhalation : Remarks: May cause sensitization of susceptible persons.
Skin contact : Symptoms: Dermatitis
Remarks: May irritate skin.
Eye contact : Remarks: May irritate eyes.
Ingestion : Symptoms: May cause, Gastrointestinal disturbance, Rash
Remarks: May cause sensitization of susceptible persons.

Gentamicin:

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Peanut oil:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Method: Directive 67/548/EEC, Annex V, C.2.
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: Directive 67/548/EEC, Annex V, C.3.
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

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
Exposure time: 72 h

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/17/2025
5.1	12/06/2025	1936034-00021	Date of first issue: 09/11/2017

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: 288.7 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Gentamicin:

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

Bioaccumulative potential

Components:

cloxacillin:

Partition coefficient: n-octanol/water : log Pow: 2.44

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 : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version 5.1 Revision Date: 12/06/2025 SDS Number: 1936034-00021 Date of last issue: 06/17/2025
Date of first issue: 09/11/2017

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
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(Gentamicin)

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/17/2025
5.1	12/06/2025	1936034-00021	Date of first issue: 09/11/2017

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

CA. DSL : not determined

IECSC : not determined

Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Gentamicin / Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06/17/2025
5.1	12/06/2025	1936034-00021	Date of first issue: 09/11/2017

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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - 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

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

Revision Date : 12/06/2025
Date format : mm/dd/yyyy

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.

CA / Z8