according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

SECTION 1. IDENTIFICATION

Product name : Cloxacillin / Ampicillin Formulation Other means of identification : Bovaclox Dry Cow (A004495)

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

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.

Precautionary Statements : Prevention:

P261 Avoid breathing vapors.

P272 Contaminated work clothing must not be allowed out of

the workplace.

P280 Wear protective gloves.

P285 In case of inadequate ventilation wear respiratory protec-

tion.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P304 + P341 IF INHALED: If breathing is difficult, remove per-

son to fresh air and keep comfortable for breathing.

P333 + P313 If skin irritation or rash occurs: Get medical atten-

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 09/30/2023 12/05/2023 10843346-00005 Date of first issue: 08/30/2022 1.4

tion.

P342 + P311 If experiencing respiratory symptoms: Call a doc-

P363 Wash contaminated clothing before reuse.

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)
White mineral oil (petroleum)	8042-47-5	76.32
cloxacillin	61-72-3	14.2
Ampicillin	69-53-4	6.48
Hydroxyaluminum distearate	300-92-5	3

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.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms

May cause an allergic skin reaction.

and effects, both acute and

May cause allergy or asthma symptoms or breathing difficul-

delayed

ties if inhaled.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

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

and use the recommended personal protective equipment

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

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 Sulfur oxides Metal oxides

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, protective 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.

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.

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

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 : Use only with adequate ventilation.

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

Avoid breathing 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.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : No special restrictions on storage with other products.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis	
111111111111111111111111111111111111111	22.12.17.7	exposure)	concentration	4000	
White mineral oil (petroleum)	8042-47-5	TWA (Inhal-	5 mg/m³	ACGIH	
		able particu-			
		late matter)			
		TWA (Mist)	5 mg/m ³	OSHA Z-1	
		TWA (Mist)	5 mg/m³	NIOSH REL	
		ST (Mist)	10 mg/m ³	NIOSH REL	
cloxacillin	61-72-3	TWA	100 μg/m3 (OEB	Internal	
			2)		
	Further information: RSEN, DSEN				
		Wipe limit	100 μg/100 cm2	Internal	
Ampicillin	69-53-4	TWA	0.6 mg/m3 (OEB	Internal	
			2)		
	Further information: RSEN				
Hydroxyaluminum distearate	300-92-5	TWA (Inhal-	10 mg/m ³	ACGIH	
		able particu-			
		late matter)			
		TWA (Res-	3 mg/m³	ACGIH	
		pirable par-			

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09/30/2023

 1.4
 12/05/2023
 10843346-00005
 Date of first issue: 08/30/2022

ticulate mat- ter)		
TWA (Res-	1 mg/m³	ACGIH
pirable par-	(Aluminum)	
ticulate mat-		
ter)		

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, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : cream

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

Color : off-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 : Not applicable

Flammability (solid, gas) : No data available

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 : Not applicable

Relative vapor density : Not applicable

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 : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

Particle size : $< 30 \mu m$

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

None known.

Possibility of hazardous reac-

tions

Conditions to avoid : None known.

Incompatible materials : None.

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

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

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

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

Assessment: The substance or mixture has no acute dermal

toxicity

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

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

> 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

Ampicillin:

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

LD50 (Mouse): 15,200 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Rat): 6,200 mg/kg

Application Route: Intravenous

LD50 (Mouse): 4,600 mg/kg Application Route: Intravenous

Hydroxyaluminum distearate:

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

Method: OECD Test Guideline 423

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Skin corrosion/irritation

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species : Rabbit

Result : No skin irritation

cloxacillin:

Remarks : Not classified due to lack of data.

Hydroxyaluminum distearate:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 431

Remarks : Based on data from similar materials

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Remarks : Based on data from similar materials

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species : Rabbit

Result : No eye irritation

cloxacillin:

Remarks : Not classified due to lack of data.

Hydroxyaluminum distearate:

Species : Bovine cornea

Method : OECD Test Guideline 437

Remarks : Based on data from similar materials

Result : No 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:

White mineral oil (petroleum):

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

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

Ampicillin:

Routes of exposure : Inhalation Result : Sensitizer

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

Hydroxyaluminum distearate:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

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.

Ampicillin:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Result: negative

Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: negative

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

> Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat

Application Route: Oral

Result: negative

Hydroxyaluminum distearate:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species : Rat
Application Route : Ingestion
Exposure time : 24 Months
Result : negative

cloxacillin:

Remarks : Not classified due to lack of data.

Ampicillin:

Species : Rat
Application Route : Oral
Exposure time : 2 Years

750 mg/kg body weight

Tumor Type : adrenal, Leukemia, breast tumors

Species : Mouse
Application Route : Oral
Exposure time : 2 Years

3,000 mg/kg body weight

Tumor Type : Lungs

Remarks : Benign tumor(s)

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

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

Not classified based on available information.

Components:

White mineral oil (petroleum):

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Skin contact

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

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.

Ampicillin:

Effects on fertility : Test Type: Fertility

Species: Guinea pig

Target Organs: Uterus (including cervix)

Effects on fetal development : Test Type: Development

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

Species: Rat

Developmental Toxicity: NOAEL: 250 mg/kg body weight

Result: No effects on fetal development.

Hydroxyaluminum distearate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

White mineral oil (petroleum):

Species : Rat
LOAEL : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat LOAEL : >= 1 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 4 Weeks

Method : OECD Test Guideline 412

cloxacillin:

Species : Rat

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

Ampicillin:

Species : Rat

LOAEL : 3,000 mg/kg

Application Route : Oral

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

Exposure time : 13 Weeks Symptoms : Diarrhea

Species : Mouse
LOAEL : 2,000 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Symptoms : Diarrhea

Species : Rat

LOAEL : 750 mg/kg
Application Route : Oral
Exposure time : 2 y

Target Organs : Thyroid, forestomach

Symptoms : Diarrhea, Salivation, decreased activity

Species : Mouse LOAEL : 2,000 mg/kg

Application Route : Oral Exposure time : 2 y

Target Organs : forestomach

Symptoms : Ulceration, Inflammation, fungal infections

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.

Ampicillin:

Inhalation : Symptoms: Asthma, Hay fever

Remarks: May cause allergy or asthma symptoms or breath-

ing difficulties if inhaled.

Ingestion : Symptoms: skin rash, Nausea, Diarrhea, Vomiting, colitis,

urticaria

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

: NOEC (Pseudokirchneriella subcapitata (green algae)): 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l

Exposure time: 28 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 1,000 mg/l

Exposure time: 21 d

Ampicillin:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 1,000 mg/l

Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae): 190 μg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 13 µg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 9 mg/l Exposure time: 3 h

Test Type: Respiration inhibition

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

Method: OECD Test Guideline 209

Hydroxyaluminum distearate:

Ecotoxicology Assessment

Chronic aquatic toxicity : No toxicity at the limit of solubility.

Persistence and degradability

Components:

White mineral oil (petroleum):

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 31 % Exposure time: 28 d

Ampicillin:

Biodegradability : Result: rapidly degradable

Biodegradation: 35 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Hydroxyaluminum distearate:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

cloxacillin:

Partition coefficient: n- : log Pow: 2.44

octanol/water

Ampicillin:

Partition coefficient: n- : log Pow: -2.0

octanol/water pH: 7

Hydroxyaluminum distearate:

Partition coefficient: n- : log Pow: 15.088 octanol/water : Remarks: Calculation

Mobility in soil

No data available

Other adverse effects

No data available

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

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

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not regulated as a dangerous good

Special precautions for user

Not applicable

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

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

White mineral oil (petroleum) 8042-47-5

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

cloxacillin 61-72-3 Ampicillin 69-53-4 Hydroxyaluminum distearate 300-92-5

California List of Hazardous Substances

White mineral oil (petroleum) 8042-47-5

California Permissible Exposure Limits for Chemical Contaminants

White mineral oil (petroleum) 8042-47-5 Hydroxyaluminum distearate 300-92-5

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

AICS : not determined

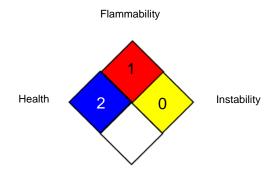
DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

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

NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded

at any time during a workday

according to the OSHA Hazard Communication Standard



Cloxacillin / Ampicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 1.4 12/05/2023 10843346-00005 Date of first issue: 08/30/2022

OSHA Z-1 / TWA : 8-hour time weighted average

AllC - 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 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 Agen-

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

Revision Date : 12/05/2023

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