1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin / Cloxacillin Formulation

Manufacturer or supplier's details
Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

GHS Classification
Respiratory sensitisation : Category 1
Skin sensitisation : Category 1
Reproductive toxicity : Category 1A
Short-term (acute) aquatic hazard : 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.
H360D May damage the unborn child.
H400 Very toxic to aquatic life.

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

<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.
Get medical attention if irritation develops and persists.
Rinse mouth thoroughly with water.
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).
Treat symptomatically and supportively.

Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
Sulphur compounds

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.

In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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 (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)</td>
<td>139-44-6</td>
<td>PEL (long term)</td>
<td>10 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Res-</td>
<td>3 mg/m3</td>
<td>ACGIH</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 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
Colour: white
Odour: No data available
Odour Threshold: No data available
SAFETY DATA SHEET

Gentamicin / Cloxacillin Formulation

Version 1.9
Revision Date: 27.08.2021
SDS Number: 1936060-00010
Date of last issue: 10.10.2020
Date of first issue: 11.09.2017

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) : No data available
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
Viscosity, kinematic : No data available
Explosive properties : Not explosive
 Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : Not applicable

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.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- 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):
  Application Route: Intramuscular
  LD50 (Mouse): 1,117 mg/kg
  Application Route: Intravenous
  LD50 (Mouse): 916 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
- Probability of respiratory sensitisation in humans based on animal testing: 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:
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:
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

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
Eye contact: Remarks: May irritate eyes.
Ingestion: Remarks: 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: EL50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
plants
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
M-Factor (Chronic aquatic toxicity): 1
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

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.
15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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.

SG / EN