

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version
6.0

Revision Date:
2025/06/17

SDS Number:
1936041-00020

Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin / Cloxacillin Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 1A

Short-term (acute) aquatic hazard

Long-term (chronic) aquatic hazard : Category 3

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.

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version
6.0

Revision Date:
2025/06/17

SDS Number:
1936041-00020

Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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

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 vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284 Wear respiratory protection.

: 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 advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.
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) |
|--|-----------|-----------------------|
| 1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate) | 139-44-6 | < 10 |
| cloxacillin | 61-72-3 | >= 1 - < 10 |
| Gentamicin | 1403-66-3 | >= 0.3 - < 1 |

4. FIRST AID MEASURES

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 6.0 | Revision Date: 2025/06/17 | SDS Number: 1936041-00020 | Date of last issue: 2025/04/14 Date of first issue: 2017/09/11 |
|----------------|------------------------------|------------------------------|---|

| | |
|---|--|
| 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. Get medical attention. |
| In case of skin contact | : In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact | : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists. |
| If swallowed | : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage the unborn child. |
| 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 Chlorine compounds Nitrogen oxides (NO _x) Sulphur 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 |

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version
6.0

Revision Date:
2025/06/17

SDS Number:
1936041-00020

Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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 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 mist or vapours. 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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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 |
|--|---|-------------------------------------|--|----------|
| 1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate) | 139-44-6 | NAB | 10 mg/m ³ | ID OEL |
| | Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals | | | |
| | | 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., dripless 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

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

| | |
|--------------------------|--|
| 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. 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|---------------------|
| Appearance | : suspension |
| Colour | : white |
| Odour | : No data available |
| Odour Threshold | : No data available |
| pH | : No data available |
| Melting point/freezing point | : No data available |
| Initial boiling point and boiling range | : No data available |
| Flash point | : No data available |
| Evaporation rate | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Flammability (liquids) | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

| | |
|--|--|
| 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 | : Not applicable |
| 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. |
| Particle characteristics | |
| Particle size | : Not applicable |

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:

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

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version
6.0

Revision Date:
2025/06/17

SDS Number:
1936041-00020

Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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
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:

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

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

| | | |
|---------|---|--------------------------------------|
| 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:

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 |

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

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

Components:

cloxacillin:

| | | |
|-----------------|---|--|
| Exposure routes | : | Dermal |
| Assessment | : | Probability or evidence of skin sensitisation in humans |
| Result | : | positive |
| Assessment | : | Probability of respiratory sensitisation in humans based on animal testing |
| Result | : | positive |

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

Gentamicin:

||| Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

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:

||| 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 - Assess- : No data available

Gentamicin / Cloxacillin FormulationVersion
6.0Revision Date:
2025/06/17SDS Number:
1936041-00020Date of last issue: 2025/04/14
Date of first issue: 2017/09/11**[[ment****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 foetal 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 foetal development |

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 |

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version
6.0

Revision Date:
2025/06/17

SDS Number:
1936041-00020

Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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

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

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

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

| | | |
|-------------------|---|---------------|
| 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 sensitisation 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 sensitisation of susceptible persons. |

Gentamicin:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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 |
|---|---|---|

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version
6.0

Revision Date:
2025/06/17

SDS Number:
1936041-00020

Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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
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
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:

Gentamicin:

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

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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

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.

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

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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.

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version 6.0 Revision Date: 2025/06/17 SDS Number: 1936041-00020 Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/06/17

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)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
ID OEL / NAB : Long term exposure limit

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 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recom-

SAFETY DATA SHEET



Gentamicin / Cloxacillin Formulation

Version
6.0

Revision Date:
2025/06/17

SDS Number:
1936041-00020

Date of last issue: 2025/04/14
Date of first issue: 2017/09/11

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.

ID / EN