Section 1: Identification

Product name : Gentamicin / Cloxacillin Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification

Respiratory sensitisation : Category 1
Skin sensitisation : Category 1
Reproductive toxicity : Category 1A

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.
                      H360D May damage the unborn child.

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.
                          P280 Wear protective gloves.
                          P281 Use personal protective equipment as required.
                          P285 In case of inadequate ventilation wear respiratory protec-
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Gentamicin / Cloxacillin Formulation

Section 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>

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. 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 pre-existing 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 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.

Hazchem Code:
3Z

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 spills cannot be contained.

Methods and materials for containment and cleaning up:
Soak up with inert absorbent material.
For large spills, provide dyeing or other appropriate contain-
Section 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.

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.

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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of)</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
</table>

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Version 1.8  Revision Date: 10.10.2020  SDS Number: 1936059-00009  Date of last issue: 23.03.2020  Date of first issue: 11.09.2017

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
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<td>139-44-6</td>
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<tr>
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<td>61-72-3</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
</tr>
</tbody>
</table>

Further information: RSEN

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

Personal protective equipment
Respiratory protection:
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type:
Combined particulates and organic vapour type
Hand protection:
Material:
Chemical-resistant gloves
Eye protection:
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection:
Work uniform or laboratory coat.

Section 9: Physical and chemical properties

Appearance:
suspension
Colour:
white
Odour:
No data available
Odour Threshold:
No data available
pH:
No data available
Melting point/freezing point:
No data available
**Section 10: Stability and reactivity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>
Section 11: Toxicological information

Exposure routes: Inhalation  
Skin contact  
Ingestion  
Eye contact

Acute toxicity
Not classified based on available information.

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

**Gentamicin:**
Remarks: No data available

**Chronic toxicity**

**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.

**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.
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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 Organ: 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 Organ: Kidney
Symptoms: Vomiting, Salivation

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

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

Species: Rat
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<table>
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<tr>
<th>Version</th>
<th>Revision Date:</th>
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<tr>
<td>1.8</td>
<td>10.10.2020</td>
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<td>23.03.2020</td>
<td>11.09.2017</td>
</tr>
</tbody>
</table>

- **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

**Section 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
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

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

**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

Section 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.

Section 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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
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NZS 5433
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z

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.

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 16: Other information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
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.