SAFETY DATA SHEET
Betamethasone / Gentamicin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone / Gentamicin Formulation

Supplier's company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

#### Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 20 - &lt; 30</td>
<td>2-234</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-207</td>
</tr>
<tr>
<td>Methyl p-Hydroxybenzoate</td>
<td>99-76-3</td>
<td>1.3</td>
<td>3-1585</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></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.
SAFETY DATA SHEET

Betamethasone / Gentamicin Formulation

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

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.
Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact:
Oxidizing agents
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.

Storage
Conditions for safe storage:
Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>ACL</td>
<td>200 ppm</td>
<td>JP OEL ISHL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-C</td>
<td>400 ppm 980 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 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

Wipe limit 10 µg/100 cm² Internal

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Target substance</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
Hand protection: Combined particulates and organic vapour type

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 face shield 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid
Colour : No data available
Odour : No data available
Odour Threshold : No data available
Melting point/freezing point : No data available
Boiling point, initial boiling point and boiling range : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Lower explosion limit and upper explosion limit / flammability limit
  Upper explosion limit / Upper flammability limit : No data available
  Lower explosion limit / Lower flammability limit : No data available
Flash point : No data available
Decomposition temperature : No data available
pH : No data available
Evaporation rate : No data available
Auto-ignition temperature : 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

### Density and/or relative density
- Relative density: No data available
- Density: No data available
- Relative vapour density: No data available

### Explosive properties
- Not explosive

### Oxidizing properties
- The substance or mixture is not classified as oxidizing.

### Molecular weight
- No data available

### Particle characteristics
- Particle size: Not applicable

### 10. STABILITY AND REACTIVITY

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

### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

**Acute toxicity**
Not classified based on available information.

**Components:**

**Propylene glycol:**
- **Acute oral toxicity**: LD50 (Rat): 22,000 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): > 44.9 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

**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
   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:**

**Propylene glycol:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**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:**

**Propylene glycol:**
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

**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:

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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 sensitiser

Germ cell mutagenicity
Not classified based on available information.

Components:

Propylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

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

**Propylene glycol:**
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

**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:**

**Propylene glycol:**
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

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

**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
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

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
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:**

**Propylene glycol:**
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

**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
## SAFETY DATA SHEET

**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>
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<tbody>
<tr>
<td>4.1</td>
<td>2021/08/27</td>
<td>5344796-00006</td>
<td>2021/04/09</td>
<td>2019/12/09</td>
</tr>
</tbody>
</table>

**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.

Experience with human exposure

Components:

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

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylene glycol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms:
NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

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:

Propylene glycol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
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:

Propylene glycol:
Partition coefficient: n-octanol/water : log Pow: -1.07

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

Hazardous to the ozone layer
Not applicable

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 Annex II of MARPOL 73/78 and the IBC Code
- Not applicable for product as supplied.

National Regulations
- Refer to section 15 for specific national regulation.

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
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
<tr>
<td>Isopropyl alcohol</td>
<td>102</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propyl alcohol</td>
<td>494</td>
<td>&gt;=10 - &lt;20</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propyl alcohol</td>
<td>494</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Organic Solvents Class 2
Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic acid, 4-hydroxy-, methyl ester</td>
<td>334</td>
<td>1.3</td>
</tr>
</tbody>
</table>

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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
SAFETY DATA SHEET

Betamethasone / Gentamicin Formulation

Date format: yyyy/mm/dd

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
JP OEL ISHL: Japan. Administrative Control Levels

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
JP OEL ISHL / ACL: Administrative Control level
JP OEL JSOH / OEL-C: Occupational Exposure Limit-Ceiling

AIIIC - 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 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 Conventation for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SDAT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS 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.