1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone / Clotrimazole Ointment Formulation

Supplier's company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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 protec-
tion/ 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  

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixtures</th>
</tr>
</thead>
</table>

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.
3.23
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 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.
7. HANDLING AND STORAGE

Handling
Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling : Do not get on skin or clothing.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents
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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<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>TWA (Inhalable particulate)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Viscous semi-solid
Colours: No data available
Odours: No data available
Odour threshold: No data available
Melting point/freezing point: No data available
Boiling point, initial boiling point and boiling range: No data available
Flammability (solid, gas): Not classified as a flammability hazard
Flammability (liquids): No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / upper flammability limit: No data available
Lower explosion limit / lower flammability limit: No data available
Flash point: Not applicable
Decomposition temperature: No data available
pH: No data available

Evaporation rate: Not applicable
Auto-ignition temperature: No data available
Viscosity
Viscosity, kinematic: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: Not applicable
Density and/or relative density
Density: No data available
Relative density: No data available
Relative vapour density: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Betamethasone / Clotrimazole Ointment Formulation

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

**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 inhala-
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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum:</td>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>White mineral oil (petroleum):</td>
<td>Rabbit</td>
<td></td>
<td>No eye irritation</td>
<td></td>
</tr>
<tr>
<td>clotrimazole:</td>
<td>Rabbit</td>
<td></td>
<td>Mild eye irritation</td>
<td></td>
</tr>
<tr>
<td>betamethasone:</td>
<td>Rabbit</td>
<td></td>
<td>No eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

Respiratory or skin sensitisation

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

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

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum:</td>
<td>Buehler Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>White mineral oil (petroleum):</td>
<td>Buehler Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>betamethasone:</td>
<td>Dermal</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Weak sensitizer</td>
<td></td>
</tr>
</tbody>
</table>
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

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

**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: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects

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

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 200 mg/kg body weight
Result: No effects on foetal development
SAFETY DATA SHEET

Betamethasone / Clotrimazole Ointment Formulation

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:
### White mineral oil (petroleum):
- **Species**: Rat
- **NOAEL**: 5,000 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 2 yr

### betamethasone:
- **Species**: Rabbit
- **LOAEL**: 0.05%
- **Application Route**: Skin contact
- **Exposure time**: 10 - 30 d
- **Target Organs**: Pituitary gland, Immune system, muscle

### clotrimazole:
- **Species**: Rabbit
- **LOAEL**: 5 - 40 mg/kg
- **Application Route**: Skin contact
- **Exposure time**: 3 Weeks
- **Target Organs**: Skin
- **Symptoms**: Oedema, Fissuring, Necrosis, Redness

### betamethasone:
- **Species**: Dog
- **LOAEL**: 25 mg/kg
- **Application Route**: Oral
- **Exposure time**: 6 - 12 Months
- **Target Organs**: Adrenal gland
- **Symptoms**: Salivation, Lachrymation, Vomiting

### Species:
- **Species**: Rat
- **LOAEL**: >= 1 mg/l
- **Application Route**: Inhalation (dust/mist/fume)
- **Exposure time**: 4 Weeks
- **Method**: OECD Test Guideline 412

### Species:
- **Species**: Rat
- **LOAEL**: 10 mg/kg
- **Application Route**: Oral
- **Exposure time**: 18 Months
- **Target Organs**: Liver, Kidney, Adrenal gland

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

### Species:
- **Species**: Rat
- **LOAEL**: 160 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days

### Species:
- **Species**: Rat
- **LOAEL**: 10 mg/kg
- **Application Route**: Oral
- **Exposure time**: 18 Months
- **Target Organs**: Liver, Kidney, Adrenal gland

### Species:
- **Species**: Dog
- **LOAEL**: 25 mg/kg
- **Application Route**: Oral
- **Exposure time**: 6 - 12 Months
- **Target Organs**: Adrenal gland
- **Symptoms**: Salivation, Lachrymation, Vomiting

### Target Organs
- **Symptoms**: Oedema, Fissuring, Necrosis, Redness
- **Target Organs**: Skin
- **Target Organs**: Liver, Kidney, Adrenal gland
- **Target Organs**: Adrenal gland
- **Symptoms**: Salivation, Lachrymation, Vomiting
- **Target Organs**: Pituitary gland, Immune system, muscle
- **Target Organs**: thymus gland
Betamethasone / Clotrimazole Ointment Formulation

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

**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 fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

- 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

**M-Factor (Acute aquatic toxicity):** 10

- 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

**M-Factor (Chronic aquatic):** 10
### Betamethasone / Clotrimazole Ointment Formulation

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Test Type</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Microorganisms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50: &gt; 10,000 mg/l</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
<td></td>
</tr>
<tr>
<td><strong>Betamethasone</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50 (Americamysis): &gt; 50 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Algae/Aquatic Plants</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</td>
<td></td>
<td>No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fish (Chronic toxicity)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOEC (Daphnia magna (Water flea)): 8 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td></td>
<td></td>
<td>1,000</td>
</tr>
<tr>
<td><strong>Clotrimazole</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50 (Brachydanio rerio (zebrafish)): &gt; 0.29 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Daphnia and other aquatic invertebrates</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50 (Daphnia magna (Water flea)): 0.02 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Algae/Aquatic Plants</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l</td>
<td></td>
<td>No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td></td>
<td></td>
<td>10</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Betamethasone / Clotrimazole Ointment Formulation**

**Version** 6.0  
**Revision Date:** 2020/03/23  
**SDS Number:** 610352-00012  
**Date of last issue:** 2019/09/13  
**Date of first issue:** 2016/04/08

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**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

**M-Factor (Chronic aquatic toxicity):**  
10

**Toxicity to microorganisms:**  
EC50: > 10,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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**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)

**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
SAFETY DATA SHEET

Betamethasone / Clotrimazole Ointment Formulation

Version 6.0  Revision Date: 2020/03/23  SDS Number: 610352-00012  Date of last issue: 2019/09/13
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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 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
Subsidiary risk: ENVIRONM.
Packing group: III
Labels: 9 (ENVIRONM.)
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.
Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
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</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
<td>&gt;=90 - &lt;=100</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<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
16. OTHER INFORMATION

Further information
Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
SAFETY DATA SHEET

Betamethasone / Clotrimazole Ointment Formulation

Version 6.0  Revision Date: 2020/03/23  SDS Number: 610352-00012  Date of last issue: 2019/09/13

Date format: yyyy/mm/dd

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LDS50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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