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

Betamethasone / Gentamicin Formulation

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

1.1 Product identifier
Trade name : Betamethasone / Gentamicin 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
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2
Reproductive toxicity, Category 1B
Specific target organ toxicity - repeated exposure, Category 1
Long-term (chronic) aquatic hazard, Category 1

H319: Causes serious eye irritation.
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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements :
H319 Causes serious eye irritation.
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.
- 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.
- P337 + P313 If eye irritation persists: Get medical advice/attention.
- P391 Collect spillage.

Hazardous components which must be listed on the label:
- betamethasone

### 2.3 Other hazards

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

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

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

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>603-117-00-0</td>
<td>Flam. Liq.; H225 Eye Irrit.; H319 STOT SE 3; H336</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td></td>
<td>Aquatic Chronic 2; H411</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>215-765-8</td>
<td></td>
<td>Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1;</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>
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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.
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Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

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 : Causes serious eye irritation.
May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

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.
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Date of first issue: 09.12.2019

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Environmental precautions:
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling:
Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
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according to Regulation (EC) No. 1907/2006

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Hygiene measures:
Take care to prevent spills, waste and minimize release to the environment.
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers:
Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)
Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>25 ppm 79 mg/m3</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>100 ppm 245 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>
<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: Skin
Wipe limit 10 µg/100 cm² Internal

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>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Long-term systemic effects</td>
<td>168 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m3</td>
</tr>
</tbody>
</table>
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Consumers  Inhalation  Long-term systemic effects  50 mg/m³

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57,2 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>Fresh water</td>
<td>2,4 µg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0,112 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,24 µg/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>0,0632 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,0063 mg/kg/kg</td>
</tr>
</tbody>
</table>

Workers  Inhalation  Long-term systemic effects  500 mg/m³

Workers  Skin contact  Long-term systemic effects  888 mg/kg bw/day

Consumers  Inhalation  Long-term systemic effects  89 mg/m³

Consumers  Skin contact  Long-term systemic effects  319 mg/kg bw/day

Consumers  Ingestion  Long-term systemic effects  26 mg/kg bw/day

Workers  Inhalation  Long-term systemic effects  58,76 mg/m³

Workers  Skin contact  Long-term systemic effects  9,8 mg/kg bw/day

Consumers  Inhalation  Long-term systemic effects  14,49 mg/m³

Consumers  Skin contact  Long-term systemic effects  4,2 mg/kg bw/day

Consumers  Ingestion  Long-term systemic effects  4,16 mg/kg bw/day

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

- 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.

**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 NS EN 14387

**Filter type**

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

### SECTION 9: Physical and chemical properties

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

<table>
<thead>
<tr>
<th><strong>Property</strong></th>
<th><strong>Value</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</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>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>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: No data available
Auto-ignition temperature: No data available
 Decomposition temperature: No data available
pH: No data available
Viscosity
  Viscosity, kinematic: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: No data available
Relative density: No data available
Density: No data available
Relative vapour density: No data available
Particle characteristics
  Particle size: Not applicable
9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: No data available
Molecular weight: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

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

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity
Not classified based on available information.

Components:

Propan-2-ol:
- Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 25 mg/l
  Exposure time: 6 h
  Test atmosphere: vapour
- Acute dermal toxicity: LD50 (Rabbit): > 5.000 mg/kg

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
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<table>
<thead>
<tr>
<th>Version</th>
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<th>SDS Number</th>
<th>Date of last issue</th>
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<tr>
<td>2.4</td>
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<td>5345529-00006</td>
<td>09.04.2021</td>
<td>09.12.2019</td>
</tr>
</tbody>
</table>

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  

- **Skin corrosion/irritation:**  
  Not classified based on available information.  

- **Components:**  
  - **Propan-2-ol:**  
    - **Species:** Rabbit  
    - **Result:** No skin irritation  
  
  - **Methyl p-Hydroxybenzoate:**  
    - **Species:** Rabbit  
    - **Result:** No eye irritation  
  
  - **Gentamicin:**  
    - **Species:** Rabbit  
    - **Result:** Mild skin irritation  

- **Serious eye damage/eye irritation:**  
  Causes serious eye irritation.  

- **Components:**  
  - **Propan-2-ol:**  
    - **Species:** Rabbit  
    - **Result:** Irritation to eyes, reversing within 21 days  
  
  - **Methyl p-Hydroxybenzoate:**  
    - **Species:** Rabbit  
    - **Result:** No eye irritation  

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

**Betamethasone:**
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Propan-2-ol:**
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

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

**Gentamicin:**
Remarks: No data available

**Betamethasone:**
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Propan-2-ol:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative
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Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative

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

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

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

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.
Carcinogenicity
Not classified based on available information.

Components:

Propan-2-ol:
Species: Rat
Application Route: inhalation (vapour)
Exposure time: 104 weeks
Method: OECD Test Guideline 451
Result: negative

Gentamicin:
Carcinogenicity - Assessment: No data available

Reproductive toxicity
May damage the unborn child.

Components:

Propan-2-ol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

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

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

Effects on foetal development: Test Type: 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.

STOT - single exposure
Not classified based on available information.

Components:
Propan-2-ol:
Assessment: May cause drowsiness or dizziness.

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, Adrenal gland
- **Assessment**: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Propan-2-ol:**

- **Species**: Rat
- **NOAEL**: 12.5 mg/l
- **Application Route**: inhalation (vapour)
- **Exposure time**: 104 Weeks

**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  

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  

Aspiration toxicity  
Not classified based on available information.  

11.2 Information on other hazards  

Endocrine disrupting properties  

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

**Components:**

**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, pruritus, Irritation

SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Propan-2-ol:**
Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): 9.640 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 10.000 mg/l
  Exposure time: 24 h

Toxicity to microorganisms:
- EC50 (Pseudomonas putida): > 1.050 mg/l
  Exposure time: 16 h

**Methyl p-Hydroxybenzoate:**
Toxicity to fish:
- LC50 (Oryzias latipes (Japanese medaka)): 59.5 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 11.2 mg/l
  Exposure time: 48 h
  Method: ISO 6341

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

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

Toxicity to fish (Chronic toxicity):
- NOEC: 0.024 mg/l
  Exposure time: 70 d
  Species: Danio rerio (zebra fish)

Toxicity to daphnia and other:
- NOEC: 0.2 mg/l
### Gentamicin:

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 86 mg/l</th>
<th>Exposure time: 48 h</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
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<tr>
<td></td>
<td>LC50 (Americamysis): 30 mg/l</td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: US-EPA OPPTS 850.1035</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l</th>
<th>Exposure time: 72 h</th>
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<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
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<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 1,5 µg/l</td>
<td>Exposure time: 72 h</td>
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<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 µg/l</td>
<td>Exposure time: 72 h</td>
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<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
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<tr>
<td></td>
<td>NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l</td>
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<td>Method: OECD Test Guideline 201</td>
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</table>

**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: 288,7 mg/l</th>
<th>Exposure time: 3 h</th>
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<tbody>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
<td>Method: OECD Test Guideline 209</td>
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**Betamethasone:**

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Americamysis): &gt; 50 mg/l</th>
<th>Exposure time: 96 h</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td>Exposure time: 72 h</td>
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</table>
Betamethasone / Gentamicin Formulation

<table>
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<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
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<td>27.08.2021</td>
<td>5345529-00006</td>
<td>09.04.2021</td>
<td>09.12.2019</td>
</tr>
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</table>

**Method**: OECD Test Guideline 201
**Remarks**: No toxicity at the limit of solubility

**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

### 12.2 Persistence and degradability

#### Components:

**Propan-2-ol**
- Biodegradability: Result: rapidly degradable
- BOD/COD:
  - BOD: 1.19 (BOD5)
  - COD: 2.23
  - BOD/COD: 53 %

**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:

**Propan-2-ol**
- Partition coefficient: n-octanol/water: log Pow: 0.05

**Methyl p-Hydroxybenzoate:**
Betamethasone / Gentamicin Formulation

Partition coefficient: n-octanol/water
- Gentamicin: log Pow: < -2
- betamethasone: log Pow: 2.11

12.4 Mobility in soil
No data available

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

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

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

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

**Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number
**ADN:** UN 3082
## 14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</th>
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<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
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<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
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<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
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<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (betamethasone)</td>
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</table>

## 14.3 Transport hazard class(es)

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

## 14.4 Packing group

### ADN

<table>
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<tbody>
<tr>
<td>Classification Code</td>
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<td>Hazard Identification Number</td>
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### ADR

<table>
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<tbody>
<tr>
<td>Classification Code</td>
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<td>Labels</td>
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<td>Tunnel restriction code :</td>
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</table>

### RID

<table>
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<th>Packing group</th>
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<tbody>
<tr>
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<tr>
<td>Hazard Identification Number</td>
<td>90</td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
</tr>
</tbody>
</table>
IMDG
Packing group: III
Labels: 9
EmS Code: F-A, S-F

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

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

14.5 Environmental hazards
ADN
Environmentally hazardous: yes
ADR
Environmentally hazardous: yes
RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

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

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered:
Number on list 3
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 (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 t</td>
<td>200 t</td>
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</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
H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.
H330: Fatal if inhaled.
H336: May cause drowsiness or dizziness.
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.

Full text of other abbreviations
Betamethasone / Gentamicin Formulation

Version: 2.4
Revision Date: 27.08.2021
SDS Number: 5345529-00006
Date of first issue: 09.12.2019
Date of last issue: 09.04.2021

Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Irrit.: Eye irritation
Flam. Liq.: Flammable liquids
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
FOR-2011-12-06-1358: Norway. Occupational Exposure limits
FOR-2011-12-06-1358: Long term exposure limit
TWA

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances (Japan); IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - Quantitative Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information
Classification of the mixture: Eye Irrit. 2
Classification procedure: Calculation method

Date of first issue: 09.12.2019
Date of last issue: 09.04.2021

5345529-00006
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