1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone / Gentamicin Formulation

Manufacturer or supplier's details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Serious eye damage/eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements: H319 Causes serious eye irritation.
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.
H401 Toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P203 Obtain, read and follow all safety instructions before use.
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:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P318 IF exposed or concerned, get medical advice.
P337 + P317 If eye irritation persists: Get medical help.
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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>99-76-3</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</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: 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.

Most important symptoms and effects, both acute and delayed: Causes serious eye irritation. 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 (see section 7) and personal protective equipment recommendations (see section 8).

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.

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 determine 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 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.
- 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>Propan-2-ol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</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: Skin

<table>
<thead>
<tr>
<th>Wipe limit</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 µg/100 cm²</td>
<td></td>
</tr>
</tbody>
</table>

**Biological occupational exposure limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>40 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

**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**

**Respiratory protection**

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter type: Combined particulates and organic vapour type

**Hand protection**

Material: Chemical-resistant gloves

Remarks: 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

- **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
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
SAFETY DATA SHEET
Betamethasone / Gentamicin Formulation

Version 2.3
Revision Date: 27.08.2021
SDS Number: 5344795-00005
Date of last issue: 10.10.2020
Date of first issue: 09.12.2019

Molecular weight : No data available
Particle size : Not applicable

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
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.

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
SAFETY DATA SHEET

Betamethasone / Gentamicin Formulation

Version 2.3  Revision Date: 27.08.2021  SDS Number: 5344795-00005  Date of last issue: 10.10.2020
Date of first issue: 09.12.2019

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 skin irritation

Gentamicin:
Species: Rabbit
Result: Mild skin irritation

betamethasone:
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

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

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

Genotoxicity in vivo: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 478
Result: negative

**Gentamicin:**
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: equivocal

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intravenous injection
Result: negative

**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.
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

Reprouductive 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
  - 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 (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.

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: 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
1. PHYSICAL AND CHEMICAL PROPERTIES

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

2. HUMAN HEALTH EFFECTS

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.

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propan-2-ol:
# Betamethasone / Gentamicin 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>27.08.2021</td>
<td>5344795-00005</td>
<td>10.10.2020</td>
<td>09.12.2019</td>
</tr>
</tbody>
</table>

## Toxicity to Fish
- **Methyl p-Hydroxybenzoate:**
  - **Toxicity to fish:** $LC_50$ (Oryzias latipes (Japanese medaka)): 59.5 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

## Toxicity to Daphnia and Other Aquatic Invertebrates
- **Methyl p-Hydroxybenzoate:**
  - **Toxicity to daphnia and other aquatic invertebrates:** $EC_50$ (Daphnia magna (Water flea)): 11.2 mg/l
  - Exposure time: 48 h
  - Method: ISO 6341

- **Toxicity to algae/aquatic plants:** $ErC_50$ (Pseudokirchneriella subcapitata (green algae)): 91 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 aquatic invertebrates (Chronic toxicity):** NOEC: 0.2 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211

## Gentamicin:
- **Toxicity to daphnia and other aquatic invertebrates:** $EC_50$ (Daphnia magna (Water flea)): 86 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants:** $EC_50$ (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- **LC50 (Americamysis):** 30 mg/l
  - Exposure time: 96 h

- **Toxicity to algae/aquatic plants:** NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
**Betamethasone / Gentamicin Formulation**

<table>
<thead>
<tr>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

**M-Factor (Acute aquatic toxicity):** 100

**Toxicity to microorganisms:**

<table>
<thead>
<tr>
<th>Exposure time: 3 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Respiration inhibition</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method: OECD Test Guideline 209</th>
</tr>
</thead>
</table>

**M-Factor (Chronic aquatic toxicity):** 1

**betamethasone:**

<table>
<thead>
<tr>
<th>Species: Pimephales promelas (fathead minnow)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC: 0.052 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC: 0.07 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 219 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species: Oryzias latipes (Japanese medaka)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 229</td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Exposure time: 32 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Pimephales promelas (fathead minnow)</td>
</tr>
</tbody>
</table>

<table>
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<th>NOEC: 0.07 µg/l</th>
</tr>
</thead>
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<td>Exposure time: 219 d</td>
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<th>Species: Oryzias latipes (Japanese medaka)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 229</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Exposure time: 21 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Daphnia magna (Water flea)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC: 8 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method: OECD Test Guideline 211</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

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

Bioaccumulative potential

Components:

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

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

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

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

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. (betamethasone)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (betamethasone)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments
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

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet:

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA, ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit

AICIC - Australian Inventory of Industrial Chemicals; 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; 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, Evalue-
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.

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