SAFETY DATA SHEET
Betamethasone / Gentamicin Formulation

SECTION 1. IDENTIFICATION

Product name: Betamethasone / Gentamicin Formulation

Manufacturer or supplier's details
Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
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:**
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 vapors.
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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: 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.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

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

### SECTION 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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media:
None known.

Specific hazards during fire fighting:
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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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...
Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 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 vapors. 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 labeled 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 Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>CMP</td>
<td>400 ppm</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT</td>
<td>500 ppm</td>
<td>AR OEL</td>
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</table>
SAFETY DATA SHEET

Betamethasone / Gentamicin Formulation

<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>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>Urine</td>
<td></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>Urine</td>
<td></td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

Wipe limit: 10 µg/100 cm² Internal

Biological occupational exposure limits

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 vapor type

Hand protection
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Color : No data available
Odor : No data available
Odor 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
Vapor pressure : No data available
Relative vapor 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
Autoignition 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.
Molecular weight : No data available
Particle size : Not applicable

SECTION 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.

SECTION 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: vapor
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

   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

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 sensitization**

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

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

**Components:**

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

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

**Gentamicin:**
- **Remarks:** No data available

**Betamethasone:**
- **Routes of exposure:** 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 (vapor)
- **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 fetal development**
  - **Test Type:** Embryo-fetal development
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Result:** negative

**Methyl p-Hydroxybenzoate:**

- **Effects on fetal development**
  - **Test Type:** Embryo-fetal 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 fetal development:

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

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

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

Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: Fetal mortality, No malformations were observed.

Reproductive toxicity - Assessment:
Positive evidence of adverse effects on development from human epidemiological studies.

Betamethasone:

Effects on fetal 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 (vapor)
- **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

#### Gentamicin:
- **Species**: Monkey
- **LOAEL**: 50 mg/kg
- **Application Route**: Subcutaneous
- **Exposure time**: 3 Weeks
- **Target Organs**: Kidney, inner ear

#### Gentamicin:
- **Species**: Monkey
- **LOAEL**: 6 mg/kg
- **Application Route**: Intramuscular
- **Exposure time**: 3 Weeks
**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>2.3</td>
<td>27.08.2021</td>
<td>5344771-00005</td>
<td>10.10.2020</td>
<td>09.12.2019</td>
</tr>
</tbody>
</table>

**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 days
**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 days
**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, pruritis, Irritation

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

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 (Danio rerio (zebra fish)): 0,024 mg/l Exposure time: 70 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0,2 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

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

**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

**SECTION 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.

SECTION 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 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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry: Not applicable

18 / 20
Control of precursors and essential chemicals for the preparation of drugs: Propan-2-ol

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

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

**SECTION 16. OTHER INFORMATION**

**Further information**

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

**Full text of other abbreviations**

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- AR BEI: Argentina. Biological Exposure Indices
- AR OEL: Argentina. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
AR OEL / CMP: TLV (Threshold Limit Value)
AR OEL / CMP - CPT: STEL (Short Term Limit Value)

AIIC - 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; ICS50 - 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 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; 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 Substanc-
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.