

Cloxacillin / Ampicillin Formulation

Version 1.4 Revision Date: 05.12.2023 SDS Number: 10843347-00005 Date of last issue: 30.09.2023
Date of first issue: 30.08.2022

1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier's details

Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION**GHS Classification**

Respiratory sensitisation : Category 1
Skin sensitisation : 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 vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Cloxacillin / Ampicillin Formulation

Version 1.4 Revision Date: 05.12.2023 SDS Number: 10843347-00005 Date of last issue: 30.09.2023
Date of first issue: 30.08.2022

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 advice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	>= 70 -< 90
cloxacillin	61-72-3	>= 10 -< 20
ampicillin	69-53-4	>= 2.5 -< 10
Hydroxyaluminum distearate	300-92-5	>= 1 -< 10

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.

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

Most important symptoms and effects, both acute and delayed	:	<p>Get medical attention if symptoms occur. Rinse mouth thoroughly with water. 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).</p>
Protection of first-aiders	:	<p>First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).</p>
Notes to physician	:	<p>Treat symptomatically and supportively.</p>

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	<p>Water spray Alcohol-resistant foam Carbon dioxide (CO₂) Dry chemical</p>
Unsuitable extinguishing media	:	<p>None known.</p>
Specific hazards during fire-fighting	:	<p>Exposure to combustion products may be a hazard to health.</p>
Hazardous combustion products	:	<p>Carbon oxides Chlorine compounds Nitrogen oxides (NO_x) Sulphur compounds Sulphur oxides Metal oxides</p>
Specific extinguishing methods	:	<p>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.</p>
Special protective equipment for firefighters	:	<p>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</p>

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	<p>Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</p>
Environmental precautions	:	<p>Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.</p>

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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.

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 vapours.
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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.
Keep tightly closed.
Store in accordance with the particular national regulations.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	PEL (long term) (Mist)	5 mg/m ³	SG OEL
		PEL (short term) (Mist)	10 mg/m ³	SG OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH

Cloxacillin / Ampicillin Formulation

Version 1.4 Revision Date: 05.12.2023 SDS Number: 10843347-00005 Date of last issue: 30.09.2023
 Date of first issue: 30.08.2022

cloxacillin	61-72-3	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: RSEN, DSEN				
		Wipe limit	100 µg/100 cm ²	Internal
ampicillin	69-53-4	TWA	0.6 mg/m ³ (OEB 2)	Internal
Further information: RSEN				
Hydroxylaluminum distearate	300-92-5	PEL (long term)	10 mg/m ³	SG OEL
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	1 mg/m ³ (Aluminium)	ACGIH

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 : 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 vapour 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 : Work uniform or laboratory coat.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
 When using do not eat, drink or smoke.
 Contaminated work clothing should not be allowed out of the workplace.
 Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	cream
Colour	:	off-white
Odour	:	No data available
Odour 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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

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

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.

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: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

LD50 (Mouse): 5,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 1,117 mg/kg
Application Route: Intramuscular

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

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

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

LD50 (Rat): 4,200 mg/kg
Application Route: Subcutaneous

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.

Cloxacillin / Ampicillin Formulation

Version 1.4 Revision Date: 05.12.2023 SDS Number: 10843347-00005 Date of last issue: 30.09.2023
Date of first issue: 30.08.2022

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

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:**White mineral oil (petroleum):**

Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

cloxacillin:

Exposure routes : Dermal
Assessment : Probability or evidence of skin sensitisation in humans
Result : positive

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

Assessment : Probability of respiratory sensitisation in humans based on animal testing
 Result : positive

ampicillin:

Exposure routes : Inhalation
 Result : Sensitiser

Hydroxyaluminum distearate:

Test Type : Local lymph node assay (LLNA)
 Exposure routes : 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

Cloxacillin / Ampicillin Formulation

Version 1.4 Revision Date: 05.12.2023 SDS Number: 10843347-00005 Date of last issue: 30.09.2023
Date of first issue: 30.08.2022

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

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

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

Exposure time	:	2 Years
	:	750 mg/kg body weight
Tumor Type	:	adrenal, Leukaemia, 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 - 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 foetal development	:	Test Type: Embryo-foetal 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 foetal 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 foetal development

ampicillin:

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

Effects on fertility : Test Type: Fertility
Species: Guinea pig
Target Organs: Uterus (including cervix)

Effects on foetal development : Test Type: Development
Species: Rat
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Result: No effects on foetal 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 foetal 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

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

Symptoms : Hypoglycemia

ampicillin:

Species : Rat
 LOAEL : 3,000 mg/kg
 Application Route : Oral
 Exposure time : 13 Weeks
 Symptoms : Diarrhoea

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

Species : Rat
 LOAEL : 750 mg/kg
 Application Route : Oral
 Exposure time : 2 yr
 Target Organs : Thyroid, forestomach
 Symptoms : Diarrhoea, Salivation, decreased activity

Species : Mouse
 LOAEL : 2,000 mg/kg
 Application Route : Oral
 Exposure time : 2 yr
 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 sensitisation 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 sensitisation 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, Diarrhoea, Vomiting, colitis, urticaria

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates : Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : NOEC (Pseudokirchneriella subcapitata (green algae)): 100
plants : mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 1,000 mg/l
aquatic invertebrates (Chron- : Exposure time: 21 d
ic toxicity)

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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates : Exposure time: 48 h

Toxicity to algae/aquatic : EC50 (Anabaena flos-aquae): 190 µg/l
plants : 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

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

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

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

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

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

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.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 05.12.2023

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
1.4	05.12.2023	10843347-00005	Date of first issue: 30.08.2022

SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

AIIIC - 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 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

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.

SG / EN