SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 8.0  Revision Date: 2021/04/09  SDS Number: 610543-00014  Date of last issue: 2020/10/10
Revision Date: 2016/04/29

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Clotrimazole / Gentamicin / Betamethasone (0.05%) 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 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

**Substance / Mixture:** Mixture

<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;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-234</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 2.5 - &lt; 10</td>
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</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>3-1011</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&gt;= 0.1 - &lt; 0.25</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. 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 containment 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 mist or vapours. 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
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>Clotrimazole</td>
<td>23593-75-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>OEL-C</td>
<td>25 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.

Filter type: Combined particulates and organic vapour type

Hand protection: 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.

Hand protection: Combined particulates and organic vapour type
Material : Chemical-resistant gloves

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

Skin and body protection :
  - Work uniform or laboratory coat.
  - Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
  - Use appropriate degowning techniques to remove potentially contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : No data available

Odour : 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 applicable

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 : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

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 : No data available

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

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 : 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 inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
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Test atmosphere: dust/mist
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

**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

**Paraffin oil:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

**Hexadecan-1-ol. Ethoxylated:**
- Acute oral toxicity: LD50 (Rat): 2,500 mg/kg

**Benzyl alcohol:**
- Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403
### 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

### Gentamicin:
- **Acute oral toxicity**
  - LD50 (Rat): 8,000 - 10,000 mg/kg
  - LD50 (Mouse): 10,000 mg/kg
- **Acute inhalation toxicity**
  - LC50 (Rat): > 0.2 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Remarks: No mortality observed at this dose.

### 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

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

Paraffin oil:
Species: Rabbit
Result: No skin irritation

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Clotrimazole:
Species: Rabbit
Result: No skin irritation

Gentamicin:
Species: Rabbit
Result: Mild 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

Paraffin oil:
Species: Rabbit
Result: No eye irritation

Hexadecan-1-ol. Ethoxylated:
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

**Benzyl alcohol:**
- **Species:** Rabbit
- **Result:** Irritation to eyes, reversing within 21 days
- **Method:** OECD Test Guideline 405

**Clotrimazole:**
- **Species:** Rabbit
- **Result:** Mild eye irritation

**Gentamicin:**
- **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

**Benzyl alcohol:**
- **Test Type:** Maximisation Test
- **Exposure routes:** Skin contact
- **Species:** Guinea pig
- **Method:** OECD Test Guideline 406
- **Result:** negative
Gentamicin:
Remarks : No data available

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

Propylene glycol:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
                     Result: negative

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

Benzyl alcohol:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
                     Result: negative

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

Clotrimazole:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
                     Result: negative
<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Result</th>
<th>Genotoxicity in vitro</th>
<th>Result</th>
<th>Genotoxicity in vivo</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>negative</td>
<td>Test Type: in vitro micronucleus test</td>
<td>negative</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td></td>
<td>Application Route: Oral</td>
<td></td>
<td>Species: Hamster</td>
</tr>
<tr>
<td>Germ cell mutagenicity - Assessment</td>
<td>Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)</td>
<td>negative</td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
<td></td>
<td>Application Route: Intravenous injection</td>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Germ cell mutagenicity - Assessment</td>
<td>Weight of evidence does not support classification as a germ cell mutagen.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Gentamicin:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Result</th>
<th>Genotoxicity in vivo</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>equivocal</td>
</tr>
<tr>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route: Intravenous injection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Result</th>
<th>Genotoxicity in vivo</th>
<th>Result</th>
<th>Germ cell mutagenicity - Assessment</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>positive</td>
<td>Weight of evidence does not support classification as a germ cell mutagen.</td>
<td></td>
</tr>
<tr>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td>Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)</td>
<td>negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
<td>Species: Hamster</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
<td>Application Route: Oral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type: Chromosome aberration test in vitro</td>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
<td>Result: negative</td>
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<td>Test Type: Chromosome aberration test in vitro</td>
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<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
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<td></td>
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</tr>
<tr>
<td>Result: positive</td>
<td></td>
<td>Species: Mouse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td></td>
<td>Application Route: Oral</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td>Result: equivocal</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

**Benzyl alcohol:**
- Species: Mouse
- Application Route: Ingestion
- Exposure time: 103 weeks
- Method: OECD Test Guideline 451
- Result: negative

**Clotrimazole:**
- Species: Rat
- Application Route: Oral
- Exposure time: 78 weeks
- Result: negative

**Gentamicin:**
- Carcinogenicity - Assessment: No data available
- 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

**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: Embryo-foetal development
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

**Benzyl alcohol:**

- **Effects on fertility**
  - Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

- **Effects on foetal development**
  - Test Type: Embryo-foetal development
  - Species: Mouse
  - 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.

Gentamicin:

Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Fertility: NOAEL: 20 mg/kg body weight
Result: No significant adverse effects were reported

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: foetal mortality, No malformations were observed.

Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.

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.
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

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.

Gentamicin:
Target Organs : Kidney, inner ear
Assessment : Causes 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

Propylene glycol:
Species : Rat, male
NOAEL : 1,700 mg/kg
Application Route : Ingestion
Exposure time : 2 yr
<table>
<thead>
<tr>
<th>Paraffin oil:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat, female</td>
</tr>
<tr>
<td>LOAEL</td>
<td>161 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benzyl alcohol:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>NOAEL</td>
<td>1.072 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>Inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 412</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>clotrimazole:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rabbit</td>
</tr>
<tr>
<td>LOAEL</td>
<td>5 - 40 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Skin</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Oedema, Fissuring, Necrosis, Redness</td>
</tr>
</tbody>
</table>

| 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 |

<table>
<thead>
<tr>
<th>Gentamicin:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Dog</td>
</tr>
<tr>
<td>LOAEL</td>
<td>3 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Vomiting, Salivation</td>
</tr>
</tbody>
</table>

| Species | Monkey |
| LOAEL | 50 mg/kg |
| Application Route | Subcutaneous |
| Exposure time | 3 Weeks |
| Target Organs | Kidney, inner ear |

| Species | Monkey |
| LOAEL | 6 mg/kg |
| Application Route | Intramuscular |
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 8.0  Revision Date: 2021/04/09  SDS Number: 610543-00014  Date of last issue: 2020/10/10  Date of first issue: 2016/04/29

Exposure time: 3 Weeks
Target Organs: Blood, Kidney, inner ear, Liver

Species: Rat
NOAEL: 5 mg/kg
LOAEL: 10 mg/kg
Application Route: Intramuscular
Exposure time: 52 Weeks
Target Organs: Kidney, Blood

Species: Rat
NOAEL: 12.5 mg/kg
LOAEL: 50 mg/kg
Application Route: Intramuscular
Exposure time: 13 Weeks
Target Organs: Kidney

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.

Components:

Paraffin oil:
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.
Experience with human exposure

**Components:**

**clotrimazole:**
- Skin contact: Symptoms: Rash, Itching, Blistering, Oedema, Redness
- Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

**Gentamicin:**
- Ingestion: Target Organs: Kidney
  - Target Organs: inner ear
  - Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

**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

Paraffin oil:
Toxicity to fish: LL50 (Scophthalmus maximus (turbot)): > 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates: EL50 (Acartia tonsa): > 100 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants: EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Hexadecan-1-ol. Ethoxylated:
Toxicity to fish: LC50: > 1 - 10 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates: EC50: > 1 - 10 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants: EC50: > 10 - 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials
**SAFETY DATA SHEET**

**Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0</td>
<td>2021/04/09</td>
<td>610543-00014</td>
<td>2020/10/10</td>
<td>2016/04/29</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benzy alcohol:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish:</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates:</td>
<td>EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants:</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):</td>
<td>NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>clotrimazole:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish:</td>
<td>LC50 (Brachydanio rerio (zebrafish)): &gt; 0.29 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates:</td>
<td>EC50 (Daphnia magna (Water flea)): 0.02 mg/l Exposure time: 48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants:</td>
<td>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</td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity):</td>
<td>10</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity):</td>
<td>NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l Exposure time: 32 d Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):</td>
<td>NOEC (Daphnia magna (Water flea)): 0.01 mg/l Exposure time: 21 d Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity):</td>
<td>10</td>
</tr>
<tr>
<td>Toxicity to microorganisms:</td>
<td>EC50: &gt; 10,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>
Gentamicin:

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 86 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

LC50 (Americamysis): 30 mg/l
- Exposure time: 96 h

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity):
- 100

M-Factor (Chronic aquatic toxicity):
- 1

Toxicity to microorganisms:
- EC50: 288.7 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

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

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

Hexadecan-1-ol. Ethoxylated:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 99 %
Exposure time: 19 d

Benzyl alcohol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

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

Gentamicin:
Biodegradability: Result: rapidly degradable
Biodegradation: 100 %
Exposure time: 28 d
Method: OECD Test Guideline 314
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Bioaccumulative potential

Components:

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

Paraffin oil:
Partition coefficient: n-octanol/water : log Pow: > 4
Remarks: Calculation

Benzyl alcohol:
Partition coefficient: n-octanol/water : log Pow: 1.05

Gentamicin:
Partition coefficient: n-octanol/water : log Pow: < -2

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 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(betamethasone, clotrimazole)
Class : 9
Packing group : III
Labels : 9
IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (betamethasone, clotrimazole)
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. (betamethasone, clotrimazole)
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

<table>
<thead>
<tr>
<th>Chemical Substance</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
<tr>
<td>alpha-Alkyl(C=9-11)-omega-hydroxy(poly(oxyethylene) (It is limited that a number-average molecular weight of the polymer is less than 1,000.)</td>
<td>188</td>
</tr>
<tr>
<td>alpha-Alkyl(C=12-15)-omega-hydroxy(poly(oxyethylene) (It is limited that a number-average molecular weight of the polymer is less than 1,000.)</td>
<td>189</td>
</tr>
<tr>
<td>[alpha-(Alkyl(C=16-18))-omega-hydroxy(poly(oxyethane-1,2-diyl) or alpha-(alkeny(C=16-18))-omega-hydroxy(poly(oxyethane-1,2-diyl)]</td>
<td>250</td>
</tr>
</tbody>
</table>
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;=20 - &lt;30</td>
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</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

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
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
JP OEL JSOH / OEL-C: Occupational Exposure Limit-Ceiling

AIIC - 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 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.

JP / EN