1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone / Clotrimazole Cream Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
 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 mist or vapours.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-234</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>clotrimazole</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>betamethasone</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.
In case of eye contact : Thoroughly clean shoes before reuse.
  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 and personal protective equipment
  recommendations.

Environmental precautions :
  Discharge into the environment must be avoided.
  Prevent further leakage or spillage if safe to do so.
  Prevent spreading over a wide area (e.g. by containment or oil
  barriers).
  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 :
  Soak up with inert absorbent material.
  For large spills, provide dyking or other appropriate contain-
  ment to keep material from spreading. If dyked material can
  be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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 vapours or spray mist.
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
Hygiene measures: Oxidizing agents
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
SAFETY DATA SHEET

Betamethasone / Clotrimazole Cream Formula-

Version 6.0  Revision Date: 2020/03/23  SDS Number: 412903-00013  Date of last issue: 2019/09/13  Date of first issue: 2015/12/14

Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis
--- | --- | --- | --- | ---
Petrolatum | 8009-03-8 | OEL-M (Mist) | 3 mg/m³ | JP OEL JSOH

Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA (Inhalable particulate matter)</td>
</tr>
</tbody>
</table>

White mineral oil (petroleum) | 8042-47-5 | OEL-M (Mist) | 3 mg/m³ | JP OEL JSOH

Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA (Inhalable particulate matter)</td>
</tr>
</tbody>
</table>

clotrimazole | 23593-75-1 | TWA | 0.2 mg/m³ (OEB 2) | Internal

betamethasone | 378-44-9 | TWA | 1 µg/m³ (OEB 4) | Internal

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

Engineering measures: 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. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapour type

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>cream</td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
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</tr>
<tr>
<td>Melting point/freezing point</td>
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</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
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</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>No data available</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>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
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<tr>
<td>Viscosity, kinematic</td>
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</tr>
<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Density and / or relative density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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: Inhalation, 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
Propylene glycol:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rabbit): > 159 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

White mineral oil (petroleum):
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rabbit): > 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

Alcohols, C16-18, ethoxylated:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  Remarks: Based on data from similar materials

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

Remarks: Based on data from similar materials
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

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

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

Alcohols, C16-18, ethoxylated:
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
- Remarks: Based on data from similar materials

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

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

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

Alcohols, C16-18, ethoxylated:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

clotrimazole:
Species: Rabbit
Result: Mild eye irritation

betamethasone:
Species: Rabbit
Result: No eye irritation

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

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

White mineral oil (petroleum):
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
<table>
<thead>
<tr>
<th><strong>Alcohols, C16-18, ethoxylated:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Type</strong></td>
<td>Buehler Test</td>
</tr>
<tr>
<td><strong>Exposure routes</strong></td>
<td>Skin contact</td>
</tr>
<tr>
<td><strong>Species</strong></td>
<td>Guinea pig</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>negative</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Betamethasone:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exposure routes</strong></td>
<td>Dermal</td>
</tr>
<tr>
<td><strong>Species</strong></td>
<td>Guinea pig</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>Weak sensitizer</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th><strong>Petrolatum:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: Chromosome aberration test in vitro</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

| 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 |

<table>
<thead>
<tr>
<th><strong>Propylene glycol:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

| Genotoxicity in vivo             | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) |
|----------------------------------| Species: Mouse |
|                                  | Application Route: Intraperitoneal injection |
|                                  | Result: negative |

<table>
<thead>
<tr>
<th><strong>White mineral oil (petroleum):</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

| Genotoxicity in vivo              | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) |
|----------------------------------| Species: Mouse |
|                                  | Application Route: Intraperitoneal injection |
Alcohols, C16-18, ethoxylated:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  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
  Remarks: Based on data from similar materials

- 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

Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials
Genotoxicity in vivo:
- 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

Propylene glycol:
- 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: Embry-o-foetal development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Propylene glycol:

Effects on fertility
: Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development
: Test Type: Embry-o-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

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: Embry-o-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Alcohols, C16-18, ethoxylated:

Effects on fertility
: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development
: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

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.

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:

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

**Clotrimazole**:
- **Target Organs**: Liver, Kidney, Adrenal gland
- **Assessment**: May cause 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

**Propylene glycol**:
- **Species**: Rat, male
- **NOAEL**: 1,700 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**:
- **Species**: Rat
- **LOAEL**: >= 1 mg/l
- **Application Route**: inhalation (dust/mist/fume)
- **Exposure time**: 4 Weeks
- **Method**: OECD Test Guideline 412

**Alcohols, C16-18, ethoxylated**:
- **Species**: Rat
- **NOAEL**: > 100 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days
Method: OECD Test Guideline 408
Remarks: Based on data from similar materials

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 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
- 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

**Propylene glycol:**
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  - Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  - Exposure time: 48 h
Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d

Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

White mineral oil (petroleum):

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

Alcohols, C16-18, ethoxylated:

Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials

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 (Onchorhynchus 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

**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

**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 toxicity):
- 10

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

Persisted and degradability

Components:

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

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

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

**Alcohols, C16-18, ethoxylated:**
- Biodegradability:
  - Result: Readily biodegradable.
Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

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

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

### Bioaccumulative potential

**Components:**

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

**Alcohols, C16-18, ethoxylated:**
Bioaccumulation: Species: Fish
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water: log Pow: > 4

**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.
UNRTDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(clotrimazole, betamethasone)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(clotrimazole, betamethasone)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(clotrimazole, betamethasone)
Class : 9
Packing group : III
Labels : 9
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
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
</table>
Propane-1,2-diol 106

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>Number</th>
<th>Concentration (%)</th>
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<td>168</td>
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</tbody>
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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
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 Z)  
Pack transportation: Classified as marine pollutant

**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**  

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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
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.