# SAFETY DATA SHEET

## Cloxacillin (with Peanut Oil) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>2020/03/23</td>
<td>4267350-00004</td>
<td>2019/09/13</td>
<td>2019/05/09</td>
</tr>
</tbody>
</table>

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Chemical product name**: Cloxacillin (with Peanut Oil) Formulation

**Supplier’s company name, address and phone number**

- **Company name of supplier**: MSD
- **Address**: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
- **Telephone**: 048-588-8411
- **E-mail address**: EHSDATASTEWARD@msd.com
- **Emergency telephone number**: 1-908-423-6000

**Recommended use of the chemical and restrictions on use**

- **Recommended use**: Veterinary product

## 2. HAZARDS IDENTIFICATION

**GHS classification of chemical product**

- **Respiratory sensitisation**: Category 1
- **Skin sensitisation**: Category 1

**GHS label elements**

- **Hazard pictograms**: ![Hazard Pictogram]
- **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.
CLOXACILLIN (WITH PEANUT OIL) FORMULATION

SAFETY DATA SHEET

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>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cloxacillin</td>
<td>61-72-3</td>
</tr>
<tr>
<td>Dimethyldichlorosilane reaction with Silica</td>
<td>68611-44-9</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of an 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

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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
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 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

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSOAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Avoid inhalation of vapour or mist.
- 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.

Avoidance of contact:
- Oxidizing agents

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.
- 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.

Storage

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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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.
SAFETY DATA SHEET

Cloxacillin (with Peanut Oil) Formulation

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 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: suspension

Colour: light yellow

Odour: characteristic

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Flash point: No data available

Decomposition temperature: No data available

pH: No data available

Evaporation rate: No data available

Auto-ignition temperature: No data available

Viscosity

Viscosity, kinematic: No data available
## 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</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

### 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) LD50 (Mouse): 1,117 mg/kg
**SAFETY DATA SHEET**

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**Application Route**

- **Intramuscular**
  - LD50 (Mouse): 916 mg/kg

- **Intravenous**
  - LD50 (Mouse): 1,500 mg/kg
  - LD50 (Rat): 1,660 mg/kg
  - LD50 (Rat): 4,200 mg/kg

- **Subcutaneous**
  - LD50 (Rat): 1,660 mg/kg
  - LD50 (Rat): 4,200 mg/kg

**Dimethyldichlorosilane reaction with Silica:**

- **Acute oral toxicity**
  - LD50 (Rat): > 5,000 mg/kg

- **Acute inhalation toxicity**
  - LC50 (Rat): > 2.8 mg/l
    - Exposure time: 1 h
    - Test atmosphere: dust/mist
    - Assessment: The substance or mixture has no acute inhalation toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

- **Cloxacillin**
  - Remarks: Not classified due to lack of data.

- **Dimethyldichlorosilane reaction with Silica**
  - **Species**: Rabbit
  - **Result**: No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

- **Cloxacillin**
  - Remarks: Not classified due to lack of data.

- **Dimethyldichlorosilane reaction with Silica**
  - **Species**: Rabbit
  - **Result**: No eye irritation

**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
  - 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.

Dimethyldichlorosilane reaction with Silica:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Cloxacillin:
- Remarks: Not classified due to lack of data.

Dimethyldichlorosilane reaction with Silica:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Result: negative

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

**Dimethyldichlorosilane reaction with Silica:**

- **Effects on fertility**
  - Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

- **Effects on foetal development**
  - Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Not classified based on available information.

Components:

**Dimethyldichlorosilane reaction with Silica:**

- Exposure routes: inhalation (dust/mist/fume)
- Assessment: No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

**Repeated dose toxicity**

Components:

**Cloxacillin:**

- Species: Rat
LOAEL: 7,000 mg/kg  
Application Route: Intravenous  
Exposure time: 4 Weeks  
Symptoms: Hypoglycemia

**Dimethyldichlorosilane reaction with Silica:**

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.035 mg/l</td>
<td>inhalation (dust/mist/fume)</td>
<td>13 Weeks</td>
</tr>
</tbody>
</table>

Aspiration toxicity

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Cloxacillin:**

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Remarks: May cause sensitisation of susceptible persons.</th>
</tr>
</thead>
</table>
| 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**

**Components:**

**Dimethyldichlorosilane reaction with Silica:**

| Toxicity to fish | LC50 (Brachydanio rerio (zebrafish)): > 10,000 mg/l  
Exposure time: 96 h |
|-----------------|--------------------------------------------------|
| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): > 10,000 mg/l  
Exposure time: 24 h |
| Toxicity to algae/aquatic plants | EC50 (Scenedesmus subspicatus): > 10,000 mg/l  
Exposure time: 72 h |

**Persistence and degradability**

No data available

**Bioaccumulative potential**

**Components:**

**Cloxacillin:**
Partition coefficient: n-octanol/water

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable
Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalline silica</td>
<td>165</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalline silica</td>
<td>165</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good
### Marine Pollution and Sea Disaster Prevention etc Law

- **Bulk transportation**: Noxious liquid substance (Category Y)
- **Pack transportation**: Not classified as marine pollutant

### Narcotics and Psychotropics Control Act

- **Narcotic or Psychotropic Raw Material (Export / Import Permission)**
  - Not applicable
- **Specific Narcotic or Psychotropic Raw Material (Export / Import permission)**
  - Not applicable

### Waste Disposal and Public Cleansing Law

- **Industrial waste**

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Further information**

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

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

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; 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
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.