1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.05%) Ointment Formulation

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

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

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : ointment
Colour : white to off-white
Odour : No data available

May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : ![Danger](image)

Signal word : Danger
Hazard statements : H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
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 dust/ fume/ gas/ mist/ vapours/ spray.
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:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards
Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components:**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 70 -&lt; 90</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 -&lt; 0.1</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.
Betamethasone (0.05%) Ointment 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>2020/03/23</td>
<td>1681984-00007</td>
<td>2019/09/13</td>
<td>2017/05/18</td>
</tr>
</tbody>
</table>

**5. FIREFIGHTING 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>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
</tbody>
</table>

Specific hazards during firefighting:

- Vapours 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 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 and personal protective equipment recommendations.

Environmental precautions:

- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
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 swallow.
                      : Avoid contact with eyes.
                      : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
                      : Keep container tightly closed.
                      : Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact : Oxidizing agents

Storage
Conditions for safe storage : Keep in properly labelled 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
Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Betamethasone (0.05%) Ointment Formulation

<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>Betamethasone</th>
<th>TWA (Respirable particulate matter)</th>
<th>3 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td></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>Further information: Skin</td>
<td></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>

Engineering measures:
- Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).
- 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.

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: Particulates type
  - Eye/face 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.

Hygiene measures:
- Hand protection:
  - Material: Chemical-resistant gloves
  - Remarks: Consider double gloving.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES
**SAFETY DATA SHEET**

**Betamethasone (0.05%) Ointment Formulation**

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</table>

- **Appearance**: ointment
- **Colour**: white to off-white
- **Odour**: No data available
- **Odour 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**: > 93.3 °C

- **Evaporation rate**: Not applicable
- **Flammability (solid, gas)**: Not classified as a flammability hazard
- **Flammability (liquids)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available

- **Relative vapour density**: Not applicable
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**: No data available
- **Water solubility**: No data available

- **Partition coefficient: n-octanol/water**: Not applicable
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available

- **Viscosity**
  - **Viscosity, kinematic**: Not applicable
  - **Explosive properties**: Not explosive

- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
Betamethasone (0.05%) Ointment Formulation

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- Vapours may form explosive mixture with air.
- Can react with strong oxidizing agents.

Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

**Petrolatum:**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

**Propylene glycol monostearate:**
Acute oral toxicity: LD50 (Mouse): > 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:

Petrolatum:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Propylene glycol monostearate:
Result: No skin irritation

Betamethasone:
Species: Rabbit
Result: Mild skin irritation
Remarks: Based on data from similar materials

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

Components:

Petrolatum:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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:

Petrolatum:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Betamethasone:
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer
Betamethasone (0.05%) Ointment Formulation

Germ cell mutagenicity
Not classified based on available information.

Components:

**Petrolatum:**
- Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
  - Result: negative
  - Remarks: Based on data from similar materials
- Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

**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:

**Petrolatum:**
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Result: negative

Reproductive toxicity
May damage the unborn child.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Betamethasone (0.05%) Ointment Formulation

Components:

Petrolatum:
- Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
  Species: Rat
  Application Route: Ingestion
  Result: negative
  Remarks: Based on data from similar materials

- Effects on foetal development: Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Skin contact
  Result: negative
  Remarks: Based on data from similar materials

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
  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 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:**

**Petrolatum:**
- **Species:** Rat
- **NOAEL:** 5,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 2 yr

**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

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Petrolatum:**
## Toxicity to fish
- **LL50** (Pimephales promelas (fathead minnow)): > 100 mg/l
  - Exposure time: 96 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 203
  - Remarks: Based on data from similar materials

## Toxicity to daphnia and other aquatic invertebrates
- **EC50** (Daphnia magna (Water flea)): > 10,000 mg/l
  - Exposure time: 48 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 203
  - Remarks: Based on data from similar materials

## Toxicity to algae/aquatic plants
- **NOEL** (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

## Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **NOEC** (Daphnia magna (Water flea)): 10 mg/l
  - Exposure time: 21 d
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

## 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:**

**Petrolatum:**
- **Biodegradability:**
  - Result: Not readily biodegradable.
  - Biodegradation: 31 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301F
  - Remarks: Based on data from similar materials

Bioaccumulative potential

**Components:**

**Betamethasone:**
- **Partition coefficient: n-octanol/water:**
  - log Pow: 2.11

Mobility in soil
- No data available

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 3077
- **Proper shipping name:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)

**Class:** 9
**Packing group:** III
**Labels:** Miscellaneous

**IATA-DGR**
- **UN/ID No.:** UN 3077
- **Proper shipping name:** Environmentally hazardous substance, solid, n.o.s. (betamethasone)

**Class:** 9
**Packing group:** III
**Labels:** Miscellaneous
**Packing instruction (cargo)**: 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)

Class: 9
Subsidiary risk: ENVIRONM.
Packing group: III
Labels: 9 (ENVIRONM.)
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
GB 6944/12268
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)

Class: 9
Packing group: III
Labels: 9

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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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
Betamethasone (0.05%) Ointment Formulation

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

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

Date format: yyyy/mm/dd

Full text of other abbreviations:
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

Disclaimer:
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 use.
Betamethasone (0.05%) Ointment Formulation

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.

CN / EN