

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version 2.11      Revision Date: 30.09.2023      SDS Number: 1131237-00017      Date of last issue: 09.08.2023  
Date of first issue: 30.11.2016

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Cloxacillin Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Respiratory sensitisation, Category 1      H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation, Category 1      H317: May cause an allergic skin reaction.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

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.

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# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version 2.11      Revision Date: 30.09.2023      SDS Number: 1131237-00017      Date of last issue: 09.08.2023  
Date of first issue: 30.11.2016

Precautionary statements : **Prevention:**  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves.  
**Response:**  
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.

Hazardous components which must be listed on the label:  
cloxacillin

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
cloxacillin	61-72-3 200-514-7	Resp. Sens. 1; H334 Skin Sens. 1; H317	>= 1 - < 10

For explanation of abbreviations see section 16.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : 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).

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

---

Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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>)  
Sulphur compounds

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for 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 dis-

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

---

posal 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |  |
|-------------------------|---|--|
| 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.<br>Avoid breathing mist or vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>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.<br>Take care to prevent spills, waste and minimize release to the environment. |
| 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.<br>Wash contaminated clothing before re-use.<br>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.                 |

### 7.2 Conditions for safe storage, including any incompatibilities

- |   |   |   |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Keep tightly closed.<br>Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Gases  |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version 2.11      Revision Date: 30.09.2023      SDS Number: 1131237-00017      Date of last issue: 09.08.2023  
Date of first issue: 30.11.2016

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
cloxacillin	61-72-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: RSEN, DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

##### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Glycerides, mixed decanoyl and octanoyl	Workers	Inhalation	Long-term systemic effects	177,79 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	25,21 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	43,84 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	12,61 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12,61 mg/kg bw/day

##### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Glycerides, mixed decanoyl and octanoyl	Oral (Secondary Poisoning)	0,03 mg/kg food

#### 8.2 Exposure controls

##### 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

Eye/face 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.

Hand protection  
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

---

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	No data available
Odour	:	characteristic
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	insoluble
Partition coefficient: n-octanol/water	:	No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

---

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure :  
Inhalation  
Skin contact  
Ingestion  
Eye contact



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

---

### Acute toxicity

Not classified based on available information.

### Components:

#### cloxacillin:

Acute oral toxicity : LD50 (Rat): 5.000 mg/kg  
LD50 (Mouse): 5.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 1.117 mg/kg  
Application Route: Intramuscular

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

LD50 (Mouse): 1.500 mg/kg  
Application Route: Subcutaneous

LD50 (Rat): 1.660 mg/kg  
Application Route: Intravenous

LD50 (Rat): 4.200 mg/kg  
Application Route: Subcutaneous

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### cloxacillin:

Remarks : Not classified due to lack of data.

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### cloxacillin:

Remarks : Not classified due to lack of data.

### 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:

#### cloxacillin:

Exposure routes : Dermal

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

---

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

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

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### **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.

### Carcinogenicity

Not classified based on available information.

#### Components:

##### **cloxacillin:**

Remarks : Not classified due to lack of data.

### Reproductive toxicity

Not classified based on available information.

#### Components:

##### **cloxacillin:**

Effects on fertility : Test Type: Multi-generation study  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 500 mg/kg body weight  
Result: No effects on fertility, No effects on reproduction pa-  
rameters

Effects on foetal develop- : Test Type: Development  
ment : Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 100 mg/kg body weight  
Result: No malformations were observed.

Test Type: Development

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

---

Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: NOAEL: 250 mg/kg body weight  
Result: No effects on foetal development

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### **cloxacillin:**

Species	:	Rat
LOAEL	:	7.000 mg/kg
Application Route	:	Intravenous
Exposure time	:	4 Weeks
Symptoms	:	Hypoglycemia

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 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.

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## SECTION 12: Ecological information

### 12.1 Toxicity

No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

---

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

##### **cloxacillin:**

Partition coefficient: n- : log Pow: 2,44  
octanol/water

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
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.

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## SECTION 14: Transport information

### 14.1 UN number or ID number

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version 2.11	Revision Date: 30.09.2023	SDS Number: 1131237-00017	Date of last issue: 09.08.2023 Date of first issue: 30.11.2016
-----------------	------------------------------	------------------------------	---

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**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.2 UN proper shipping name

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA (Cargo)** : Not regulated as a dangerous good  
**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, : Conditions of restriction for the following entries should be considered:

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

mixtures and articles (Annex XVII)

Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

### Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of H-Statements

H317 : May cause an allergic skin reaction.

H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Full text of other abbreviations

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

Resp. Sens. : Respiratory sensitisation  
Skin Sens. : Skin sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECl - 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

### 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/>

### Classification of the mixture:

Resp. Sens. 1 H334  
Skin Sens. 1 H317

### Classification procedure:

Calculation method  
Calculation method

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 mate-

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Cloxacillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.08.2023
2.11	30.09.2023	1131237-00017	Date of first issue: 30.11.2016

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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.

NO / EN