SAFETY DATA SHEET
Betamethasone (0.05%) Lotion Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.05%) Lotion Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil  B-2220
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 ABNT NBR 14725 Standard
Flammable liquids : Category 2
Eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure : Category 3
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms : 
Signal Word : Danger
Hazard Statements : H225 Highly flammable liquid and vapor.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune
Precautionary Statements:

**Prevention:**
P201 Obtain special instructions before use.
P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Other hazards which do not result in classification
Vapors may form explosive mixture with air.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>Flammable liquids, Category 2 Eye irritation, Category 2A Specific target organ toxicity - single exposure, Category 3</td>
<td>&gt;= 30 &lt; 50</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>Acute toxicity (Inhalation), Category 2 Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland), Category 1 Long-term (chronic) aquatic hazard, Category 1</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 attention.
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 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 cause drowsiness or dizziness.
- 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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media | High volume water jet |

| Specific hazards during fire fighting | Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. 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. |
SAFETY DATA SHEET
Betamethasone (0.05%) Lotion Formulation

Version: 3.1
Revision Date: 09.04.2021
SDS Number: 4371262-00006
Date of last issue: 30.09.2020
Date of first issue: 30.05.2019

Personal precautions, protective equipment and emergency procedures:
- Remove all sources of ignition.
- Ventilate the area.
- 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:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapors/mists with a water spray jet.
- 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.
- Use explosion-proof electrical, ventilating and lighting equipment.

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.
- Non-sparking tools should be used.
- Keep container tightly closed.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Take precautionary measures against static discharges.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the...
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.


Materials to avoid: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Flammable solids
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Substances and mixtures which in contact with water emit flammable gases
- 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>LT</td>
<td>310 ppm 765 mg/m³</td>
<td>BR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Absorption through the skin, Degree of harmfulness: medium</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Biological occupational exposure limits

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

Use explosion-proof electrical, ventilating and lighting equipment.

### 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**

Organic vapor Type

**Hand protection**

Material

Chemical-resistant gloves

**Remarks**

Consider double gloving. Take note that the product is flammable, which may impact the selection of hand 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 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

lotion

**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 : 21.4 °C
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 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. Highly flammable liquid and vapor. Vapors may form explosive mixture with air. Can react with strong oxidizing agents.

## Possibility of hazardous reactions
Highly flammable liquid and vapor. Vapors may form explosive mixture with air. Can react with strong oxidizing agents.

## Conditions to avoid
Heat, flames and sparks. Oxidizing agents

## 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

**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

**Betamethasone:**
- **Species**: Rabbit
- **Result**: Mild skin irritation
Serious eye damage/eye irritation
Causes serious eye irritation.

**Components:**

**Propan-2-ol:**
- **Species:** Rabbit
- **Result:** Irritation to eyes, reversing within 21 days

**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

**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
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

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

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**
May cause drowsiness or dizziness.

**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:**

**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

**Betamethasone:**
Species: Rabbit
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 10 - 30 d
Target Organs: Pituitary gland, Immune system, muscle
SECTION 11. TOXICOLOGICAL INFORMATION

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:

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

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 %

Bioaccumulative potential

Components:

Propan-2-ol:
Partition coefficient: n-octanol/water: log Pow: 0,05

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. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other
sources of ignition. They may explode and cause injury and/or death.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 1219
Proper shipping name : ISOPROPAHOL SOLUTION
Class : 3
Packing group : II
Labels :

IATA-DGR
UN/ID No. : UN 1219
Proper shipping name : Isopropanol solution
Class : 3
Packing group : II
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

IMDG-Code
UN number : UN 1219
Proper shipping name : ISOPROPAHOL SOLUTION (Betamethasone)
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
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

ANTT
UN number : UN 1219
Proper shipping name : ISOPROPAHOL, SOLUTION
Class : 3
Packing group : II
Labels : 3
Hazard Identification Number : 33

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Propan-2-ol

International Regulations

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


Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

BR BEI : Brazil. NR7. Parameters for Biological Control of Occupational Exposure to Some Chemical Agents

BR OEL : Brazil. NR 15 - Unhealthy activities and operations

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : Short-term exposure limit

BR OEL / LT : Up to 48 hours /week
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.