SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cloxacillin / Ampicillin Formulation

SECTION 1. IDENTIFICATION

Product name: Cloxacillin / Ampicillin Formulation
Other means of identification: No data available

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 Hazardous Products Regulations
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 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 attention.
P342 + P311 If experiencing respiratory symptoms: Call a doc-
SECTION 1. IDENTIFICATION

Product identifier: Cloxacillin / Ampicillin Formulation

Section 1.2. Number: 10843364-00004

Section 1.3. Revision Date: 09/30/2023

Section 1.4. Date of last issue: 08/09/2023

Section 1.5. Date of first issue: 08/30/2022

SECTION 2. HAZARDS IDENTIFICATION

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>Paraffinum liquidum</td>
<td>8042-47-5</td>
<td>76.32</td>
<td></td>
</tr>
<tr>
<td>cloxacillin</td>
<td>No data available</td>
<td>61-72-3</td>
<td>14.2</td>
<td></td>
</tr>
<tr>
<td>Ampicillin</td>
<td>6-[(Aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid</td>
<td>69-53-4</td>
<td>6.48</td>
<td></td>
</tr>
<tr>
<td>Hydroxyaluminum distearate</td>
<td>Aluminum, hydroxybis(octadecanoato-κO)-</td>
<td>300-92-5</td>
<td>3</td>
<td></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.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal: P501 Dispose of contents and container to an approved waste disposal plant.
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according to the Hazardous Products Regulations

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In case of eye contact: Thoroughly clean shoes before reuse. 
Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

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.

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 fire fighting:
Hazardous combustion products: Exposure to combustion products may be a hazard to health.
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</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 (Mist)</td>
<td>5 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Mist)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
</tbody>
</table>
### Cloxacillin / Ampicillin Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Inhalable particulate matter)</th>
<th>TWA (Respirable particulate matter)</th>
<th>TWA (Respirable particulate matter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>cloxacillin</td>
<td>5 mg/m³</td>
<td>100 µg/m³ (OEB 2)</td>
<td>100 µg/m³ (OEB 2)</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>0.6 mg/m³ (OEB 2)</td>
<td>0.6 mg/m³ (OEB 2)</td>
<td>0.6 mg/m³ (OEB 2)</td>
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<tr>
<td>Hydroxyaluminum distearate</td>
<td>10 mg/m³</td>
<td>1 mg/m³ (Aluminum)</td>
<td>1 mg/m³ (Aluminum)</td>
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<tr>
<td></td>
<td>TWA (Respirable)</td>
<td>CA AB OEL</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWAEV</td>
<td>CA QC OEL</td>
<td>CA BC OEL</td>
</tr>
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<td></td>
<td>TWA (Inhalable)</td>
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<tr>
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<tr>
<td></td>
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<tr>
<td></td>
<td>TWAEV</td>
<td>CA QC OEL</td>
<td>CA BC OEL</td>
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<td>TWAEV</td>
<td>CA QC OEL</td>
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<tr>
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<tr>
<td></td>
<td>TWA (Respirable particulate matter)</td>
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<td>CA AB OEL</td>
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<tr>
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<td>3 mg/m³</td>
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<tr>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>CA AB OEL</td>
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</tr>
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<td></td>
<td>TWAEV</td>
<td>CA QC OEL</td>
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<td>1 mg/m³ (Aluminum)</td>
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<tr>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>CA AB OEL</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWAEV</td>
<td>CA QC OEL</td>
<td>CA AB OEL</td>
</tr>
</tbody>
</table>

### 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 vapor type

**Hand protection**

- Material: Chemical-resistant gloves
Cloxacillin / Ampicillin Formulation

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: cream
Color: off-white
Odor: No data available
Odor 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: Not applicable
Flammability (solid, gas): No data available
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor density: Not applicable
**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>1.3</td>
<td>09/30/2023</td>
<td>10843364-00004</td>
<td>08/09/2023</td>
<td>08/30/2022</td>
</tr>
</tbody>
</table>

- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**: No data available
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**: Not applicable
  - **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 reactions**: None known.
- **Conditions to avoid**: None known.
- **Incompatible materials**: None.
- **Hazardous decomposition products**: No hazardous decomposition products are known.

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

Hydroxyaluminum distearate:
Species: Bovine cornea
Method: OECD Test Guideline 437
Remarks: Based on data from similar materials
Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Components:

White mineral oil (petroleum):
- Test Type: Buehler Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Result: negative

cloxacillin:
- Routes of exposure: Dermal
- Assessment: Probability or evidence of skin sensitization in humans
- Result: positive
- Assessment: Probability of respiratory sensitization in humans based on animal testing
- Result: positive

Ampicillin:
- Routes of exposure: Inhalation
- Result: Sensitizer

Hydroxyaluminum distearate:
- Test Type: Local lymph node assay (LLNA)
- Routes of exposure: Skin contact
- Species: Mouse
- Method: OECD Test Guideline 429
- Result: negative
- Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

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
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

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
Application Route: Ingestion
Method: OECD Test Guideline 416
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.

**Repeated dose toxicity**

**Components:**

**White mineral oil (petroleum):**
Species : Rat
LOAEL : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
LOAEL : >= 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
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Method: OECD Test Guideline 412

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

Ampicillin:
Species: Rat
LOAEL: 3,000 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Symptoms: Diarrhea

Species: Mouse
LOAEL: 2,000 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Symptoms: Diarrhea

Species: Rat
LOAEL: 750 mg/kg
Application Route: Oral
Exposure time: 2 y
Target Organs: Thyroid, forestomach
Symptoms: Diarrhea, Salivation, decreased activity

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
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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

Ampicillin:

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

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

Ampicillin:
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 : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste
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

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

Domestic regulation
TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
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<td>CA AB OEL</td>
<td>Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)</td>
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<tr>
<td>CA BC OEL</td>
<td>Canada. British Columbia OEL</td>
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<tr>
<td>CA QC OEL</td>
<td>Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants</td>
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<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
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<td>CA AB OEL / TWA</td>
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<tr>
<td>CA AB OEL / STEL</td>
<td>15-minute occupational exposure limit</td>
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<tr>
<td>CA BC OEL / TWA</td>
<td>8-hour time weighted average</td>
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<tr>
<td>CA QC OEL / TWAEV</td>
<td>Time-weighted average exposure value</td>
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ACGIH - 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 Chemicals and Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

SAFETY DATA SHEET
according to the Hazardous Products Regulations

Cloxacillin / Ampicillin Formulation

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<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 08/09/2023</th>
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<td>10843364-00004</td>
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Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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.

CA / Z8