

# SAFETY DATA SHEET



## Gentamicin / Cloxacillin Formulation

Version 4.3      Revision Date: 10/01/2022      SDS Number: 1936061-00014      Date of last issue: 07/25/2022  
Date of first issue: 09/11/2017

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### SECTION 1. IDENTIFICATION

Product name : Gentamicin / Cloxacillin Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
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

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 must not be allowed out of the workplace.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.  
P285 In case of inadequate ventilation wear respiratory protection.

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### Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
 P304 + P341 IF INHALED: If breathing is difficult, 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.  
 P363 Wash contaminated clothing 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	CAS-No.	Concentration (% w/w)
Peanut oil	8002-03-7	90 - 95
1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)	139-44-6	3.5
Cloxacillin	61-72-3	2.2
Gentamicin	1403-66-3	0.5

## 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.  
 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.

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Most important symptoms and effects, both acute and delayed	:	<p>Get medical attention. Rinse mouth thoroughly with water. 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).</p>
Protection of first-aiders	:	<p>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).</p>
Notes to physician	:	<p>Treat symptomatically and supportively.</p>

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	<p>Water spray Alcohol-resistant foam Carbon dioxide (CO<sub>2</sub>) Dry chemical</p>
Unsuitable extinguishing media	:	<p>None known.</p>
Specific hazards during fire fighting	:	<p>Exposure to combustion products may be a hazard to health.</p>
Hazardous combustion products	:	<p>Carbon oxides Chlorine compounds Nitrogen oxides (NO<sub>x</sub>) Sulfur compounds</p>
Specific extinguishing methods	:	<p>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.</p>
Special protective equipment for fire-fighters	:	<p>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</p>

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	<p>Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</p>
Environmental precautions	:	<p>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.</p>
Methods and materials for containment and cleaning up	:	<p>Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material</p>

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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.  
 Avoid breathing 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.
- 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	TWA (mist - total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (mist - respirable)	5 mg/m <sup>3</sup>	NIOSH REL

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1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)	139-44-6	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Cloxacillin	61-72-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: RSEN				
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**  
**Material**

: Chemical-resistant gloves

**Eye protection**

: Wear safety glasses with side shields or goggles.  
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**  
**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,

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appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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**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
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

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Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle size	:	Not applicable

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**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.

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**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: > 5,000 mg/kg Method: Calculation method
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**Components:****Peanut oil:**

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
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Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: Based on data from similar materials
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**1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Remarks: Based on data from similar materials
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Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: Based on data from similar materials
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**Cloxacillin:**

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

#### 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:



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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

**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

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**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:**

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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is

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identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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  
 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

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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

#### 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

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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

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## 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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
 aquatic invertebrates : 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

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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  
 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

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### 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

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## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
 Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
 If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

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

#### **IATA-DGR**

UN/ID No. : UN 3082  
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)  
 Class : 9  
 Packing group : III  
 Labels : Miscellaneous  
 Packing instruction (cargo aircraft) : 964  
 Packing instruction (passenger aircraft) : 964  
 Environmentally hazardous : yes

#### **IMDG-Code**

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

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	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

#### 49 CFR

UN/ID/NA number	: UN 3082
Proper shipping name	: Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
Class	: 9
Packing group	: III
Labels	: CLASS 9
ERG Code	: 171
Marine pollutant	: yes(Gentamicin)
Remarks	: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### 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.

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## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

<b>SARA 311/312 Hazards</b>	: Respiratory or skin sensitization Reproductive toxicity
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<b>SARA 313</b>	: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
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### US State Regulations

#### Pennsylvania Right To Know



## Gentamicin / Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07/25/2022
4.3	10/01/2022	1936061-00014	Date of first issue: 09/11/2017

Peanut oil	8002-03-7
1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)	139-44-6

### California Prop. 65

WARNING: This product can expose you to chemicals including Gentamicin, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### California Permissible Exposure Limits for Chemical Contaminants

Peanut oil	8002-03-7
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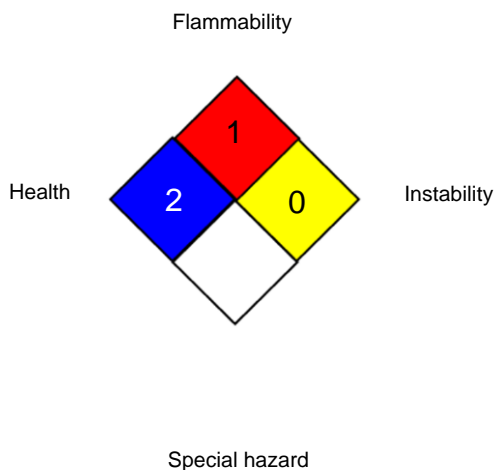
The ingredients of this product are reported in the following inventories:

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

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

<b>HEALTH</b>	*	<b>2</b>
<b>FLAMMABILITY</b>		<b>1</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Sub-

**Gentamicin / Cloxacillin Formulation**

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stances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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 : 10/01/2022

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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