

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Gentamicin / Cloxacillin Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

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

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1A	H360D: May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version 5.0      Revision Date: 17.06.2025      SDS Number: 1936780-00021      Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

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. H410      Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<b>Prevention:</b> P201      Obtain special instructions before use. P273      Avoid release to the environment. P280      Wear protective gloves/ protective clothing/ eye protection/ face protection.  <b>Response:</b> P304 + P340      IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311      If experiencing respiratory symptoms: Call a POISON CENTER/ doctor. P391      Collect spillage.

### Hazardous components which must be listed on the label:

cloxacillin  
Gentamicin

### 2.3 Other hazards

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

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version 5.0 Revision Date: 17.06.2025 SDS Number: 1936780-00021 Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

cloxacillin	61-72-3 200-514-7	Resp. Sens. 1; H334 Skin Sens. 1; H317	>= 1 - < 10
Gentamicin	1403-66-3 215-765-8	Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	>= 0.3 - < 1

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.  
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.

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

Risks : Excessive exposure may aggravate preexisting asthma and

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

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.

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

Treatment : Treat symptomatically and supportively.

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

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

Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Nitrogen oxides (NO<sub>x</sub>)  
Sulphur compounds

### 5.3 Advice for firefighters

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

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

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

### 6.2 Environmental precautions

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

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

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

### 6.4 Reference to other sections

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

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe 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 respiratory irritants or sensitisers.  
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

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.

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

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

### 7.3 Specific end use(s)

Specific use(s)	: No data available
-----------------	---------------------

---

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)	139-44-6	OELV - 8 hrs (TWA)	10 mg/m <sup>3</sup>	IE OEL
cloxacillin	61-72-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (OEB 2)	Internal
	Further information: OTO			

### 8.2 Exposure controls

#### Engineering measures

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

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

Laboratory operations do not require special containment.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

### Personal protective equipment

Eye/face protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to I.S. EN 14387
Filter type	: Combined particulates and organic vapour type (A-P)

---

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	: suspension
Colour	: white
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: 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
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version 5.0      Revision Date: 17.06.2025      SDS Number: 1936780-00021      Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
5.0 17.06.2025 1936780-00021 Date of first issue: 11.09.2017

## SECTION 11: Toxicological information

## 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

## Acute toxicity

Not classified based on available information.

## **Components:**

## **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version 5.0      Revision Date: 17.06.2025      SDS Number: 1936780-00021      Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

### **Skin corrosion/irritation**

Not classified based on available information.

#### **Components:**

##### **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:**

##### **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

##### **Gentamicin:**

||| Remarks : No data available

### **Germ cell mutagenicity**

Not classified based on available information.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

### Components:

#### **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 - 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
----------------------	---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

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
<b>Gentamicin:</b>	
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

Not classified based on available information.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

### 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

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version 5.0      Revision Date: 17.06.2025      SDS Number: 1936780-00021      Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

Not classified based on available information.

#### Product:

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

### 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
-----------	---

---

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

μg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 μg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

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

M-Factor (Acute aquatic toxicity) : 100

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

M-Factor (Chronic aquatic toxicity) : 1

### 12.2 Persistence and degradability

#### Components:

##### **Gentamicin:**

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

### 12.3 Bioaccumulative potential

#### Components:

##### **cloxacillin:**

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

##### **Gentamicin:**

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment

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

### 12.7 Other adverse effects

No data available

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product

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

---

## SECTION 14: Transport information

### 14.1 UN number or ID number

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

### 14.2 UN proper shipping name

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

## SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
5.0 17.06.2025 1936780-00021 Date of first issue: 11.09.2017

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

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

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	:	9
<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

## 14.4 Packing group

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

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

<b>RID</b>	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9

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

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

**IATA (Passenger)**  
Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Gentamicin / Cloxacillin Formulation**

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
5.0 17.06.2025 1936780-00021 Date of first issue: 11.09.2017

Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

**ADN**  
Environmentally hazardous : yes

**ADR** Environmentally hazardous : yes

**RID** Environmentally hazardous : yes

## **IMDG**

Marine pollutant : yes

## IATA (Passenger)

## IATA (Cargo)

## 14.6 Special precautions for user

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

## 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

---

## SECTION 15: Regulatory information

## 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Gentamicin / Cloxacillin Formulation**

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
5.0 17.06.2025 1936780-00021 Date of first issue: 11.09.2017

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation : Not applicable  
(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Major accident hazards involving dangerous substances	Quantity 1	Quantity 2
E1 ENVIRONMENTAL HAZARDS	100 t	200 t

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSI : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

#### **10.2 Chemical Safety Assessment**

---

**SECTION 16: Other information**

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

## Full text of H-Statements

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.  
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

## Full text of other abbreviations

Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Repr.	:	Reproductive toxicity
Resp. Sens.	:	Respiratory sensitisation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version 5.0	Revision Date: 17.06.2025	SDS Number: 1936780-00021	Date of last issue: 14.04.2025 Date of first issue: 11.09.2017
----------------	------------------------------	------------------------------	---

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2  
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

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

### Classification of the mixture:

Resp. Sens. 1	H334
Skin Sens. 1	H317
Repr. 1A	H360D
Aquatic Acute 1	H400
Aquatic Chronic 3	H412

### Classification procedure:

Calculation method

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Gentamicin / Cloxacillin Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
1936780-00021

Date of last issue: 14.04.2025  
Date of first issue: 11.09.2017

---

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

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.

IE / EN