

## Cloxacillin / Ampicillin Formulation

Version 1.1      Revision Date: 04/04/2023      SDS Number: 10843364-00002      Date of last issue: 08/30/2022  
Date of first issue: 08/30/2022

---

### SECTION 1. IDENTIFICATION

Product name : Cloxacillin / Ampicillin Formulation  
Other means of identification : No data available

#### 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 difficulties 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 attention.  
P342 + P311 If experiencing respiratory symptoms: Call a doc-

## Cloxacillin / Ampicillin Formulation

Version 1.1      Revision Date: 04/04/2023      SDS Number: 10843364-00002      Date of last issue: 08/30/2022  
 Date of first issue: 08/30/2022

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 available	61-72-3	14.2
Ampicillin	6-[(Aminophenyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid	69-53-4	6.48
Hydroxyaluminum distearate	Aluminum, hydroxybis(octadecanoato- $\kappa$ .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.  
 Thoroughly clean shoes before reuse.

## Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

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 and effects, both acute and delayed	:	Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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 (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Chlorine compounds Nitrogen oxides (NO <sub>x</sub> ) Sulfur compounds Sulfur oxides Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
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 emergency 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.

## Cloxacillin / Ampicillin Formulation

Version 1.1      Revision Date: 04/04/2023      SDS Number: 10843364-00002      Date of last issue: 08/30/2022  
 Date of first issue: 08/30/2022

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 : 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 exposure)	Control parameters / Permissible concentration	Basis
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
		TWAEV (Mist)	5 mg/m <sup>3</sup>	CA QC OEL
		STEV (Mist)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Mist)	1 mg/m <sup>3</sup>	CA BC OEL
		TWA	5 mg/m <sup>3</sup>	ACGIH

**Cloxacillin / Ampicillin Formulation**

Version 1.1      Revision Date: 04/04/2023      SDS Number: 10843364-00002      Date of last issue: 08/30/2022  
 Date of first issue: 08/30/2022

		(Inhalable particulate matter)		
Cloxacillin	61-72-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: RSEN				
Ampicillin	69-53-4	TWA	0.6 mg/m <sup>3</sup> (OEB 2)	Internal
Further information: RSEN				
Hydroxyaluminum distearate	300-92-5	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Respirable)	1 mg/m <sup>3</sup> (Aluminum)	CA BC OEL
		TWAEV	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhalable)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminum)	ACGIH

**Engineering measures** : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapor type  
 Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
 Safety glasses

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.

## Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

Hygiene measures : Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).  
 : 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.

---

### 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
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

**Cloxacillin / Ampicillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

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 size : < 30 µm

---

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : None known.

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 inhalation 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

---

**Cloxacillin / Ampicillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

LD50 (Mouse): 5,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 1,117 mg/kg  
Application Route: IntramuscularLD50 (Mouse): 916 mg/kg  
Application Route: IntravenousLD50 (Mouse): 1,500 mg/kg  
Application Route: SubcutaneousLD50 (Rat): 1,660 mg/kg  
Application Route: IntravenousLD50 (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: IntravenousLD50 (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 materialsAcute 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:**



**Cloxacillin / Ampicillin Formulation**

Version 1.1      Revision Date: 04/04/2023      SDS Number: 10843364-00002      Date of last issue: 08/30/2022  
Date of first issue: 08/30/2022

---

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

**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

**Cloxacillin / Ampicillin Formulation**

Version 1.1      Revision Date: 04/04/2023      SDS Number: 10843364-00002      Date of last issue: 08/30/2022  
Date of first issue: 08/30/2022

---

**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  
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

## Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

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

### Hydroxylaluminum 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

**Cloxacillin / Ampicillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

Remarks : Benign tumor(s)

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

**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  
Species: Rat  
Developmental Toxicity: NOAEL: 250 mg/kg body weight  
Result: No effects on fetal development.

**Hydroxyaluminum distearate:**

## Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

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 :  $\geq 1$  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 : 13 Weeks  
 Symptoms : Diarrhea

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

## Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

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 breathing 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

## Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l  
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic 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  
Method: OECD Test Guideline 209

### Hydroxylaluminum distearate:

#### Ecotoxicology Assessment

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

**Cloxacillin / Ampicillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

**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-octanol/water : log Pow: 2.44

**Ampicillin:**

Partition coefficient: n-octanol/water : log Pow: -2.0  
pH: 7

**Hydroxyaluminum distearate:**

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

**Mobility in soil**

No 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.



## Cloxacillin / Ampicillin Formulation

Version 1.1      Revision Date: 04/04/2023      SDS Number: 10843364-00002      Date of last issue: 08/30/2022  
Date of first issue: 08/30/2022

---

### 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

---

### 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 safety, Schedule 1, Part 1: Permissible exposure values for airborne 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  
CA QC OEL / STEV : Short-term exposure value

AIC - 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

**Cloxacillin / Ampicillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08/30/2022
1.1	04/04/2023	10843364-00002	Date of first issue: 08/30/2022

---

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 Temperature; 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 Agency, <http://echa.europa.eu/>

Revision Date : 04/04/2023  
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