SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

SECTION 1. IDENTIFICATION

Product name : Betamethasone (0.05%) Ointment Formulation
Other means of identification : No data available

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTeward@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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 dust/ fume/ gas/ mist/ vapors/ spray.
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/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
</tr>
</tbody>
</table>

<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;= 80 - &lt;= 100</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.01 - &lt; 0.1</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range 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

Unsuitable extinguishing media:
None known.

Specific hazards during firefighting:
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.

SECTION 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.
Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal.
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 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.

**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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Vapour and aerosols)</td>
<td>50 ppm 155 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</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>
</tbody>
</table>

**Further information:** Skin
- Wipe limit 10 µg/100 cm² Internal

**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
- **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.

**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**: ointment
- **Color**: white to off-white
- **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 : > 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

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)
   Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition 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.

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 : Vapors 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.
 SECTION 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

**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:**

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

**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
**SAFETY DATA SHEET**

**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>
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<tbody>
<tr>
<td>4.0</td>
<td>03/23/2020</td>
<td>1681987-00007</td>
<td>09/13/2019</td>
<td>05/18/2017</td>
</tr>
</tbody>
</table>

**Method**

<table>
<thead>
<tr>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Propylene glycol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Propylene glycol monostearate:**

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild skin irritation</td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Propylene glycol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buehler Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Propylene glycol:
- **Test Type**: Maximization Test
- **Routes of exposure**: Skin contact
- **Species**: Guinea pig
- **Result**: negative

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

#### 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

#### 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

#### 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)
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

**Propylene glycol:**

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

**Reproductive toxicity**

May damage the unborn child.

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

**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
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:  
Petrolatum:  
Species: Rat  
NOAEL: 5,000 mg/kg  
Application Route: Ingestion  
Exposure time: 2 y  
Propylene glycol:  
Species: Rat, male  
NOAEL: 1,700 mg/kg  
Application Route: Ingestion  
Exposure time: 2 y
**Betamethasone (0.05%) Ointment Formulation**

**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:**

**Petrolatum:**

- **Toxicity to fish**
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 203
  - Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates**
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

- **Toxicity to algae/aquatic**
  - NOEL (Pseudokirchneriella subcapitata (green algae)): >=
### Plants

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Daphnia magna (Water flea)): 10 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

### Propylene glycol

<table>
<thead>
<tr>
<th>Test substance</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

### Betamethasone

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>32 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>219 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 229</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Daphnia magna (Water flea)): 8 mg/l</th>
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</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Daphnia magna (Water flea)): 8 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Daphnia magna (Water flea)): 10 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
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</tr>
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<td>Remarks</td>
<td>Based on data from similar materials</td>
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</tbody>
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<td>Remarks</td>
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</tbody>
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<th>NOEC (Daphnia magna (Water flea)): 8 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Daphnia magna (Water flea)): 8 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates:**

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<tr>
<th>Test substance</th>
<th>NOEC (Daphnia magna (Water flea)): 10 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
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<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

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

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

Bioaccumulative potential

Components:

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

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 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

Class : 9
Packing group : III
Labels : 9

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 aircraft) : 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.

Domestic regulation

TDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Betamethasone)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(Betamethasone)

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

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

Version 4.0  Revision Date: 03/23/2020  SDS Number: 1681987-00007  Date of last issue: 09/13/2019  Date of first issue: 05/18/2017

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>CA AB OEL</td>
<td>Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)</td>
</tr>
<tr>
<td>CA BC OEL</td>
<td>Canada. British Columbia OEL</td>
</tr>
<tr>
<td>CA ON OEL</td>
<td>Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.</td>
</tr>
<tr>
<td>CA QC OEL</td>
<td>Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>CA AB OEL / TWA</td>
<td>8-hour Occupational exposure limit</td>
</tr>
<tr>
<td>CA BC OEL / STEL</td>
<td>15-minute occupational exposure limit</td>
</tr>
<tr>
<td>CA BC OEL / TWA</td>
<td>8-hour time weighted average</td>
</tr>
<tr>
<td>CA ON OEL / TWA</td>
<td>Time-Weighted Average Limit (TWA)</td>
</tr>
<tr>
<td>CA QC OEL / TWAEV</td>
<td>Time-weighted average exposure value</td>
</tr>
<tr>
<td>CA QC OEL / STEV</td>
<td>Short-term exposure value</td>
</tr>
</tbody>
</table>

AICS - Australian Inventory of Chemical Substances; 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 Standardisation; 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; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; 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

Revision Date: 03/23/2020

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.