SAFETY DATA SHEET

Gentamicin Ointment Formulation

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

1.1 Product identifier
   Trade name : Gentamicin Ointment Formulation

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

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              117 16th Road
              07033 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   Telefax : 908-735-1496
   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)
   Reproductive toxicity, Category 1A
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 3

   H360D: May damage the unborn child.
   H400: Very toxic to aquatic life.
   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 : H360D  May damage the unborn child.
                      H410   Very toxic to aquatic life with long lasting effects.

   Precautionary statements : Prevention:
                            P201 Obtain special instructions before use.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313  IF exposed or concerned: Get medical advice/ attention.
P391  Collect spillage.

Storage:
P405  Store locked up.

Hazardous components which must be listed on the label:
Gentamicin

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
<td>EC-No.</td>
<td>Index-No.</td>
<td>Classification</td>
</tr>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td></td>
<td>Aquatic Chronic3;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>H412</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td></td>
<td>Repr.1A; H360D STOT RE1; H372 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

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. 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 damage the unborn child.

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 : Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

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
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions
Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. 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. 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. 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 Explosives Gases

7.3 Specific end use(s)

Specific use(s): No data available

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>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl p-Hydroxybenzoate Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>14,7 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Workers Skin contact</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2,45 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers Inhalation</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3,62 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Consumers Skin contact</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1,23 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers Ingestion</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1,04 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Propyl p-hydroxybenzoate Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>57,6 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Workers Skin contact</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>20,42 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers Inhalation</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>14,2 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Consumers Skin contact</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10,21 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers Ingestion</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4,08 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:
8.2 Exposure controls

**Engineering measures**
Use feasible engineering controls to minimize exposure to the compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Personal protective equipment**

<table>
<thead>
<tr>
<th>Component</th>
<th>Environmental Compartiment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>Fresh water</td>
<td>0.004 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.112 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.126 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.013 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.023 mg/kg</td>
</tr>
<tr>
<td>Propyl p-hydroxybenzoate</td>
<td>Fresh water</td>
<td>0.0064 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0064 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.064 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.2065 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.0206 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.0375 mg/kg</td>
</tr>
</tbody>
</table>

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>ointment</td>
</tr>
<tr>
<td>Colour</td>
<td>colourless</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>
</tbody>
</table>
Flash point : > 93,3 °C
Evaporation rate : No data available
Flammability (solid, gas) : Not classified as a flammability hazard
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : Not applicable
Particle size : Not applicable

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 : Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid
SAFETY DATA SHEET

Gentamicin Ointment 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>2.2</td>
<td>09/13/2019</td>
<td>2050352-00006</td>
<td>24.04.2019</td>
<td>09.10.2017</td>
</tr>
</tbody>
</table>

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

Acute toxicity
Not classified based on available information.

Components:

Methyl p-Hydroxybenzoate:
Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
Method: OECD Test Guideline 401

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:

Methyl p-Hydroxybenzoate:
Species : Rabbit
Result : No skin irritation
Gentamicin Ointment Formulation

Gentamicin:
Species : Rabbit
Result : Mild skin irritation

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

Components:
Methyl p-Hydroxybenzoate:
Species : Rabbit
Result : No eye irritation

Gentamicin:
Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Methyl p-Hydroxybenzoate:
Test Type : Maurer optimisation test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Gentamicin:
Remarks : No data available

Germ cell mutagenicity
Not classified based on available information.

Components:
Methyl p-Hydroxybenzoate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
SAFETY DATA SHEET

Gentamicin Ointment Formulation

Version: 2.2
Revision Date: 09/13/2019
SDS Number: 2050352-00006
Date of last issue: 24.04.2019
Date of first issue: 09.10.2017

Application Route: Ingestion
Method: OECD Test Guideline 478
Result: negative

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:

Gentamicin:
Carcinogenicity - Assessment:
No data available

Reproductive toxicity
May damage the unborn child.

Components:

Methyl p-Hydroxybenzoate:
Effects on foetal development:
Test Type: Embryofetal development
Species: Rabbit
Application Route: Ingestion
Result: negative

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: Embryofetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3,6 mg/kg body weight
Result: No embryo-fetal toxicity
Test Type: Embryofetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-fetal toxicity
SAFETY DATA SHEET
Gentamicin Ointment Formulation

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:

Methyl p-Hydroxybenzoate:
Species: Rat
NOAEL: 250 mg/kg
LOAEL: 1.000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days
Method: OECD Test Guideline 407

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
SAFETY DATA SHEET

Gentamicin Ointment Formulation

Version: 2.2
Revision Date: 09/13/2019
SDS Number: 2050352-00006
Date of last issue: 24.04.2019
Date of first issue: 09.10.2017

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.

Product:
No aspiration toxicity classification

Experience with human exposure

Components:

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:

Methyl p-Hydroxybenzoate:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): 59,5 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 11,2 mg/l
Exposure time: 48 h
Method: ISO 6341

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): 91 mg/l
Exposure time: 72 h
Method: ISO 8692

EC10 (Pseudokirchneriella subcapitata (green algae)): 31 mg/l
Exposure time: 72 h
Method: ISO 8692

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC: 0.2 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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:

Methyl p-Hydroxybenzoate:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 89 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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

### 12.3 Bioaccumulative potential

**Components:**

**Methyl p-Hydroxybenzoate:**
Partition coefficient: n-octanol/water : log Pow: 1.98

**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
Not relevant

### 12.6 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

**ADN** : UN 3077
**ADR** : UN 3077
**RID** : UN 3077
**IMDG** : UN 3077
**IATA** : UN 3077
SAFETY DATA SHEET

Gentamicin Ointment 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>2.2</td>
<td>09/13/2019</td>
<td>2050352-00006</td>
<td>24.04.2019</td>
<td>09.10.2017</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

| ADN       | Packing group : III |
| Classification Code : M7 |
| Hazard Identification Number : 90 |
| Labels : 9 |
| ADR       | Packing group : III |
| Classification Code : M7 |
| Hazard Identification Number : 90 |
| Labels : 9 |
| Tunnel restriction code : (-) |
| RID       | Packing group : III |
| Classification Code : M7 |
| Hazard Identification Number : 90 |
| Labels : 9 |
| IMDG      | Packing group : III |
| Labels : 9 |
| EmS Code : F-A, S-F |
| IATA (Cargo) | Packing instruction (cargo aircraft) : 956 |
| Packing instruction (LQ) : Y956 |
SAFETY DATA SHEET

Gentamicin Ointment Formulation

Version 2.2
Revision Date: 09/13/2019
SDS Number: 2050352-00006
Date of last issue: 24.04.2019
Date of first issue: 09.10.2017

Packing group: III
Labels: Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft): 956
Packing instruction (LQ): Y956
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

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: 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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

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
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.
H412: Harmful 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
STOT RE: Specific target organ toxicity - repeated exposure

Further information:
SAFETY DATA SHEET

Gentamicin Ointment Formulation

Classification of the mixture:

<table>
<thead>
<tr>
<th>Repr. 1A</th>
<th>H360D</th>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 3</td>
<td>H412</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

ZA / EN