1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone / Clotrimazole Ointment Formulation

Supplier's company name, address and phone number
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard : Category 2
Long-term (chronic) aquatic hazard : Category 1

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.
                   H401 Toxic to aquatic life.
                   H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  

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

Storage:  
P405 Store locked up.  

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

Other hazards which do not result in classification  
None known.  

3. COMPOSITION/INFORMATION ON INGREDIENTS  

Substance / Mixture : Mixture  

Components  

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 90 - &lt;= 100</td>
<td></td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES  

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.  

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.

5. FIREFIGHTING 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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (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.
7. HANDLING AND STORAGE

Handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust, fume, gas, mist, vapours 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.

Avoidance of contact:
- Oxidizing agents

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.

Storage

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>OEL-M (Mist)</td>
<td>3 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
</tbody>
</table>

Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to hu-
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Inhalable particulate matter)</th>
<th>OEL-M (Mist)</th>
<th>JP OEL-JSOH</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal protective equipment</td>
<td>Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter type: Combined particulates and organic vapour type Hand protection: Chemical-resistant gloves</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye protection</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Betamethasone / Clotrimazole Ointment Formulation

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Viscous semi-solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Density and / or relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle characteristics:
Particle size: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

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: > 2,000 mg/kg
   Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 2,000 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
<table>
<thead>
<tr>
<th>Components:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Petrolatum:</strong></td>
</tr>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result: No skin irritation</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

| **clotrimazole:** |
| Species: Rabbit |
| Result: No skin irritation |

| **betamethasone:** |
| Species: Rabbit |

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.
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 sensitisation**

**Respiratory sensitisation**
Not classified based on available information.

**Skin sensitisation**
Not classified based on available information.

**Components:**

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

**White mineral oil (petroleum):**
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

**Betamethasone:**
Exposure routes: 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
SAFETY DATA SHEET

Betamethasone / Clotrimazole Ointment Formulation

Version: 6.1  
Revision Date: 2020/10/10  
SDS Number: 610352-00013  
Date of last issue: 2020/03/23  
Date of first issue: 2016/04/08

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

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

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

Carcinogenicity
Not classified based on available information.

Components:

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

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

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

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

  Test Type: Embryo-foetal development
  Species: Mouse
  Application Route: Oral
  Developmental Toxicity: NOAEL: 200 mg/kg body weight
  Result: No effects on foetal development
Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 180 mg/kg body weight
Result: No effects on foetal 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 foetal development:
: Species: Rabbit
  Application Route: Intramuscular
  Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
  Result: Fetotoxicity, Malformations were observed.

  Species: Rat
  Application Route: Subcutaneous
  Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
  Result: Malformations were observed.

  Species: Mouse
  Application Route: Intramuscular
  Developmental Toxicity: LOAEL: 1 mg/kg body weight
  Result: Malformations were observed.

Reproductive toxicity - Assessment:
: Clear evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

**Components:**

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

**betamethasone:**
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

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

**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: Oedema, 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, Oedema, Redness
Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

betamethasone:
Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritis, Irritation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

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

Toxicity to algae/aquatic: NOEL (Pseudokirchneriella subcapitata (green algae)): >=
## Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**Test substance:** Water Accommodated Fraction  
**Method:** OECD Test Guideline 201  
**Remarks:** Based on data from similar materials

### White mineral oil (petroleum):

**Toxicity to fish**  
**Exposure time:** 96 h  
**Method:** OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates**  
**Exposure time:** 48 h  
**Method:** OECD Test Guideline 202

**Toxicity to algae/aquatic plants**  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201

**Toxicity to fish (Chronic toxicity)**  
**Exposure time:** 28 d

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**  
**Exposure time:** 21 d

### clotrimazole:

**Toxicity to fish**  
**Exposure time:** 96 h  
**Method:** OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates**  
**Exposure time:** 48 h

**Toxicity to algae/aquatic plants**  
**Exposure time:** 72 h  
**NOEC:** 0.017 mg/l

**M-Factor (Acute aquatic toxicity)**  
**Toxicity to fish (Chronic toxicity)**  
**Exposure time:** 32 d  
**Method:** OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**  
**NOEC:** 0.01 mg/l
### aquatic invertebrates (Chronic toxicity)
- **Exposure time:** 21 d
- **Method:** OECD Test Guideline 211

### M-Factor (Chronic aquatic toxicity)
- **Toxicity to microorganisms:**
  - **EC50:** > 10,000 mg/l
  - **Exposure time:** 3 h
  - **Test Type:** Respiration inhibition
  - **Method:** OECD Test Guideline 209
- **Value:** 10

### betamethasone:
- **Toxicity to daphnia and other aquatic invertebrates:**
  - **EC50 (Americamysis):** > 50 mg/l
  - **Exposure time:** 96 h
- **Toxicity to algae/aquatic plants:**
  - **EC50 (Pseudokirchneriella subcapitata (green algae)):** > 34 mg/l
  - **Exposure time:** 72 h
  - **Method:** OECD Test Guideline 201
  - **Remarks:** No toxicity at the limit of solubility
  - **NOEC (Pseudokirchneriella subcapitata (green algae)):** 34 mg/l
  - **Exposure time:** 72 h
  - **Method:** OECD Test Guideline 201
  - **Remarks:** No toxicity at the limit of solubility
- **Toxicity to fish (Chronic toxicity):**
  - **NOEC (Pimephales promelas (fathead minnow)):** 0.052 mg/l
  - **Exposure time:** 32 d
  - **Method:** OECD Test Guideline 210
  - **NOEC (Oryzias latipes (Japanese medaka)):** 0.07 µg/l
  - **Exposure time:** 219 d
  - **Method:** OECD Test Guideline 229

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **NOEC (Daphnia magna (Water flea)):** 8 mg/l
- **Exposure time:** 21 d
- **Method:** OECD Test Guideline 211
- **M-Factor (Chronic aquatic toxicity):** 1,000

### Persistence and degradability

**Components:**

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

**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

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone, 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): 956
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

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<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
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<tr>
<td>Mineral oil</td>
<td>168</td>
<td>&gt;=90 - &lt;=100</td>
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Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

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<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance(Category Y)
Pack transportation : Classified as marine pollutant
SAFETY DATA SHEET
Betamethasone / Clotrimazole Ointment Formulation

Version 6.1  Revision Date: 2020/10/10  SDS Number: 610352-00013  Date of last issue: 2020/03/23  Date of first issue: 2016/04/08

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)

- ACGIH / TWA: 8-hour, time-weighted average
- JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect
<table>
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<tr>
<th>Version</th>
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<td>2016/04/08</td>
</tr>
</tbody>
</table>

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

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JP / EN