

Cloxacillin Formulation

Version 2.10 Revision Date: 30.09.2023 SDS Number: 1131222-00016 Date of last issue: 09.08.2023
Date of first issue: 30.11.2016

SECTION 1. IDENTIFICATION

Product name : Cloxacillin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.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**

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 mist or 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.

Cloxacillin Formulation

Version 2.10 Revision Date: 30.09.2023 SDS Number: 1131222-00016 Date of last issue: 09.08.2023
 Date of first issue: 30.11.2016

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|---------|-----------------------|
| cloxacillin | 61-72-3 | >= 1 -< 5 |

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
 If not breathing, give artificial respiration.
 If breathing is difficult, give oxygen.
 Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
 Remove contaminated clothing and shoes.
 Get medical attention.
 Wash clothing before reuse.
 Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
 Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
 Get medical attention if symptoms occur.
 Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

Cloxacillin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.08.2023 |
| 2.10 | 30.09.2023 | 1131222-00016 | Date of first issue: 30.11.2016 |

Notes to physician : when the potential for exposure exists (see section 8).
: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Chlorine compounds
Nitrogen oxides (NO_x)
Sulfur compounds

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.

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.

Cloxacillin Formulation

Version 2.10 Revision Date: 30.09.2023 SDS Number: 1131222-00016 Date of last issue: 09.08.2023
 Date of first issue: 30.11.2016

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 mist or 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 : Do not store with the following product types:
 Strong oxidizing agents
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

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

- 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 vapor type
- Hand protection : Chemical-resistant gloves
- Material : Chemical-resistant gloves

Cloxacillin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.08.2023 |
| 2.10 | 30.09.2023 | 1131222-00016 | Date of first issue: 30.11.2016 |

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--|---|-------------------|
| Appearance | : | liquid |
| Color | : | No data available |
| Odor | : | characteristic |
| 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 | : | 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 |
| Vapor pressure | : | No data available |
| Relative vapor density | : | No data available |

Cloxacillin Formulation

Version 2.10 Revision Date: 30.09.2023 SDS Number: 1131222-00016 Date of last issue: 09.08.2023
Date of first issue: 30.11.2016

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : insoluble

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

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:**cloxacillin:**

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

Acute toxicity (other routes of exposure) : LD50 (Mouse): 1.117 mg/kg

Cloxacillin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.08.2023 |
| 2.10 | 30.09.2023 | 1131222-00016 | Date of first issue: 30.11.2016 |

administration)

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 sensitization**Skin sensitization**

May cause an allergic skin reaction.

Respiratory sensitization

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

Components:**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 |

Germ cell mutagenicity

Not classified based on available information.

Cloxacillin Formulation

Version 2.10 Revision Date: 30.09.2023 SDS Number: 1131222-00016 Date of last issue: 09.08.2023
Date of first issue: 30.11.2016

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 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.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Cloxacillin Formulation

Version 2.10 Revision Date: 30.09.2023 SDS Number: 1131222-00016 Date of last issue: 09.08.2023
Date of first issue: 30.11.2016

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.

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.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential**Components:****cloxacillin:**

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

Cloxacillin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.08.2023 |
| 2.10 | 30.09.2023 | 1131222-00016 | Date of first issue: 30.11.2016 |

If not otherwise specified: Dispose of as unused product.

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

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Special precautions for user

Not applicable

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

Further information

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/>

Full text of other abbreviations

Cloxacillin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 09.08.2023 |
| 2.10 | 30.09.2023 | 1131222-00016 | Date of first issue: 30.11.2016 |

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; 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; 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.

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