SAFETY DATA SHEET

Cloxacillin (with Peanut Oil) Formulation

Product name: Cloxacillin (with Peanut Oil) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 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

1. PRODUCT AND COMPANY IDENTIFICATION

2. HAZARDS IDENTIFICATION

GHS Classification
Respiratory sensitisation: Category 1
Skin sensitisation: Category 1

GHS label elements
Hazard pictograms: 

Signal word: Danger

Hazard statements: H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements: Prevention:
P261 Avoid breathing mist or vapours.
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.
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.
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Date of first issue: 2019/05/09

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cloxacillin</td>
<td>61-72-3</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
</tbody>
</table>

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 when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES
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</tbody>
</table>

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

- **Unsuitable extinguishing media**
  - None known.

- **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

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

### 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 spills 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 absorbent.
  - Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
  - Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

- **Technical measures**
  - See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

- **Local/Total ventilation**
  - Use only with adequate ventilation.
Advice on safe handling: Do not get on skin or clothing. Avoid breathing 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.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapour type

Hand protection: 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 face shield 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 work-
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 : suspension
Colour : light yellow
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
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 : Not applicable
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

**Acute toxicity**

Not classified based on available information.

**Components:**

**Cloxacillin:**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 5,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 5,000 mg/kg</td>
</tr>
<tr>
<td>Acute toxicity (other routes of</td>
<td>LD50 (Mouse): 1,117 mg/kg</td>
</tr>
<tr>
<td>administration)</td>
<td>Application Route: Intramuscular</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 916 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 1,500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Subcutaneous</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 1,660 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
</tbody>
</table>
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
  - 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
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### 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.

---

similar substances.
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-octanol/water:** log Pow: 2.44
- **Mobility in soil**
  No data available
- **Other adverse effects**
  No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- **Waste from residues:** Dispose of in accordance with local regulations.
- **Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal.
  If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

**International Regulations**

- **UNRTDG**
  Not regulated as a dangerous good

- **IATA-DGR**
  Not regulated as a dangerous good

- **IMDG-Code**
  Not regulated as a dangerous good
15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

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

Date format : yyyy/mm/dd
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Full text of other abbreviations

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); ISOC - 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; 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.

ID / EN