SECTION 1. IDENTIFICATION
Product name: Betamethasone / Clotrimazole Ointment Formulation

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33nd floor
         Jersey City, New Jersey, U.S.A 07302
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 the OSHA Hazard Communication Standard (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)

Specific target organ toxicity - repeated exposure (Oral):
- Category 2 (Liver, Kidney, Adrenal gland)

GHS label elements
Hazard pictograms: 

Signal Word: Danger

Hazard Statements:
- H360Df May damage the unborn child. Suspected of damaging fertility.
- H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
- H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

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 or 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.
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.

Most important symptoms and effects, both acute and delayed : May damage the unborn child. Suspected of damaging fertility.
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.
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:
- 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.
- 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:
- 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 breathe dust, fume, gas, mist, vapors or spray.
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.

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>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
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<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
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<td></td>
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<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>clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
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<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: 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: Viscous semi-solid
Color: No data available
Odor: No data available
### Odor Threshold
- No data available

### pH
- No data available

### Melting point/freezing point
- No data available

### Initial boiling point and boiling range
- No data available

### Flash point
- Not applicable

### Evaporation rate
- Not applicable

### Flammability (solid, gas)
- Not classified as a flammability hazard

### Flammability (liquids)
- No data available

### Upper explosion limit / Upper flammability limit
- No data available

### Lower explosion limit / Lower flammability limit
- No data available

### Vapor pressure
- Not applicable

### Relative vapor density
- Not applicable

### Relative density
- No data available

### Density
- No data available

### Solubility(ies)
- No data available
  - Water solubility

### Partition coefficient: n-octanol/water
- Not applicable

### Autoignition temperature
- No data available

### Decomposition temperature
- No data available

### Viscosity
- Not applicable
  - Viscosity, kinematic

### 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.
**SAFETY DATA SHEET**

**Betamethasone / Clotrimazole 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>
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<td>7.4</td>
<td>10/10/2020</td>
<td>610358-00013</td>
<td>03/23/2020</td>
<td>04/08/2016</td>
</tr>
</tbody>
</table>

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**

**Skin contact**

**Ingestion**

**Eye contact**

**Acute toxicity**

Not classified based on available information.

**Product:**

**Acute oral toxicity**

- Acute toxicity estimate: > 5,000 mg/kg
  - Method: Calculation method

**Acute dermal toxicity**

- Acute toxicity estimate: > 5,000 mg/kg
  - Method: Calculation method

**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

**White mineral oil (petroleum):**

**Acute oral toxicity**

- LD50 (Rat): > 5,000 mg/kg

**Acute inhalation toxicity**

- LC50 (Rat): > 5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity

**Acute dermal toxicity**

- LD50 (Rabbit): > 2,000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity

**clotrimazole:**
Acute oral toxicity: LD50 (Rat): 708 mg/kg  
LD50 (Mouse): 761 mg/kg  
LD50 (Rabbit): > 1,000 mg/kg  

Acute inhalation toxicity: LC50 (Rat): > 0.73 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  

Acute dermal toxicity: LD50 (Mouse): 923 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  

**White mineral oil (petroleum):**  
Species: Rabbit  
Result: No skin irritation  

**Clotrimazole:**  
Species: Rabbit  
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

White mineral oil (petroleum):
Species : Rabbit
Result : No eye irritation

clotrimazole:
Species : Rabbit
Result : Mild eye irritation

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

White mineral oil (petroleum):
Test Type : Buehler 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

White mineral oil (petroleum):
Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

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

clotrimazole:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: Chromosome aberration test in vitro
  - Result: negative
- Test Type: in vitro micronucleus test
  - Result: negative

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Rat
  - Application Route: Oral
  - Result: negative
  
  Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)
  - Species: Hamster
  - Result: negative

Germ cell mutagenicity - Assessment:
- Weight of evidence does not support classification as a germ cell mutagen.

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

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Oral  
Result: equivocal

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

White mineral oil (petroleum):
Species: Rat  
Application Route: Ingestion  
Exposure time: 24 Months  
Result: negative

clotrimazole:
Species: Rat  
Application Route: Oral  
Exposure time: 78 weeks  
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. Suspected of damaging fertility.
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

White mineral oil (petroleum):
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Skin contact
Result: negative

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

clotrimazole:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: LOAEL: 50 mg/kg body weight
Result: Effects on fertility.

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg body weight
Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Embryo-fetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 200 mg/kg body weight
Result: No effects on fetal development.
Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 180 mg/kg body weight  
Result: No effects on fetal development.

Reproductive toxicity - Assessment: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

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.  
May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

Components:  

clotrimazole:  
Target Organs Assessment: Liver, Kidney, Adrenal gland  
May cause damage to organs through prolonged or repeated exposure.

Betamethasone:  
Target Organs Assessment: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland  
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

**White mineral oil (petroleum):**
- Species: Rat
- LOAEL: 160 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days
- Species: Rat
- LOAEL: >= 1 mg/l
- Application Route: Inhalation (dust/mist/fume)
- Exposure time: 4 Weeks
- Method: OECD Test Guideline 412

**Clotrimazole:**
- Species: Rabbit
- LOAEL: 5 - 40 mg/kg
- Application Route: Skin contact
- Exposure time: 3 Weeks
- Target Organs: Skin
- Symptoms: Edema, Fissuring, Necrosis, Redness
- Species: Rat
- LOAEL: 10 mg/kg
- Application Route: Oral
- Exposure time: 18 Months
- Target Organs: Liver, Kidney, Adrenal gland
- Species: Dog
- LOAEL: 25 mg/kg
- Application Route: Oral
- Exposure time: 6 - 12 Months
- Target Organs: Adrenal gland
- Symptoms: Salivation, Lachrymation, Vomiting

**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:

clotrimazole:
Skin contact: Symptoms: Rash, Itching, Blistering, Edema, Redness
Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea

Betamethasone:
Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritus, 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
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
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
White mineral oil (petroleum):

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
- Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): > 100 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

- NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):

- NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
- Exposure time: 28 d

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

- NOEC (Daphnia magna (Water flea)): 1,000 mg/l
- Exposure time: 21 d

**Clotrimazole:**

Toxicity to fish:

- LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l
- Exposure time: 96 h
- Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): 0.02 mg/l
- Exposure time: 48 h

Toxicity to algae/aquatic plants:

- EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l
- Exposure time: 72 h
- NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l
- Exposure time: 72 h

Toxicity to fish (Chronic toxicity):

- NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l
- Exposure time: 32 d
- Method: OECD Test Guideline 210

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

- NOEC (Daphnia magna (Water flea)): 0.01 mg/l
- Exposure time: 21 d
- Method: OECD Test Guideline 211

Toxicity to microorganisms:

- EC50: > 10,000 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
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

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

White mineral oil (petroleum):
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

Clotrimazole:
Stability in water: Hydrolysis: 50 % (242 d)
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

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, clotrimazole)
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, clotrimazole)
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, clotrimazole)
Class: 9
Packing group: III
 våpenledning av Annex II av MARPOL 73/78 och den IBC Code

Hjemmolyktig för den produkt som tillhandahålls.

Domestic regulation

49 CFR
UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Betamethasone, clotrimazole)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes (Betamethasone, clotrimazole)
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 users

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

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

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Betamethasone / Clotrimazole Ointment Formulation

Version 7.4  Revision Date: 10/10/2020  SDS Number: 610358-00013  Date of last issue: 03/23/2020
Date of first issue: 04/08/2016

California List of Hazardous Substances

Petrolatum  8009-03-8
White mineral oil (petroleum)  8042-47-5

California Permissible Exposure Limits for Chemical Contaminants

Petrolatum  8009-03-8
White mineral oil (petroleum)  8042-47-5

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

NFPA 704:

HMIS® IV:

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
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
SAFETY DATA SHEET

Betamethasone / Clotrimazole Ointment Formulation

Version 7.4  Revision Date: 10/10/2020  SDS Number: 610358-00013  Date of last issue: 03/23/2020  Date of first issue: 04/08/2016

All terms and conditions in this Safety Data Sheet apply 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 other materials or in any process, unless specified in the text. Material users should refer to 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.

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

Revision Date: 10/10/2020

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.

US / Z8