1. PRODUCT AND COMPANY IDENTIFICATION

**Product name**: Gentamicin / Betamethasone Formulation

**Manufacturer or supplier’s details**

*Company*: MSD  
*Address*: JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia  
*Telephone*: 908-740-4000  
*Emergency telephone number*: 1-908-423-6000  
*E-mail address*: EHSDATASTEWARD@msd.com  
*Telefax*: 908-735-1496

**Recommended use of the chemical and restrictions on use**

**Recommended use**: Veterinary product

2. HAZARDS IDENTIFICATION

**GHS Classification**

**Reproductive toxicity**: Category 1A

**Specific target organ toxicity - repeated exposure**: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

**Short-term (acute) aquatic hazard**: Category 1

**Long-term (chronic) aquatic hazard**: Category 1

**GHS label elements**

**Hazard pictograms**

![Hazard pictograms](image)

**Signal word**: Danger

**Hazard statements**

H360D May damage the unborn child.  
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

**Precautionary statements**

**Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>0.49</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>0.1</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>0.01</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
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.
### SAFETY DATA SHEET

**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>4.5</td>
<td>2020/03/23</td>
<td>434589-00015</td>
<td>2019/09/13</td>
<td>2016/01/06</td>
</tr>
</tbody>
</table>

- **Most important symptoms and effects, both acute and delayed:**
  - May damage the unborn child.
  - Causes damage to organs through prolonged or repeated exposure.

- **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).

- **Notes to physician:**
  - Treat symptomatically and supportively.

## 5. FIREFIGHTING MEASURES

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

- **Unsuitable extinguishing media:**
  - None known.

- **Specific hazards during firefighting:**
  - Exposure to combustion products may be a hazard to health.

- **Hazardous combustion products:**
  - Carbon oxides

- **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.

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

## 6. ACCIDENTAL RELEASE MEASURES

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

- **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.
  - Local authorities should be advised if significant spills cannot be contained.

- **Methods and materials for containment and cleaning up:**
  - Soak up with inert absorbent material.
  - For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
  - Clean up remaining materials from spill with suitable absorbent.
  - Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-
mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding
certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE
CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust
ventilation.
Advice on safe handling : Do not get on skin or clothing.
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 as-
essment
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the
environment.

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>NAB</td>
<td>10 mg/m3</td>
<td>ID OEL</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>3 mg/m3</td>
<td>ACGIH</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>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Adopted in Year 1996, Not classified as car-
cinogenic to humans. Not enough data to classify these materials
as carcinogenic to humans or animals

Further information: Skin
Wipe limit 10 µg/100 cm² Internal

Engineering measures : All engineering controls should be implemented by facility
5. WORK PRACTICE AND PERSONAL PROTECTION

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**

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

**Hand protection**: Chemical-resistant gloves
- **Material**: Consider double gloving.

**Eye protection**: Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**: Work uniform or laboratory coat.
- 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.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</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>Property</td>
<td>Value</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</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>No data available</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>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
</tbody>
</table>
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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:**

**Polyethylene glycol stearate:**
Acute oral toxicity:
- LD50 (Rat): > 5,000 mg/kg

**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

**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:**
SAFETY DATA SHEET

Gentamicin / Betamethasone Formulation

Version: 4.5  Revision Date: 2020/03/23  SDS Number: 434589-00015  Date of last issue: 2019/09/13
Date of first issue: 2016/01/06

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
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:

Polyethylene glycol stearate:
Species: Rabbit
Result: No skin irritation

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:

Polyethylene glycol stearate:
Species: Rabbit
Result: No eye irritation

Gentamicin:
Species: Rabbit
Result: Mild eye irritation

betamethasone:
Species: Rabbit
Result: No eye irritation
SAFETY DATA SHEET

Gentamicin / Betamethasone Formulation

Version: 4.5
Revision Date: 2020/03/23
SDS Number: 434589-00015
Date of last issue: 2019/09/13
Date of first issue: 2016/01/06

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:

Polyethylene glycol stearate:
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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:

Polyethylene glycol stearate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
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

**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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>2 Years</td>
<td>OECD Test Guideline 453</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

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

### Reproductive toxicity

May damage the unborn child.

#### Components:

### Gentamicin:

#### Effects on fertility:

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
<th>Fertility: NOAEL</th>
<th>Result: No significant adverse effects were reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Two-generation reproduction toxicity study</td>
<td>20 mg/kg body weight</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

#### Effects on foetal development:

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Type: Embryo-foetal development</th>
<th>Developmental Toxicity: NOAEL</th>
<th>Result: No embryo-foetal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Two-generation reproduction toxicity study</td>
<td>3.6 mg/kg body weight</td>
<td>No embryo-foetal toxicity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Rat</th>
<th>Developmental Toxicity: LOAEL</th>
<th>Result: Embryo-foetal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Intraperitoneal</td>
<td>Intraperitoneal</td>
<td>75 mg/kg body weight</td>
<td>Embryo-foetal toxicity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Mouse</th>
<th>Developmental Toxicity: LOAEL</th>
<th>Result: Embryo-foetal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Intraperitoneal</td>
<td>Intraperitoneal</td>
<td>10 mg/kg body weight</td>
<td>Embryo-foetal toxicity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Rat</th>
<th>Developmental Toxicity: LOAEL</th>
<th>Result: Embryo-foetal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Intraperitoneal</td>
<td>Intraperitoneal</td>
<td>50 mg/kg body weight</td>
<td>Embryo-foetal toxicity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Rat</th>
<th>Developmental Toxicity: LOAEL</th>
<th>Result: Embryo-foetal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Intraperitoneal</td>
<td>Intraperitoneal</td>
<td>50 mg/kg body weight</td>
<td>Embryo-foetal toxicity</td>
</tr>
</tbody>
</table>

### 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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.
Benzalkonium chloride:
Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

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 : Kidney, inner ear, Liver

Species : Rat
NOAEL : 5 mg/kg
LOAEL : 10 mg/kg
Application Route : Intramuscular
Exposure time : 52 Weeks
Target Organs : Kidney, Liver

Species : Rat
NOAEL : 12.5 mg/kg
LOAEL : 50 mg/kg
Application Route : Intramuscular
Exposure time : 13 Weeks
Target Organs : Kidney

betamethasone:
Species : Rabbit
LOAEL : 0.05 %
Application Route : Skin contact
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

### 12. ECOTOXICOLOGY INFORMAION

**Ecotoxicity**

**Components:**

**Polyethylene glycol stearate:**
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h
Method: DIN 38412

Toxicity to microorganisms: EC10: > 10,000 mg/l
Exposure time: 16 h

**Gentamicin:**
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 86 mg/l 
Exposure time: 48 h 
Method: OECD Test Guideline 202 

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

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l 
Exposure time: 72 h 
Method: OECD Test Guideline 201 

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l 
Exposure time: 72 h 
Method: OECD Test Guideline 201 

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l 
Exposure time: 72 h 
Method: OECD Test Guideline 201 

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l 
Exposure time: 72 h 
Method: OECD Test Guideline 201 

M-Factor (Acute aquatic toxicity): 100 
M-Factor (Chronic aquatic toxicity): 1 
Toxicity to microorganisms: EC50: 288.7 mg/l 
Exposure time: 3 h 
Test Type: Respiration inhibition 
Method: OECD Test Guideline 209 

**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 

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l 
Exposure time: 32 d 
Method: OECD Test Guideline 210
NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l  
Exposure time: 219 d  
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC (Daphnia magna (Water flea)): 8 mg/l  
Exposure time: 21 d  
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 (Pimephales promelas (fathead minnow)): 0.032 mg/l  
Exposure time: 34 d

**Persistence and degradability**

**Components:**

**Polyethylene glycol stearate:**

Biodegradability:  
Result: Readily biodegradable.  
Biodegradation: > 70 %  
Exposure time: 10 d  
Method: OECD Test Guideline 302B

**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

**Bioaccumulative potential**

**Components:**

**Polyethylene glycol stearate:**

Partition coefficient: n-  
log Pow: 6.16
octanol/water

**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

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
: Dispose of in accordance with local regulations.
Contaminated packaging
: Empty containers should be taken to an approved waste handling site for recycling or disposal.
  If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

**UNRTDG**
UN number
: UN 3082
Proper shipping name
: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
  (Gentamicin, Benzalkonium chloride)
Class
: 9
Packing group
: III
Labels
: 9

**IATA-DGR**
UN/ID No.
: UN 3082
Proper shipping name
: Environmentally hazardous substance, liquid, n.o.s.
  (Gentamicin, Benzalkonium chloride)
Class
: 9
Packing group
: III
Labels
: Miscellaneous
Packing instruction (cargo aircraft)
: 964
Packing instruction (passen-
SAFETY DATA SHEET

Gentamicin / Betamethasone Formulation

Version 4.5 Revision Date: 2020/03/23 SDS Number: 434589-00015 Date of last issue: 2019/09/13 Date of first issue: 2016/01/06

carrier aircraft)
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin, Benzalkonium chloride)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
### 16. OTHER INFORMATION

#### Further information
- **Date format**: yyyy/mm/dd

#### Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ID OEL</td>
<td>Indonesia. Occupational Exposure Limits</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ID OEL / NAB</td>
<td>Long term exposure limit</td>
</tr>
</tbody>
</table>

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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 mate-
rial 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 ap-
propriateness of the SDS material in the user’s end product, if applicable.

ID / EN