SAFETY DATA SHEET

Cloxacillin / Ampicillin Formulation

SECTION 1. IDENTIFICATION

Product name : Cloxacillin / Ampicillin Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
            Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
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 vapors.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
P285 In case of inadequate ventilation wear respiratory protection.

**Response:**
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P342 + P311 If experiencing respiratory symptoms: Call a doc-
SAFETY DATA SHEET

Cloxacillin / Ampicillin Formulation

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>76.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cloxacillin</td>
<td>61-72-3</td>
<td>14.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ampicillin</td>
<td>69-53-4</td>
<td>6.48</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hydroxyaluminum distearate</td>
<td>300-92-5</td>
<td>3</td>
</tr>
</tbody>
</table>

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: Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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.
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 firefighting: Exposure to combustion products may be a hazard to health.

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

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.
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 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: No special restrictions on storage with other products.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST (Mist)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Cloxacillin</td>
<td>61-72-3</td>
<td>TWA</td>
<td>100 µg/m³( OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: RSEN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ampicillin</td>
<td>69-53-4</td>
<td>TWA</td>
<td>0.6 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: RSEN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydroxyaluminum distearate</td>
<td>300-92-5</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Cloxacillin / Ampicillin Formulation

Engineering measures
Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Personal protective equipment
Respiratory protection
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material: Chemical-resistant gloves
Remarks: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection
Wear the following personal protective equipment:

Skin and body protection
Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: cream
Color: off-white
Odor: No data available
Odor Threshold: No data available
pH: No data available
### SECTION 1. IDENTIFICATION AND REFERENCE

- **Type of substance or mixture**: Cloxacillin / Ampicillin Formulation
- **Version**: 1.1
- **Revision Date**: 04/04/2023
- **SDS Number**: 10843346-00002
- **Date of last issue**: 08/30/2022
- **Date of first issue**: 08/30/2022

### SECTION 3. HAZARDS IDENTIFICATION

- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: Not applicable
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: Not applicable
- **Lower explosion limit / Lower flammability limit**: Not applicable
- **Vapor pressure**: Not applicable
- **Relative vapor density**: Not applicable
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: Not applicable
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Molecular weight**: No data available
- **Particle size**: < 30 µm

### SECTION 10. STABILITY AND REACTIVITY

- **Reactivity**: Not classified as a reactivity hazard.
- **Chemical stability**: Stable under normal conditions.
- **Possibility of hazardous reac-**: None known.
SAFETY DATA SHEET

Cloxacillin / Ampicillin Formulation

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:

White mineral oil (petroleum):
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

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

Ampicillin:
Acute oral toxicity : LD50 (Rat): 10,000 mg/kg
LD50 (Mouse): 15,200 mg/kg

Acute toxicity (other routes of administration):
LD50 (Rat): 6,200 mg/kg
Application Route: Intravenous
LD50 (Mouse): 4,600 mg/kg
Application Route: Intravenous

Hydroxyaluminum distearate:
Acute oral toxicity:
LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute inhalation toxicity:
LC50 (Rat): > 5.15 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Skin corrosion/irritation
Not classified based on available information.

Components:

White mineral oil (petroleum):
Species: Rabbit
Result: No skin irritation

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

Hydroxyaluminum distearate:
Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 431
Remarks: Based on data from similar materials

Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 439
Remarks: Based on data from similar materials
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

White mineral oil (petroleum):
Species: Rabbit
Result: No eye irritation
Cloxacillin / Ampicillin Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Remarks</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cloxacillin</td>
<td>Not classified due to lack of data.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydroxyaluminum distearate</td>
<td></td>
<td>Bovine cornea</td>
<td>OECD Test Guideline 437</td>
<td>No eye irritation</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>May cause an allergic skin reaction.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td></td>
<td></td>
<td>Buehler Test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cloxacillin</td>
<td>Routes of exposure</td>
<td>Dermal</td>
<td>Probability or evidence of skin sensitization in humans</td>
<td>positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment</td>
<td>Probability of respiratory sensitization in humans based on animal testing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Routes of exposure</td>
<td>Inhalation</td>
<td></td>
<td>Sensitizer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydroxyaluminum distearate</td>
<td>Routes of exposure</td>
<td>Skin contact</td>
<td>OECD Test Guideline 429</td>
<td>Sensitizer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type</td>
<td>Local lymph node assay (LLNA)</td>
<td>Mouse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 429</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified based on available information.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## SAFETY DATA SHEET

### Cloxacillin / Ampicillin 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>1.1</td>
<td>04/04/2023</td>
<td>10843346-00002</td>
<td>08/30/2022</td>
<td>08/30/2022</td>
</tr>
</tbody>
</table>

### Components:

**White mineral oil (petroleum):**

- **Genotoxicity in vitro:**
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

- **Genotoxicity in vivo:**
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

**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.

**Ampicillin:**

- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
  - Test system: mouse lymphoma cells
  - Result: negative
  - Test Type: sister chromatid exchange assay
  - Test system: Chinese hamster ovary cells
  - Result: negative
  - Test Type: Chromosomal aberration
  - Test system: Chinese hamster ovary cells
  - Result: negative
  - Test Type: Chromosomal aberration
  - Test system: Human lymphocytes
  - Result: negative

- **Genotoxicity in vivo:**
  - Test Type: Micronucleus test
  - Species: Rat
  - Application Route: Oral
  - Result: negative

**Hydroxyaluminum distearate:**

- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**
Not classified based on available information.

**Components:**

**White mineral oil (petroleum):**
Species: Rat  
Application Route: Ingestion  
Exposure time: 24 Months  
Result: negative

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

**Ampicillin:**
Species: Rat  
Application Route: Oral  
Exposure time: 2 Years  
Tumor Type: adrenal, Leukemia, breast tumors  
Species: Mouse  
Application Route: Oral  
Exposure time: 2 Years  
Tumor Type: Lungs  
Remarks: Benign tumor(s)

**Carcinogenicity - Assessment:** Weight of evidence does not support classification as a carcinogen

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**
Not classified based on available information.
Components:

**White mineral oil (petroleum):**
- Effects on fertility: Test Type: One-generation reproduction toxicity study
  Species: Rat
  Application Route: Skin contact
  Result: negative
- Effects on fetal development: Test Type: Embryo-fetal development
  Species: Rat
  Application Route: Ingestion
  Result: negative

**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.

**Ampicillin:**
- Effects on fertility: Test Type: Fertility
  Species: Guinea pig
  Target Organs: Uterus (including cervix)
- Effects on fetal development: Test Type: Development
  Species: Rat
  Developmental Toxicity: NOAEL: 250 mg/kg body weight
  Result: No effects on fetal development.

**Hydroxyaluminum distearate:**
- Effects on fertility: Test Type: Two-generation reproduction toxicity study
  Species: Rat
  Application Route: Ingestion
  Method: OECD Test Guideline 416
  Result: negative
  Remarks: Based on data from similar materials
- Effects on fetal development: Test Type: Two-generation reproduction toxicity study
  Species: Rat
### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>160 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>&gt;= 1 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 412</td>
</tr>
</tbody>
</table>

**Cloxacillin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>7,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Hypoglycemia</td>
</tr>
</tbody>
</table>

**Ampicillin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>3,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Diarrhea</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>2,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Diarrhea</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>750 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 y</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Thyroid, forestomach</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Diarrhea, Salivation, decreased activity</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Cloxacillin / Ampicillin Formulation

Species: Mouse
LOAEL: 2,000 mg/kg
Application Route: Oral
Exposure time: 2 y
Target Organs: forestomach
Symptoms: Ulceration, Inflammation, fungal infections

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.

Ampicillin:
Inhalation: Symptoms: Asthma, Hay fever
Remarks: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Ingestion: Symptoms: skin rash, Nausea, Diarrhea, Vomiting, colitis, urticaria

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 1,000 mg/l
Exposure time: 21 d
Ampicillin:
Toxicity to fish:
LC50 (Oryzias latipes (Japanese medaka)): > 1,000 mg/l
Exposure time: 96 h
LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
EC50 (Anabaena flos-aquae): 190 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Anabaena flos-aquae): 13 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms:
EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
NOEC: 9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Hydroxyaluminum distearate:
Ecotoxicology Assessment:
Chronic aquatic toxicity: No toxicity at the limit of solubility.

Persistence and degradability:
Components:
White mineral oil (petroleum):
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Biodegradability: Result: rapidly degradable
Biodegradation: 35%
Exposure time: 28 d
Method: OECD Test Guideline 301B

**Hydroxyaluminum distearate:**
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

**Bioaccumulative potential**

**Components:**

**Cloxacillin:**
Partition coefficient: n-octanol/water: log Pow: 2.44

**Ampicillin:**
Partition coefficient: n-octanol/water: log Pow: -2.0
pH: 7

**Hydroxyaluminum distearate:**
Partition coefficient: n-octanol/water: log Pow: 15.088
Remarks: Calculation

**Mobility in soil**
No data available

**Other adverse effects**
No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
Waste from residues: Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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

**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
SAFETY DATA SHEET

Cloxacillin / Ampicillin Formulation

Version 1.1
Revision Date: 04/04/2023
SDS Number: 10843346-00002
Date of last issue: 08/30/2022
Date of first issue: 08/30/2022

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

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Respiratory or skin sensitization

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- White mineral oil (petroleum) 8042-47-5
- Cloxacillin 61-72-3
- Ampicillin 69-53-4
- Hydroxyaluminum distearate 300-92-5

California List of Hazardous Substances
- White mineral oil (petroleum) 8042-47-5

California Permissible Exposure Limits for Chemical Contaminants
- White mineral oil (petroleum) 8042-47-5
- Hydroxyaluminum distearate 300-92-5

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

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Cloxacillin / Ampicillin Formulation

Version 1.1  Revision Date: 04/04/2023  SDS Number: 10843346-00002  Date of last issue: 08/30/2022

NFPA 704:

Health 1  FLAMMABILITY 1  Instability 2

Special hazard

HMIS® IV:

HEALTH 2  FLAMMABILITY 1  PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; IECSB - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office
SAFETY DATA SHEET

Cloxacillin / Ampicillin Formulation

Version 1.1  Revision Date: 04/04/2023  SDS Number: 10843346-00002  Date of last issue: 08/30/2022

Date of first issue: 08/30/2022

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

Revision Date: 04/04/2023

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.

US / Z8