SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

SECTION 1. IDENTIFICATION

Product name : Betamethasone (0.05%) Ointment Formulation

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 29 CFR 1910.1200
Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

GHS label elements
Hazard pictograms

Signal Word : Danger

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

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe 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.

Storage:
P405 Store locked up.
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Version 4.0  Revision Date: 03/23/2020  SDS Number: 1681972-00007  Date of last issue: 09/13/2019  Date of first issue: 05/18/2017

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>
</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;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 20</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 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
SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

Unsuitable extinguishing media : None known.
Specific hazards during fire fighting : 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>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST (Mist)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

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

Hand protection

Material : Chemical-resistant gloves
Remarks : Consider double gloving.
Eye protection : 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 : > 199.9 °F / > 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) : No data available
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Not applicable
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:

<table>
<thead>
<tr>
<th>Petrolatum:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity:</td>
<td>( \text{LD50 (Rat)}: &gt; 5,000 \text{ mg/kg} )</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 401</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Acute dermal toxicity:</td>
<td>( \text{LD50 (Rat)}: &gt; 2,000 \text{ mg/kg} )</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 402</td>
</tr>
<tr>
<td>Assessment:</td>
<td>The substance or mixture has no acute dermal toxicity</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Propylene glycol:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity:</td>
<td>( \text{LD50 (Rat)}: &gt; 5,000 \text{ mg/kg} )</td>
</tr>
<tr>
<td>Acute inhalation toxicity:</td>
<td>( \text{LC50 (Rabbit)}: &gt; 159 \text{ mg/l} )</td>
</tr>
<tr>
<td>Exposure time:</td>
<td>4 h</td>
</tr>
<tr>
<td>Test atmosphere:</td>
<td>dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity:</td>
<td>( \text{LD50 (Rabbit)}: &gt; 2,000 \text{ mg/kg} )</td>
</tr>
<tr>
<td>Assessment:</td>
<td>The substance or mixture has no acute dermal toxicity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Propylene glycol monostearate:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity:</td>
<td>( \text{LD50 (Mouse)}: &gt; 5,000 \text{ mg/kg} )</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Betamethasone:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity:</td>
<td>( \text{LD50 (Rat)}: &gt; 5,000 \text{ mg/kg} )</td>
</tr>
<tr>
<td>( \text{LD50 (Mouse)}: &gt; 4,500 \text{ mg/kg} )</td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity:</td>
<td>( \text{LC50 (Rat)}: 0.4 \text{ mg/l} )</td>
</tr>
<tr>
<td>Exposure time:</td>
<td>4 h</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Petrolatum:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Species:</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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

Propylene glycol monostearate:
Result: No skin irritation

Betamethasone:
Species: Rabbit
Result: Mild skin irritation

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

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

Betamethasone:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:
Petrolatum:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
### Remarks
- Based on data from similar materials

#### 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 - Assesment: 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

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

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

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

Reproductive toxicity
May damage the unborn child.

Components:

| Petrolatum: | 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
  - 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:**

**Petrolatum:**

- **Species**: Rat
- **NOAEL**: 5,000 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 2 y
Betamethasone (0.05%) Ointment Formulation

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

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: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
- Exposure time: 96 h
- Test substance: Water Accommodated Fraction
**Betamethasone (0.05%) Ointment Formulation**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 203</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
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</tr>
<tr>
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<tr>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 203</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
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**Propylene glycol:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>OECD Test Guideline 201</td>
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**Betamethasone:**

<table>
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<tr>
<th>Method</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
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<tr>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>EC50 or NOEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>48 h</td>
<td>&gt; 10,000 mg/l</td>
</tr>
<tr>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td>&gt;= 100 mg/l</td>
</tr>
<tr>
<td>Water Accommodated Fraction</td>
<td>21 d</td>
<td>10 mg/l</td>
</tr>
<tr>
<td>Water Accommodated Fraction</td>
<td>7 d</td>
<td>13,020 mg/l</td>
</tr>
<tr>
<td>Water Accommodated Fraction</td>
<td>18 h</td>
<td>&gt; 20,000 mg/l</td>
</tr>
<tr>
<td>Water Accommodated Fraction</td>
<td>96 h</td>
<td>&gt; 50 mg/l</td>
</tr>
<tr>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td>&gt; 34 mg/l</td>
</tr>
<tr>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td>34 mg/l</td>
</tr>
<tr>
<td>Pimephales promelas (fathead minnow)</td>
<td>72 h</td>
<td>0.052 mg/l</td>
</tr>
</tbody>
</table>
Exposure 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

Persistence and degradability

Components:

- 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

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)  
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**

**49 CFR**  
UN/ID/NA number: UN 3077  
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Betamethasone)  
Class: 9  
Packing group: III  
Labels: CLASS 9  
ERG Code: 171  
Marine pollutant: yes(Betamethasone)  
Remarks: Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO
(IATA) or IMO.

**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**

**EPCRA - Emergency Planning and Community Right-to-Know**

**CERCLA Reportable Quantity**
This material does not contain any components with a CERCLA RQ.

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

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

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

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

**US State Regulations**

**Pennsylvania Right To Know**
- Petrolatum 8009-03-8
- Propylene glycol 57-55-6
- Hydrocarbon wax 8001-75-0

**California List of Hazardous Substances**
- Petrolatum 8009-03-8

**California Permissible Exposure Limits for Chemical Contaminants**
- Petrolatum 8009-03-8

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
SAFETY DATA SHEET
Betamethasone (0.05%) Ointment Formulation

Version 4.0  Revision Date: 03/23/2020  SDS Number: 1681972-00007  Date of last issue: 09/13/2019
Date of first issue: 05/18/2017

NFPA 704:
HMIS® IV:

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<th>Instability</th>
<th>Health</th>
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<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
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<tbody>
<tr>
<td>* 3</td>
<td>1</td>
<td>0</td>
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</table>

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

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA : 8-hour time weighted average
US WEEL / TWA : 8-hr TWA

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSG - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable
SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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


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.

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