SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Gentamicin / Cloxacillin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
Kilshealan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Respiratory sensitisation, Category 1 : H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1 : H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1A : H360D: May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 3 : H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
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<br>Obtain special instructions before use.
P273<br>Avoid release to the environment.
P280<br>Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P304 + P340<br>IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308 + P313<br>IF exposed or concerned: Get medical advice/attention.
P391<br>Collect spillage.

Hazardous components which must be listed on the label:
Cloxacillin<br>Gentamicin

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cloxacillin</td>
<td>61-72-3 200-514-7</td>
<td>Resp. Sens. 1; H334 Skin Sens. 1; H317</td>
<td>2.2</td>
</tr>
<tr>
<td></td>
<td>Gentamicin</td>
<td>1403-66-3 215-765-8</td>
<td>Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>0.5</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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).

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.
SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for cleaning up: Soak up with inert absorbent material.
## SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

### Gentamicin / Cloxacillin 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>2.7</td>
<td>27.08.2021</td>
<td>1936780-00011</td>
<td>09.04.2021</td>
<td>11.09.2017</td>
</tr>
</tbody>
</table>

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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

**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.

### 7.2 Conditions for safe storage, including any incompatibilities

**Requirements for storage areas and containers**: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

**Advice on common storage**: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
Gentamicin / Cloxacillin Formulation

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3-Propanetriyl tris(12-hydroxyoctadecanoate)</td>
<td>139-44-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m3</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Cloxacillin</td>
<td>61-72-3</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN

8.2 Exposure controls

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

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.

Hand protection Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 14387

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Cloxacillin Formulation

Version 2.7  Revision Date: 27.08.2021  SDS Number: 1936780-00011  Date of last issue: 09.04.2021
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Physical state: suspension
Colour: white
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: 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
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: No data available
Viscosity: No data available
  Viscosity, kinematic: No data available
Solubility(ies):
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: No data available
Relative density: No data available
Density: No data available
Relative vapour density: No data available
Particle characteristics:
  Particle size: Not applicable

9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: No data available
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

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
Gentamicin / Cloxacillin Formulation

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:**

**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:**

**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:

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.
## Gentamicin / Cloxacillin Formulation

### 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
**SAFETY DATA SHEET**  
according to Regulation (EC) No. 1907/2006  

**Gentamicin / Cloxacillin Formulation**

**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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Cloxacillin Formulation

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

12.1 Toxicity

Components:

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

12.2 Persistence and degradability

Components:

Gentamicin:
Biodegradability:
- Result: rapidly degradable
- Biodegradation: 100 %
- Exposure time: 28 d
  Method: OECD Test Guideline 314
12.3 Bioaccumulative potential

**Components:**

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

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product** : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

14.1 UN number or ID number

**ADN** : UN 3082
Gentamicin / Cloxacillin Formulation

14.2 UN proper shipping name

| ADN | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin) |
| ADR | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin) |
| RID | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin) |
| IATA | : Environmentally hazardous substance, liquid, n.o.s. (Gentamicin) |

14.3 Transport hazard class(es)

| ADN | : 9 |
| ADR | : 9 |
| RID | : 9 |
| IMDG | : 9 |
| IATA | : 9 |

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
</tr>
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<tbody>
<tr>
<td>Packing group</td>
</tr>
<tr>
<td>Classification Code</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
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<td>Labels</td>
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<table>
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<tr>
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<td>Hazard Identification Number</td>
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<td>Tunnel restriction code</td>
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<table>
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<tr>
<td>Labels</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Cloxacillin Formulation

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

Credit:

Conditions of restriction for the following entries should be considered:
Number on list:
Not applicable:

17 / 20
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin / Cloxacillin Formulation

Version 2.7
Revision Date: 27.08.2021
SDS Number: 1936780-00011
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Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable

<table>
<thead>
<tr>
<th></th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>Quantity 1: 100 t</td>
</tr>
<tr>
<td></td>
<td>Quantity 2: 200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-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.
H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Repr.: Reproductive toxicity
Resp. Sens.: Respiratory sensitisation
Skin Sens.: Skin sensitisation
Gentamicin / Cloxacillin Formulation

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Date of last issue: 09.04.2021  
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STOT RE: Specific target organ toxicity - repeated exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Category</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resp. Sens. 1</td>
<td>H334</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>H317</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>H360D</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 3</td>
<td>H412</td>
</tr>
</tbody>
</table>

Classification procedure:
Calculation method

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIR - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative
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.