SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone Formulation

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

1.1 Product identifier
Trade name : Gentamicin / Betamethasone 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
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A
Çubuk Yolu 2. Km
Akyurt / Ankara / TÜRKİYE
Telephone : +90 312 840 53 00
Telefax : +90 312 827 18 45
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848
Reproductive toxicity, Category 1A
Specific target organ toxicity - repeated exposure, Category 1
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 1
H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling T.R. SEA No 28848
Hazard pictograms : 🔴 🔴
Signal word : Danger
Gentamicin / Betamethasone Formulation

Version: 2.3  Revision Date: 23.03.2020  SDS Number: 2054154-00006  Date of last issue: 13.09.2019
Date of first issue: 09.10.2017

Hazard statements:
- H360D  May damage the unborn child.
- H372  Causes damage to organs through prolonged or repeated exposure.
- H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements:
- Prevention:
  P201  Obtain special instructions before use.
  P264  Wash skin thoroughly after handling.
  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.

Hazardous components which must be listed on the label:
- Gentamicin
- Betamethasone

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>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td></td>
<td></td>
<td>Repr.1A; H360D STOT RE1; H372 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>0,49</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>206-825-4</td>
<td></td>
<td></td>
<td>Acute Tox.2; H330 Repr.1B; H360D STOT RE1; H372 Aquatic Chronic1;</td>
<td>0,1</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 2054154-00006 Date of last issue: 13.09.2019 Date of first issue: 09.10.2017

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazard Class</th>
<th>Description of first aid measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium chloride</td>
<td>H410</td>
<td>M-Factor (Chronic aquatic toxicity): 1.000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute Tox.3; H301 Acute Tox.2; H330 Acute Tox.3; H311 Skin Corr.1; H314 Eye Dam.1; H318 Aquatic Acute1; H400 Aquatic Chronic2; H411 M-Factor (Acute aquatic toxicity): 100</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. Causes damage to organs through prolonged or repeated
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

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 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. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water.
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 2054154-00006 Date of last issue: 13.09.2019 Date of first issue: 09.10.2017

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. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyed 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. Do not breathe vapours or spray mist. 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
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone Formulation

Version 2.3  Revision Date: 23.03.2020  SDS Number: 2054154-00006  Date of last issue: 13.09.2019
Date of first issue: 09.10.2017

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>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL):

<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>Polyethylene glycol castor oil</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>16.4 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4.67 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>2.9 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1.67 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1.67 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC):

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol castor oil</td>
<td>Fresh water</td>
<td>0.000 µg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>66.1 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.000 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water - intermittent</td>
<td>6.61 µg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.0129 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.00129 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.00258 mg/kg</td>
</tr>
</tbody>
</table>
Gentamicin / Betamethasone Formulation

8.2 Exposure controls

Engineering measures
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies.
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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
Remarks : Consider double gloving.

Skin and body protection

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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 TS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : No data available
Odour : No data available
Odour Threshold : No data available
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
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 : No data available
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) : No data available
Molecular weight : No data available
Particle size : 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 toxicological effects
   Information on likely routes of exposure :
       Inhalation
       Skin contact
       Ingestion
       Eye contact

   Acute toxicity
   Not classified based on available information.

   Product:
   Acute inhalation toxicity :
       Acute toxicity estimate: > 5 mg/l
       Exposure time: 4 h
       Test atmosphere: dust/mist
       Method: Calculation method

   Components:
   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
SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone 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>2.3</td>
<td>23.03.2020</td>
<td>2054154-00006</td>
<td>13.09.2019</td>
<td>09.10.2017</td>
</tr>
</tbody>
</table>

**Betamethasone:**

- **Acute oral toxicity**
  - LD50 (Rat): > 5,000 mg/kg
  - LD50 (Mouse): > 4,500 mg/kg

- **Acute inhalation toxicity**
  - LC50 (Rat): 0,4 mg/l
  - Exposure time: 4 h

**Benzalkonium chloride:**

- **Acute oral toxicity**
  - LD50 (Rat): 240 mg/kg

- **Acute inhalation toxicity**
  - LC50 (Rat, male): > 0,05 - 0,5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 403
  - Assessment: Corrosive to the respiratory tract.
  - Remarks: Based on data from similar materials

- **Acute dermal toxicity**
  - LD50 (Rat, female): 704 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Gentamicin:**

- **Species**: Rabbit
- **Result**: Mild skin irritation

**Betamethasone:**

- **Species**: Rabbit
- **Result**: Mild skin irritation

**Benzalkonium chloride:**

- **Species**: Human
- **Result**: Corrosive after 4 hours or less of exposure

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Gentamicin:**

- **Species**: Rabbit
- **Result**: Mild eye irritation

**Betamethasone:**

- **Species**: Rabbit
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone Formulation

Result : No eye irritation

Benzalkonium chloride:
Species : Rabbit
Result : Irreversible effects on the eye

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Components:

Gentamicin:
Remarks : No data available

betamethasone:
Exposure routes : Dermal
Species : Guinea pig
Result : Weak sensitizer

Benzalkonium chloride:
Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Species : Humans
Result : negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

betamethasone:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Result: positive

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Oral
  Result: equivocal

Germ cell mutagenicity - Assessment:
- Weight of evidence does not support classification as a germ cell mutagen.

Benzalkonium chloride:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative
  Remarks: Based on data from similar materials

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Ingestion
  Method: OECD Test Guideline 474
  Result: negative
  Remarks: Based on data from similar materials

Carcinogenicity:
Not classified based on available information.

Components:
- Gentamicin:
  Carcinogenicity - Assessment: No data available
- Benzalkonium chloride:
  Species: Rat
Gentamicin / Betamethasone Formulation

Version: 2.3  
Revision Date: 23.03.2020  
SDS Number: 2054154-00006  
Date of last issue: 13.09.2019  
Date of first issue: 09.10.2017

Application Route: Ingestion  
Exposure time: 2 Years  
Method: OECD Test Guideline 453  
Result: negative  
Remarks: Based on data from similar materials

Species: Mouse  
Application Route: Skin contact  
Exposure time: 80 weeks  
Result: negative

Species: Rabbit  
Application Route: Skin contact  
Exposure time: 90 weeks  
Result: negative

Reproductive toxicity
May damage the unborn child.

Components:

Gentamicin:
Effects on fertility: Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Fertility: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reported

Effects on foetal development: Test Type: Embryo-foetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
Result: No embryo-foetal toxicity

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

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

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.
betamethasone:
Effects on foetal development : Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
Result: Malformations were observed.

Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

Benzalkonium chloride:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs through prolonged or repeated exposure.

Components:

Gentamicin:
Target Organs : Kidney, inner ear
Assessment : Causes damage to organs through prolonged or repeated exposure.

betamethasone:
Target Organs : Pituitary gland, Immune system, muscle, thymus gland, Blood,
### Gentamicin / Betamethasone Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Adrenal gland</th>
<th>Benzalkonium chloride:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
<td>No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

#### Components:

#### Gentamicin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>3 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Vomiting, Salivation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, inner ear</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>6 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, inner ear, Liver</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, Blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>12.5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

#### Betamethasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.05 %</td>
</tr>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
</tbody>
</table>
Gentamicin / Betamethasone Formulation

Exposure time: 10 - 30 d
Target Organs: Pituitary gland, Immune system, muscle

Species: Rat
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Mouse
LOAEL: 0.1 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 28 d
Target Organs: Blood, thymus gland, Adrenal gland

Benzalkonium chloride:
Species: Rat
NOAEL: >= 100 mg/kg
Application Route: Ingestion
Exposure time: 12 Weeks

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

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

betamethasone:
Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritis, Irritation

SECTION 12: Ecological information

12.1 Toxicity

Components:

Gentamicin:
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone 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>2.3</td>
<td>23.03.2020</td>
<td>2054154-00006</td>
<td>13.09.2019</td>
<td>09.10.2017</td>
</tr>
</tbody>
</table>

| 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

**Betamethasone:**

| Toxicity to daphnia and other aquatic invertebrates | EC50 (Americamysis): > 50 mg/l  
Exposure time: 96 h |
|---|---|
| Toxicity to algae/aquatic plants | EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility  
NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility |
Gentamicin / Betamethasone 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>2.3</td>
<td>23.03.2020</td>
<td>2054154-00006</td>
<td>13.09.2019</td>
<td>09.10.2017</td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**
- NOEC: 0,052 mg/l
- Exposure time: 32 d
- Species: Pimephales promelas (fathead minnow)
- Method: OECD Test Guideline 210
- NOEC: 0,07 µg/l
- Exposure time: 219 d
- Species: Oryzias latipes (Japanese medaka)
- Method: OECD Test Guideline 229

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
- NOEC: 8 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

**M-Factor (Chronic aquatic toxicity):**
- 1.000

**Benzalkonium chloride:**
- Toxicity to fish
  - LC50 (Pimephales promelas (fathead minnow)): 0,28 mg/l
  - Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates
  - EC50 (Daphnia magna (Water flea)): 0,0056 mg/l
  - Exposure time: 48 h
- Toxicity to algae/aquatic plants
  - ErC50 (Chlorella pyrenoidosa (aglae)): 0,09 mg/l
  - Exposure time: 72 h
- M-Factor (Acute aquatic toxicity): 100

**Toxicity to fish (Chronic toxicity):**
- NOEC: 0,032 mg/l
- Exposure time: 34 d
- Species: Pimephales promelas (fathead minnow)

### 12.2 Persistence and degradability

**Components:**

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

**Benzalkonium chloride:**
- Biodegradability
  - Result: Readily biodegradable.
  - Method: OECD Test Guideline 301D
  - Remarks: Based on data from similar materials
Gentamicin / Betamethasone Formulation

12.3 Bioaccumulative potential

**Components:**

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

**Betamethasone:**
Partition coefficient: n-octanol/water: log Pow: 2.11

**Benzalkonium chloride:**
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water: log Pow: 1.692
Remarks: Calculation

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 3082
ADR: UN 3082
RID: UN 3082
IMDG: UN 3082
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone 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>2.3</td>
<td>23.03.2020</td>
<td>2054154-00006</td>
<td>13.09.2019</td>
<td>09.10.2017</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>Mode</th>
<th>UN number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 3082</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin, Benzalkonium chloride)</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 3082</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin, Benzalkonium chloride)</td>
</tr>
<tr>
<td>RID</td>
<td>UN 3082</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin, Benzalkonium chloride)</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3082</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin, Benzalkonium chloride)</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3082</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (Gentamicin, Benzalkonium chloride)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>Mode</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>9</td>
</tr>
<tr>
<td>ADR</td>
<td>9</td>
</tr>
<tr>
<td>RID</td>
<td>9</td>
</tr>
<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>Mode</th>
<th>Packing group</th>
<th>Classification Code</th>
<th>Hazard Identification Number</th>
<th>Labels</th>
<th>Tunnel restriction code</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>III</td>
<td>M6</td>
<td>90</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>ADR</td>
<td>III</td>
<td>M6</td>
<td>90</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>III</td>
<td>M6</td>
<td>90</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>III</td>
<td>M6</td>
<td>90</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>IATA</td>
<td>III</td>
<td>M6</td>
<td>90</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment
and Urbanization; Regulation on Safety data sheets regarding haz-
ardous substances and mixtures; Part I”.

Gentamicin / Betamethasone 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>2.3</td>
<td>23.03.2020</td>
<td>2054154-00006</td>
<td>13.09.2019</td>
<td>09.10.2017</td>
</tr>
</tbody>
</table>

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 var-
iations 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 mix-
ture

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous
substances, mixtures and articles (Annex 17) : Conditions of restriction for the fol-
lowing entries should be considered:
Regulation on Persistent Organic Pollutants (Number 30595) : Not applicable
Regulation on prevention of major industrial accidents. Reg number 30702

Quantity 1

Quantity 2
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 2054154-00006 Date of last issue: 13.09.2019 Date of first issue: 09.10.2017

E1 ENVIRONMENTAL HAZARDS 100 t 200 t

Other regulations:

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

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
H301 : Toxic if swallowed.
H311 : Toxic in contact with skin.
H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.
H330 : Fatal if inhaled.
H360D : May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
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.
H411 : Toxic to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
STOT RE : Specific target organ toxicity - repeated exposure
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 2054154-00006 Date of last issue: 13.09.2019 Date of first issue: 09.10.2017

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Property</th>
<th>Classification</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1A</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

Classification procedure:

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...
SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Gentamicin / Betamethasone 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>2.3</td>
<td>23.03.2020</td>
<td>2054154-00006</td>
<td>13.09.2019</td>
<td>09.10.2017</td>
</tr>
</tbody>
</table>

...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.

TR / EN