SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.05%) Liquid 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
Reproductive toxicity : Category 1B
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 : 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.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
SAFETY DATA SHEET
Betamethasone (0.05%) Liquid Formulation

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

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol#</td>
<td>Ethanol</td>
<td>64-17-5</td>
<td>Flammable liquids, Category 2 Eye irritation, Category 2A</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
<tr>
<td>Betamethasone</td>
<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>

# Voluntarily-disclosed non-hazardous substance

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages 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.

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.

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>Ethanol</td>
<td>64-17-5</td>
<td>LT</td>
<td>780 ppm 1.480 mg/m³</td>
<td>BR OEL</td>
</tr>
</tbody>
</table>
Further information: Degree of harmfulness: minimum

<table>
<thead>
<tr>
<th>Substance</th>
<th>STEL</th>
<th>TWA</th>
<th>Internal</th>
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</thead>
<tbody>
<tr>
<td>Betamethasone</td>
<td>1.000 ppm</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Further information: Skin

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

Engineering measures:

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection:

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type:

Combined particulates and organic vapor type

Hand protection:

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection:

Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection:

Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: No data available

Odor: No data available

OdorThreshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available
Betamethasone (0.05%) Liquid Formulation

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:

**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:

**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:

**Ethanol:**
- Species: Rabbit
  Method: OECD Test Guideline 405
  Result: Irritation to eyes, reversing within 21 days
Betamethasone (0.05%) Liquid Formulation

<table>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 23.03.2020</th>
<th>Date of first issue: 11.07.2019</th>
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<td>10.10.2020</td>
<td>4659287-00004</td>
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</table>

**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:**

**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:**

**Ethanol:**

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

  Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

- **Genotoxicity in vivo**
  - Test Type: Rodent dominant lethal test (germ cell) (in vivo)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: equivocal

**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

---

8 / 15
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.

Reproductive toxicity  
May damage the unborn child.

Components:

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, 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:**

**Ethanol:**
- **Species:** Rat
- **NOAEL:** 1.280 mg/kg
- **LOAEL:** 3.156 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

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

**Experience with human exposure**

**Components:**

**Betamethasone:**
- **Inhalation:** Target Organs: Adrenal gland
- **Skin contact:** Symptoms: Redness, pruritus, Irritation
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

**Ethanol:**
- Toxicity to fish: $LC_50$ (Pimephales promelas (fathead minnow)): $> 1.000$ mg/l
  Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: $EC_50$ (Ceriodaphnia (water flea)): $> 1.000$ mg/l
  Exposure time: 48 h
- Toxicity to algae/aquatic plants:
  - $ErC_50$ (Chlorella vulgaris (Fresh water algae)): 275 mg/l
    Exposure time: 72 h
  - $EC_10$ (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
    Exposure time: 72 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): $NOEC$ (Daphnia magna (Water flea)): 9.6 mg/l
  Exposure time: 9 d
- Toxicity to microorganisms:
  - $EC_50$ (Pseudomonas putida): 6.500 mg/l
    Exposure time: 16 h

**Betamethasone:**
- Toxicity to daphnia and other aquatic invertebrates: $EC_50$ (Americamysis): $> 50$ mg/l
  Exposure time: 96 h
- Toxicity to algae/aquatic plants:
  - $EC_50$ (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): 1.000
Persistence and degradability

Components:

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

Bioaccumulative potential

Components:

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

ANTT
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)

Class: 9
Packing group: III
Labels: 9
Hazard Identification Number: 90

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: Not applicable

International Regulations
The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
SECTION 16. OTHER INFORMATION

Further information

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

Full text of other abbreviations
ACGIH: USA, ACGIH Threshold Limit Values (TLV)
BR OEL: Brazil. NR 15 - Unhealthy activities and operations
ACGIH / STEL: Short-term exposure limit
BR OEL / LT: Up to 48 hours /week

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; 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; 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; NZIoG - 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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.

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