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: [Image]
Signal word: Danger
Hazard statements: H317 May cause an allergic skin reaction.
                     H334 May cause allergy or asthma symptoms or breathing
difficulties if inhaled.
H360D May damage the unborn child.
H400 Very toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P203 Obtain, read and follow all safety instructions before use.
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.
P318 IF exposed or concerned, get medical advice.
P333 + P317 If skin irritation or rash occurs: Get medical help.
P342 + P316 If experiencing respiratory symptoms: Get emergency medical help immediately.
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 (%)</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

Personal precautions, protective equipment: 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 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.
- Avoid breathing mist or vapours.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>

4 / 16
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

Hygiene measures: Work uniform or laboratory coat.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

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

Specie: 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):
SAFETY DATA SHEET

Gentamicin / Cloxacillin Formulation

Version 2.5
Revision Date: 10.10.2020
SDS Number: 1936781-00009
Date of last issue: 23.03.2020
Date of first issue: 11.09.2017

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
Method: US-EPA OPPTS 850.1035

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)
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)
SAFETY DATA SHEET

Gentamicin / Cloxacillin Formulation

Version 2.5
Revision Date: 10.10.2020
SDS Number: 1936781-00009
Date of last issue: 23.03.2020
Date of first issue: 11.09.2017

ACGIH / TWA : 8-hour, time-weighted average

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