according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

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

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 diffi-

culties 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 protec-

tion.

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

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 doc-

tor.

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

In case of eye contact

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. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 09/30/2023 09/28/2024 1936061-00018 Date of first issue: 09/11/2017 4.7

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

May cause allergy or asthma symptoms or breathing delayed 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).

First Aid responders should pay attention to self-protection, Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Chlorine compounds Nitrogen oxides (NOx) Sulfur compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec: : tive equipment and emer-

gency 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.

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 09/28/2024 1936061-00018 Date of first issue: 09/11/2017 4.7

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

Do not get on skin or clothing. Advice on safe handling

Do not breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Already sensitized individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease,

should consult their physician regarding working with

respiratory irritants or sensitizers.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage Keep in properly labeled containers.

> Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

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

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 09/30/2023 09/28/2024 1936061-00018 Date of first issue: 09/11/2017 4.7

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Peanut oil	8002-03-7	TWA (mist - total)	10 mg/m³	NIOSH REL	
		TWA (mist - respirable)	5 mg/m³	NIOSH REL	
1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)	139-44-6	TWA (Inhal- able particu- late matter)	10 mg/m ³	ACGIH	
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH	
cloxacillin	61-72-3	TWA	100 μg/m3 (OEB 2)	Internal	
	Further information: RSEN, DSEN				
		Wipe limit	100 μg/100 cm2	Internal	
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (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 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

Wear safety glasses with side shields or goggles. Eye protection

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.

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

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.

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

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

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

Components:

Peanut oil:

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

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

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

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

Remarks: Based on data from similar materials

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

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

Remarks: Based on data from similar materials

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

Remarks: Based on data from similar materials

cloxacillin:

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

LD50 (Mouse): 5,000 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Mouse): 1,117 mg/kg Application Route: Intramuscular

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

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

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

LD50 (Rat): 4,200 mg/kg

Application Route: Subcutaneous

Gentamicin:

Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg

LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.2 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Remarks: No mortality observed at this dose.

Acute toxicity (other routes of:

administration)

LD50 (Rat): 67 - 96 mg/kg

Application Route: Intravenous

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.

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

Components:

Peanut oil:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

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

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

cloxacillin:

Remarks : Not classified due to lack of data.

Gentamicin:

Species : Rabbit

Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Peanut oil:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

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

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

cloxacillin:

Remarks : Not classified due to lack of data.

Gentamicin:

Species : Rabbit

Result : Mild eye irritation

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.

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

Components:

cloxacillin:

Routes of exposure : Dermal

Assessment : Probability or evidence of skin sensitization in humans

Result : positive

Assessment : Probability of respiratory sensitization in humans based on

animal testing

Result : positive

Gentamicin:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Peanut oil:

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

Result: negative

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

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

cloxacillin:

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

Result: negative

Remarks: Information given is based on data obtained from

similar substances.

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Remarks: Information given is based on data obtained from

similar substances.

Gentamicin:

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)

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

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

ment

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

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

OSHANo 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

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

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 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 - As-

sessment

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

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

Gentamicin:

Species : Dog
LOAEL : 3 mg/kg
Application Route : Intramuscular
Exposure time : 12 Months
Target Organs : Kidney

Symptoms : Vomiting, Salivation

Species : Monkey
LOAEL : 50 mg/kg
Application Route : Subcutaneous
Exposure time : 3 Weeks

Target Organs : Kidney, inner ear

Species : Monkey
LOAEL : 6 mg/kg
Application Route : Intramuscular
Exposure time : 3 Weeks

Target Organs : Blood, Kidney, inner ear, Liver

Species : Rat

NOAEL : 5 mg/kg

LOAEL : 10 mg/kg

Application Route : Intramuscular

Exposure time : 52 Weeks

Target Organs : Kidney, Blood

Species : Rat

NOAEL : 12.5 mg/kg
LOAEL : 50 mg/kg
Application Route : Intramuscular
Exposure time : 13 Weeks
Target Organs : Kidney

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

cloxacillin:

Inhalation : Remarks: May cause sensitization of susceptible persons.

Skin contact : Symptoms: Dermatitis

Remarks: May irritate skin.

Eye contact : Remarks: May irritate eyes.

Ingestion : Symptoms: May cause, Gastrointestinal disturbance, Rash

Remarks: May cause sensitization of susceptible persons.

Gentamicin:

Ingestion : Target Organs: Kidney

Target Organs: inner ear

Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal

deafness

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Peanut oil:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Remarks: Based on data from similar materials

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

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.3. Remarks: Based on data from similar materials

Gentamicin:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 86 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

LC50 (Americamysis): 30 mg/l

Exposure time: 96 h

Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5

μg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 μg/l

Exposure time: 72 h

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 μg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: 288.7 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Gentamicin:

Biodegradability : Result: rapidly degradable

Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

cloxacillin:

Partition coefficient: n-

octanol/water

log Pow: 2.44

Gentamicin:

Partition coefficient: n-

octanol/water

log Pow: < -2

Mobility in soilNo data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Gentamicin)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Gentamicin)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Gentamicin)

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

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

Not applicable for product as supplied.

Domestic regulation

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

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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.

SARA 311/312 Hazards : Respiratory or skin sensitization

Reproductive toxicity

SARA 313 : 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.

US State Regulations

Pennsylvania Right To Know

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.

California Permissible Exposure Limits for Chemical Contaminants

Peanut oil 8002-03-7

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

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

NFPA 704:

Flammability Health 2 0 Instability

Special hazard

HMIS® IV:



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 Substances 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 concern-

according to the OSHA Hazard Communication Standard



Gentamicin / Cloxacillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.7 09/28/2024 1936061-00018 Date of first issue: 09/11/2017

ing 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 Agen-

cy, http://echa.europa.eu/

Revision Date : 09/28/2024

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.

US / Z8