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

Gentamicin Ointment Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 2054102-00006  Date of last issue: 24.04.2019
Date of first issue: 09.10.2017

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
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone : 44 1 670 59 30 00
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 : 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 : H360D May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements : Prevention:
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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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td></td>
<td>Aquatic Chronic3; H412</td>
<td>&lt;= 1</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td></td>
<td>Repr.1A; H360D</td>
<td>&gt;= 0,1 - &lt;= 0,3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT RE1; H372</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute1; H400</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic1; H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 100</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
<td></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 method
: Use extinguishing measures that are appropriate to local cir-
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

SECTON 8: Exposure controls/personal protection

8.1 Control parameters

<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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Vapour)</td>
<td>50 mg/m3</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m3</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Vapour)</td>
<td>50 mg/m3</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m3</td>
<td>FOR-2011-12-06-1358</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>

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</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>14.7 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.45 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3.62 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1.23 mg/kg bw/day</td>
</tr>
</tbody>
</table>
Gentamicin Ointment Formulation

Consumers

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</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>0,00064 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>

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to 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

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.

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

<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>
<tr>
<td>Flash point</td>
<td>&gt; 93.3 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility/ies</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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
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
Gentamicin Ointment Formulation

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:**
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:**
Gentamicin Ointment Formulation

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
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: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
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

Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-foetal toxicity

Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: foetal mortality, No malformations were observed.

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

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
Gentamicin Ointment Formulation

Target Organs: inner ear
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

SECTION 12: Ecological information

12.1 Toxicity

Components:

Methyl p-Hydroxybenzoate:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oryzias latipes (Japanese medaka)): 59.5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 203</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 11.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td>Method: ISO 6341</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>ErC50 (Pseudokirchneriella subcapitata (green algae)): 91 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>Method: ISO 8692</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC: 0.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
<td></td>
</tr>
<tr>
<td>Species: Daphnia magna (Water flea)</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 211</td>
<td></td>
</tr>
</tbody>
</table>

Gentamicin:

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 86 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 202</td>
<td></td>
</tr>
</tbody>
</table>

| LC50 (Americamysis): 30 mg/l                                         |                                             |
| Exposure time: 96 h                                                 |                                             |
| Method: US-EPA OPPTS 850.1035                                       |                                             |

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

| 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

Exposure time: 72 h

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

| UN | ADN: UN 3077 | ADR: UN 3077 | RID: UN 3077 | IMDG: UN 3077 | IATA: UN 3077 |

14.2 UN proper shipping name

| UN | 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)

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

14.4 Packing group
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Gentamicin Ointment Formulation

Version: 2.2
Revision Date: 09/13/2019
SDS Number: 2054102-00006
Date of last issue: 24.04.2019
Date of first issue: 09.10.2017

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
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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable

REACH - List of substances subject to authorisation (Annex XIV): Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable


<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>34</td>
<td>Petroleum products: (a) gasolines and naphthas, (b) kerosenes (including jet fuels), (c) gas oils (including diesel fuels, home heating oils and gas oil blending streams), (d) heavy fuel oils (e) alternative fuels serving the same purposes and with similar properties as regards flammability and environmental hazards as the products referred to in points (a) to (d)</td>
<td>2.500 t</td>
<td>25.000 t</td>
</tr>
</tbody>
</table>

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.
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

- 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
- FOR-2011-12-06-1358: Norway. Occupational Exposure limits
- TWA: Long term exposure limit
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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture: Classification procedure:
Repr. 1A H360D Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 3 H412 Calculation method

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.

NO / EN