according to the Globally Harmonized System



# **Cloxacillin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 09.08.2023

 2.10
 30.09.2023
 1131234-00016
 Date of first issue: 30.11.2016

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cloxacillin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number: +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

### 2. HAZARDS IDENTIFICATION

### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**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 mist or vapours.

P272 Contaminated work clothing should not be allowed out of

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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 + P317 If skin irritation or rash occurs: Get medical help. P342 + P316 If experiencing respiratory symptoms: Get emer-

gency medical help immediately.

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)
cloxacillin	61-72-3	>= 1 - < 5

### 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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. 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. May cause an allergic skin reaction.

Most important symptoms

In case of eye contact

and effects, both acute and May cause a

May cause allergy or asthma symptoms or breathing difficul-

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delayed ties if inhaled.

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

tive airways dysfunction syndrome).

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

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

Notes to physician : Treat symptomatically and supportively.

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Chlorine compounds Nitrogen oxides (NOx) Sulphur compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.
Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 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 absor-

bent

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

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employed in the cleanup of releases. You will need to deter-

mine 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 mist or 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 as-

sessment

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 respira-

tory 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 : Do not store with the following product types:

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
cloxacillin	61-72-3	TWA	100 μg/m3 (OEB	Internal	
			2)		
	Further information: RSEN, DSEN				
		Wipe limit	100 μg/100 cm2	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 expo-

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sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Combined particulates and organic vapour type

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 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 : liquid

Colour : No data available

Odour : characteristic

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 : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

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Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : insoluble

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition 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

### 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

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

Hazardous decomposition : No

products

: No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

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### **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

Assessment : Probability or evidence of skin sensitisation in humans

Result : positive

Assessment : Probability of respiratory sensitisation in humans based on

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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-

ment

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

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### 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.

#### **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.

### 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

No data available

# Persistence and degradability

No data available

#### Bioaccumulative potential

# **Components:**

### cloxacillin:

Partition coefficient: n-

: log Pow: 2.44

octanol/water

## Mobility in soil

No data available

### Other adverse effects

No data available

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#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 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 IMO instruments

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

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 : 30.09.2023

**Further information** 

Sources of key data used to

compile the Safety Data

Sheet

eChem Portal search results and European Chemicals Agen-

Internal technical data, data from raw material SDSs, OECD

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

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

IN / EN