according to the Hazardous Products Regulations



# **Cloxacillin / Ampicillin Formulation**

Version Revision Date: SDS Number: Date of last issue: 12/05/2023 1.5 09/28/2024 10843364-00006 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 Hazardous Products Regulations

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 should not be allowed out of

the workplace.

P280 Wear protective gloves. P284 Wear respiratory protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

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

tion.

according to the Hazardous Products Regulations



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

tor.

P362 + P364 Take off contaminated clothing and wash it 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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	Paraffinum liquidum	8042-47-5	76.32
cloxacillin	No data availa- ble	61-72-3	14.2
Ampicillin	6- [(Aminophe- nyla- cetyl)amino]- 3,3-dimethyl-7- oxo-4-thia-1- azabicy- clo[3.2.0]heptan e-2-carboxylic acid	69-53-4	6.48
Hydroxyaluminum distearate	Aluminum, hydroxybis(octade canoato-l.kappa.O)-	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.

according to the Hazardous Products Regulations



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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, DO NOT induce vomiting.

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

Most important symptoms

and effects, both acute and

delayed

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

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

reactive airways dysfunction syndrome).

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

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

Notes to physician : Treat symptomatically and supportively.

#### **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).

according to the Hazardous Products Regulations



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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.

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 Advice on safe handling Use only with adequate ventilation. Do not get on skin or clothing.

Do not breathe 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	Control parame-	Basis
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according to the Hazardous Products Regulations



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		/F	tono / Domesia silala			
		(Form of	ters / Permissible			
Mhite mineral ail (notraleum)	0040 47 5	exposure)	concentration	CAAROEL		
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	CA AB OEL		
		STEL (Mist)	10 mg/m <sup>3</sup>	CA AB OEL CA QC OEL		
		TWAEV (Mist - Inhalable	5 mg/m³	CA QC OEL		
		dust)				
		TWA (Mist)	1 mg/m³	CA BC OEL		
		TWA	5 mg/m <sup>3</sup>	ACGIH		
		(Inhalable	J mg/m	ACCIII		
		particulate				
		matter)				
cloxacillin	61-72-3	TWA	100 μg/m3 (OEB 2)	Internal		
	Further information: RSEN, DSEN					
		Wipe limit	100 μg/100 cm2	Internal		
Ampicillin	69-53-4	TWA		Internal		
·			2)			
	Further information: RSEN					
Hydroxyaluminum distearate	300-92-5	TWA	10 mg/m <sup>3</sup>	CA AB OEL		
		TWA (Res-	1 mg/m³	CA BC OEL		
		pirable)	(Aluminum)			
			10 mg/m <sup>3</sup>	CA QC OEL		
			10 mg/m <sup>3</sup>	CA BC OEL		
			3 mg/m³	CA BC OEL		
			5 mg/m³	CA QC OEL		
			10 mg/m <sup>3</sup>	ACGIH		
		'				
	-		2 m a/m3	ACCIL		
			3 mg/m	ACGIH		
		1 '				
			1 mg/m <sup>3</sup>	ACGIH		
				AGGIT		
			(, darimiditi)			
	I	matter)	1	1		
Hydroxyaluminum distearate	Further inforr	TWA  TWA  TWA  TWA (Respirable)  TWAEV  TWA (Inhalable)  TWAEV  (respirable dust)  TWA  (Inhalable particulate matter)  TWA  (Respirable particulate matter)  TWA  (Respirable particulate matter)  TWA  (Respirable particulate matter)	0.6 mg/m3 (OEB 2) 10 mg/m³ 1 mg/m³ (Aluminum)	CA AB OEL		

**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

according to the Hazardous Products Regulations



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Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Combined particulates and organic vapor type

Filter type 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

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

according to the Hazardous Products Regulations



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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

Particle characteristics

Particle size : < 30 µm

## **SECTION 10. STABILITY AND REACTIVITY**

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

Possibility of hazardous reac-

tions

None known.

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

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

according to the Hazardous Products Regulations



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**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 (M ) 040 //

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

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

according to the Hazardous Products Regulations



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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

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

according to the Hazardous Products Regulations



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### 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

## 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

according to the Hazardous Products Regulations



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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

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

according to the Hazardous Products Regulations



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### 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

#### 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** 

according to the Hazardous Products Regulations



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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

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

according to the Hazardous Products Regulations



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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

Exposure time : Oral

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:

according to the Hazardous Products Regulations



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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

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

according to the Hazardous Products Regulations



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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 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

according to the Hazardous Products Regulations



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#### Bioaccumulative potential

#### **Components:**

cloxacillin:

Partition coefficient: n-

octanol/water

: log Pow: 2.44

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

### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **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**

#### **TDG**

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

according to the Hazardous Products Regulations



# **Cloxacillin / Ampicillin Formulation**

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### **SECTION 15. REGULATORY INFORMATION**

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA AB OEL / STEL : 15-minute occupational exposure limit

CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tempera-

according to the Hazardous Products Regulations



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ture; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 Date format : mm/dd/yyyy

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.

CA / Z8