SAFETY DATA SHEET

Gentamicin / Cloxacillin Formulation

Version 2.4  Revision Date: 23.03.2020  SDS Number: 1936781-00008  Date of last issue: 13.09.2019
Date of first issue: 11.09.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin / Cloxacillin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Respiratory sensitisation : Category 1
Skin sensitisation : Category 1
Reproductive toxicity : Category 1A
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 3

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
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
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.
P308 + P313 If exposed or concerned: Get medical advice/attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (%) w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)</td>
<td>139-44-6</td>
<td>3.5</td>
</tr>
<tr>
<td>Cloxacillin</td>
<td>61-72-3</td>
<td>2.2</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>0.5</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.
- 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.
- May damage the unborn child.
- 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
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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

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

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray 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.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- 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
Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
--- | --- | --- | --- | --- |
1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate) | 139-44-6 | TWA (Inhalable particulate matter) | 10 mg/m³ | ACGIH |
 |  | TWA (Respirable particulate matter) | 3 mg/m³ | ACGIH |
Cloxacillin | 61-72-3 | TWA | 100 µg/m³ (OEB 2) | Internal |
Gentamicin | 1403-66-3 | TWA | 0.1 mg/m³ (OEB 2) | Internal |

Further information: RSEN

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

Personal protective equipment
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
Wear 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.
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: white
10. STABILITY AND REACTIVITY

- Odour: No data available
- 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: No data available
- Partition coefficient: n-octanol/water: Not applicable
- Auto-ignition temperature: No data available
- Decomposition temperature: No data available
- Viscosity
  - Viscosity, kinematic: No data available
- Explosive properties: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
- Particle size: Not applicable
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:
- Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

Components:

1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  Remarks: Based on data from similar materials
- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  Remarks: Based on data from similar materials

Cloxacillin:
- Acute oral toxicity: LD50 (Rat): 5,000 mg/kg
  LD50 (Mouse): 5,000 mg/kg

Gentamicin:
- Acute oral toxicity: LD50 (Rat): 8,000 - 10,000 mg/kg
LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity:
- LC50 (Rat): > 0.2 mg/l
- Exposure time: 4 h
- Test atmosphere: dust/mist
- Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration):
- LD50 (Rat): 67 - 96 mg/kg
  - Application Route: Intravenous
- LD50 (Rat): 371 - 384 mg/kg
  - Application Route: Intramuscular
- LDLo (Monkey): 30 mg/kg
  - Application Route: Intravenous

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):**
- **Species**: Rabbit
- **Result**: No skin irritation
- **Remarks**: Based on data from similar materials

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

**Gentamicin:**
- **Species**: Rabbit
- **Result**: Mild skin irritation

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

**Components:**

**1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):**
- **Species**: Rabbit
- **Result**: No eye irritation
- **Remarks**: Based on data from similar materials

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

**Gentamicin:**
- **Species**: Rabbit
- **Result**: Mild 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

Assessment: Probability of respiratory sensitisation in humans based on animal testing
Result: positive

Gentamicin:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
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.

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

Test Type: Chromosome aberration test in vitro
Result: equivocal

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)  
Species: Mouse  
Application Route: Intravenous injection  
Result: negative

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

**Components:**

**Cloxacillin:**

Remarks: Not classified due to lack of data.

**Gentamicin:**

Carcinogenicity - Assessment: No data available

**Reproductive toxicity**  
May damage the unborn child.

**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

**Gentamicin:**

Effects on fertility:
Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Fertility: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reported

Effects on foetal development:
Test Type: Embryo-foetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
Result: No embryo-foetal toxicity
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 75 mg/kg body weight  
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 10 mg/kg body weight  
Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 50 mg/kg body weight  
Result: foetal mortality, No malformations were observed.

Reproductive toxicity - Assessment  
Positive evidence of adverse effects on development from human epidemiological studies.

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

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

**Components:**

**Gentamicin:**
Target Organs: Kidney, inner ear  
Assessment: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

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

**Gentamicin:**
Species: Dog  
LOAEL: 3 mg/kg  
Application Route: Intramuscular  
Exposure time: 12 Months  
Target Organs: Kidney  
Symptoms: Vomiting, Salivation

Species: Monkey
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LOAEL: 50 mg/kg
Application Route: Subcutaneous
Exposure time: 3 Weeks
Target Organs: Kidney, inner ear

Species: Monkey
LOAEL: 6 mg/kg
Application Route: Intramuscular
Exposure time: 3 Weeks
Target Organs: Blood, Kidney, inner ear, Liver

Species: Rat
NOAEL: 5 mg/kg
LOAEL: 10 mg/kg
Application Route: Intramuscular
Exposure time: 52 Weeks
Target Organs: Kidney, Blood

Species: Rat
NOAEL: 12.5 mg/kg
LOAEL: 50 mg/kg
Application Route: Intramuscular
Exposure time: 13 Weeks
Target Organs: Kidney

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Cloxacillin:
Inhalation: Remarks: May cause sensitisation of susceptible persons.
Skin contact: Symptoms: Dermatitis
Remarks: May irritate skin.
Eye contact: Remarks: May irritate eyes.
Ingestion: Symptoms: May cause, Gastrointestinal disturbance, Rash
Remarks: May cause sensitisation of susceptible persons.

Gentamicin:
Ingestion: Target Organs: Kidney
Target Organs: inner ear
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate):
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
- EL50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
- EL50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

Gentamicin:

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 86 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

- LC50 (Americamysis): 30 mg/l
  - Exposure time: 96 h

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 100

Toxicity to microorganisms:
- EC50: 288.7 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity): 1
Persistence and degradability

Components:

**Gentamicin:**
Biodegradability: Result: rapidly degradable
Biodegradation: 100 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

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

**Gentamicin:**
Partition coefficient: n-octanol/water: log Pow: < -2

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**
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)

Class: 9
Packing group: III
Labels: 9

**IATA-DGR**
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
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Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

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

16. OTHER INFORMATION

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
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.

IN / EN