SECTION 1. IDENTIFICATION

Product name: Betamethasone (0.05%) Liquid Formulation

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

GHS label elements
Hazard pictograms: ☑️

Signal Word: Danger

Hazard Statements: H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.01 - &lt; 0.1</td>
</tr>
</tbody>
</table>

# Voluntarily-disclosed non-hazardous substance
Actual concentration is withheld as a trade secret

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 : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

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 : 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

Exposure to combustion products may be a hazard to health.

Carbon oxides

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.

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 cannot be contained.

- 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.
Avoid contact with 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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>TWA</td>
<td>1,000 ppm 1,900 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>1,000 ppm 1,900 mg/m³</td>
<td>OSHA Z-1</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

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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any
hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection

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

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

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
SAFETY DATA SHEET
Betamethasone (0.05%) Liquid Formulation

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 : No data available
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:**

**Glycerine:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Guinea pig): > 5,000 mg/kg

**Propylene glycol:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rabbit): > 159 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

**Ethanol:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
- Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
  - Exposure time: 4 h
  - Test atmosphere: vapor

**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:**

**Glycerine:**
- Species: Rabbit
  - Result: No skin irritation

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

Ethanol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Betamethasone:
Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Glycerine:
Species: Rabbit
Result: No eye irritation

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

Ethanol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

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:

Propylene glycol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
# SAFETY DATA SHEET

**Betamethasone (0.05%) Liquid 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>3.0</td>
<td>10/10/2020</td>
<td>4659297-00004</td>
<td>03/23/2020</td>
<td>07/11/2019</td>
</tr>
</tbody>
</table>

### Ethanol:
- **Test Type**: Local lymph node assay (LLNA)
- **Routes of exposure**: Skin contact
- **Species**: Mouse
- **Result**: negative

### Betamethasone:
- **Routes of exposure**: Dermal
- **Species**: Guinea pig
- **Result**: Weak sensitizer

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

### Components:

#### Glycerine:
- **Genotoxicity in vitro**:
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
- **Test Type**: Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Test Type**: Chromosome aberration test in vitro
  - Result: negative
- **Test Type**: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Result: negative

#### Propylene glycol:
- **Genotoxicity in vitro**:
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Genotoxicity in vivo**:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    - Species: Mouse
    - Application Route: Intraperitoneal injection
    - Result: negative

#### Ethanol:
- **Genotoxicity in vitro**:
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative
  - Test Type: Rodent dominant lethal test (germ cell) (in vivo)
    - Species: Mouse
    - Application Route: Ingestion
    - Result: equivocal
Betamethasone (0.05%) Liquid Formulation

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:

Glycerine:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage the unborn child.

Components:

Glycerine:
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

Propylene glycol:

Effects on fertility:
Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

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

Ethanol:

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

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.

STOT-repeated exposure
Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adren al gland) through prolonged or repeated exposure.
### Components:

**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:

**Glycerine:**
- **Species:** Rat
- **NOAEL:** 0.167 mg/l
- **LOAEL:** 0.622 mg/l
- **Application Route:** Inhalation (dust/mist/fume)
- **Exposure time:** 13 Weeks

**Species:** Rat
- **NOAEL:** 8,000 - 10,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 2 y

**Species:** Rabbit
- **NOAEL:** 5,040 mg/kg
- **Application Route:** Skin contact
- **Exposure time:** 45 Weeks

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

**Ethanol:**
- **Species:** Rat
- **NOAEL:** 1,280 mg/kg
- **LOAEL:** 3,156 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

**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:

Betamethasone:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glycerine:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1,955 mg/l
Exposure time: 48 h
Toxicity to microorganisms: NOEC (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

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)

**Betamethasone**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Americamysis</td>
<td>&gt; 50 mg/l</td>
<td>96 h</td>
</tr>
<tr>
<td>Pimephales promelas</td>
<td>0.052 mg/l</td>
<td>32 d</td>
</tr>
</tbody>
</table>

**Ethanol**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceriodaphnia dubia</td>
<td>13,020 mg/l</td>
<td>7 d</td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms**

**Betamethasone**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas putida</td>
<td>&gt; 20,000 mg/l</td>
<td>18 h</td>
</tr>
</tbody>
</table>

**Ethanol**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas putida</td>
<td>&gt; 20,000 mg/l</td>
<td>18 h</td>
</tr>
</tbody>
</table>

### Toxicity to fish

**Ethanol**

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pimephales promelas</td>
<td>&gt; 1,000 mg/l</td>
<td>96 h</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

**Betamethasone**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorella vulgaris</td>
<td>&gt; 34 mg/l</td>
<td>72 h</td>
</tr>
</tbody>
</table>

**Ethanol**

<table>
<thead>
<tr>
<th>Substance</th>
<th>ErC50</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorella vulgaris</td>
<td>275 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td>Pseudokirchneriella subcapitata</td>
<td>&gt; 34 mg/l</td>
<td>72 h</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**Betamethasone**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna</td>
<td>8 mg/l</td>
<td>21 d</td>
</tr>
</tbody>
</table>

**Ethanol**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceriodaphnia dubia</td>
<td>9.6 mg/l</td>
<td>9 d</td>
</tr>
<tr>
<td>Daphnia magna</td>
<td>9.6 mg/l</td>
<td>9 d</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

**Ethanol**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas putida</td>
<td>&gt; 20,000 mg/l</td>
<td>18 h</td>
</tr>
</tbody>
</table>

**Betamethasone**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata</td>
<td>&gt; 34 mg/l</td>
<td>96 h</td>
</tr>
</tbody>
</table>

### Toxicity to fish (Chronic toxicity)

**Betamethasone**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna</td>
<td>8 mg/l</td>
<td>21 d</td>
</tr>
</tbody>
</table>

**Ethanol**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oryzias latipes</td>
<td>0.07 µg/l</td>
<td>219 d</td>
</tr>
<tr>
<td>Pimephales promelas</td>
<td>0.052 mg/l</td>
<td>32 d</td>
</tr>
</tbody>
</table>
Persistence and degradability

**Components:**

**Glycerine:**
- Biodegradability: Result: Readily biodegradable.
- Biodegradation: 92%
- Exposure time: 30 d
- Method: OECD Test Guideline 301D

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

**Ethanol:**
- Biodegradability: Result: Readily biodegradable.
- Biodegradation: 84%
- Exposure time: 20 d

Bioaccumulative potential

**Components:**

**Glycerine:**
- Partition coefficient: n-octanol/water: log Pow: -1.75

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

**Ethanol:**
- Partition coefficient: n-octanol/water: log Pow: -0.35

**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.

Domestic regulation

49 CFR
UN/ID/NA number : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes (Betamethasone)
Remarks : Above applies only to containers over 119 gallons or 450 liters.; Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.
SAFETY DATA SHEET

Betamethasone (0.05%) Liquid Formulation

Version 3.0
Revision Date: 10/10/2020
SDS Number: 4659297-00004
Date of last issue: 03/23/2020
Date of first issue: 07/11/2019

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

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disodium hydrogenorthophosphate</td>
<td>7558-79-4</td>
<td>5000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
Glycerine 56-81-5
Propylene glycol 57-55-6
Water 7732-18-5
Disodium hydrogenorthophosphate 7558-79-4

California Permissible Exposure Limits for Chemical Contaminants
Glycerine 56-81-5

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSI : not determined
AICS : not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET
Betamethasone (0.05%) Liquid Formulation

Version 3.0 Revision Date: 10/10/2020 SDS Number: 4659297-00004 Date of last issue: 03/23/2020
Date of first issue: 07/11/2019

NFPA 704:

HMIS® IV:

- **HEALTH**: * 3
- **FLAMMABILITY**: 1
- **PHYSICAL HAZARD**: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / STEL: Short-term exposure limit
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA: 8-hour time weighted average
US WEEL / TWA: 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office
**SAFETY DATA SHEET**

**Betamethasone (0.05%) Liquid 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>3.0</td>
<td>10/10/2020</td>
<td>4659297-00004</td>
<td>03/23/2020</td>
<td>07/11/2019</td>
</tr>
</tbody>
</table>

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

Revision Date: 10/10/2020

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

US / Z8