SAFETY DATA SHEET

Cloxacillin (with Peanut Oil) Formulation

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

1.1 Product identifier
   Trade name : Cloxacillin (with Peanut Oil) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              20 Spartan Road
              1619 Spartan, South Africa
   Telephone : +27119239300
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   +1-908-423-6000

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.
   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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No. EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cloxacillin</td>
<td>61-72-3 200-514-7</td>
<td>Resp. Sens. 1; H334 Skin Sens. 1; H317</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

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 (CO2), Dry chemical.

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, Chlorine compounds, Nitrogen oxides (NOx), 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.

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 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.

6.4 Reference to other sections

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

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. 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 assessment.
Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. 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. 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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cloxacillin</td>
<td>61-72-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogenated castor oil</td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>23,875 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>23,875 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>83,045 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>336,75 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>47,75 mg/kg bw/day</td>
</tr>
</tbody>
</table>
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**

<table>
<thead>
<tr>
<th>Type</th>
<th>Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye protection</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Hand protection</strong></td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td><strong>Skin and body protection</strong></td>
<td>Work uniform or laboratory coat.</td>
</tr>
<tr>
<td><strong>Respiratory protection</strong></td>
<td>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 (A-P)</td>
</tr>
</tbody>
</table>

**SECTION 9: Physical and chemical properties**

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
</tr>
<tr>
<td>Colour</td>
<td>light yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>characteristic</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of : Inhalation
**SAFETY DATA SHEET**

**Cloxacillin (with Peanut Oil) Formulation**

**Version**: 1.5  
**Revision Date**: 09.04.2021  
**SDS Number**: 4267356-00006  
**Date of last issue**: 10.10.2020  
**Date of first issue**: 09.05.2019

---

**exposure**

**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 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:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment</td>
<td>Probability or evidence of skin sensitisation in humans</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
</tbody>
</table>

Assessment:

<table>
<thead>
<tr>
<th>Probability of respiratory sensitisation in humans based on animal testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
</tr>
<tr>
<td>positive</td>
</tr>
</tbody>
</table>

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 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

**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.

**SECTION 12: Ecological information**

12.1 **Toxicity**  
No data available

12.2 **Persistence and degradability**  
No data available

12.3 **Bioaccumulative potential**

**Components:**

**Cloxacillin:**

- **Partition coefficient: n-octanol/water:** log Pow: 2.44
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 Other adverse effects

Product:
Endocrine disrupting potential : 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 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.
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.

SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
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 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.
SAFETY DATA SHEET
Cloxacillin (with Peanut Oil) Formulation

SECTION 15: Regulatory information

15.1 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

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
- Resp. Sens.: Respiratory sensitisation
- Skin Sens.: Skin sensitisation
- ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- AIIC: 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: 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
- 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: Half maximal inhibitory concentration
- ICAO: International Civil Aviation Organization
- IECSC: Inventory of Existing Chemical Substances in China
- OECD: Organization for Economic Co-operation and Development
- OPPTS: Office of Chemical Safety and Pollution Prevention
- PBT: Persistent, Bioaccumulative and Toxic sub-
Further information

Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resp. Sens. 1</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
</tr>
<tr>
<td>H334</td>
</tr>
<tr>
<td>H317</td>
</tr>
</tbody>
</table>

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.

ZA / EN