SAFETY DATA SHEET

Betamethasone Ointment Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone Ointment Formulation

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

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
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.
                   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>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical ad-
vice 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.
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:
- Vapours may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling: Do not get on skin or clothing. Do not breathe dust, fume, gas, mist, vapours or spray. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage
Conditions for safe storage: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. Materials to avoid: Do not store with the following product types: Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>OEL-M (Mist)</td>
<td>3 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<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>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</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>Further information: Group 1: carcinogenic to humans</td>
</tr>
</tbody>
</table>

|                  |           | TWA (Inhalable particulate matter) | 5 mg/m3                                       | ACGIH |
|                  |           | TWA (Inhalable particulate matter) | 5 mg/m3                                       | ACGIH |
SAFETY DATA SHEET

Betamethasone Ointment Formulation

Version 5.0  Revision Date: 2021/04/09  SDS Number: 1841080-00009  Date of last issue: 2020/10/10

Date of first issue: 2017/07/19

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Exposure</th>
<th>Limit Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td></td>
</tr>
</tbody>
</table>

**Engineering measures**: Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

**Personal protective equipment**

Respiratory protection: 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 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: ointment

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 classified as a flammability hazard
Flammability (liquids) : Not applicable

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 : > 93.3 °C

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

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 : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.
SAFETY DATA SHEET

Betamethasone Ointment Formulation

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.

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

**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

**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
Paraffin oil:
  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

Paraffin oil:
  Species: Rabbit
  Result: No 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

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

**betamethasone:**

- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
    - Result: negative
  - Test Type: Chromosome aberration test in vitro
    - Result: positive

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

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

Carcinogenicity
Not classified based on available information.

Components:

**Petrolatum:**

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

Reproductive toxicity
May damage the unborn child.

Components:

**Petrolatum:**

- Effects on fertility:
  - Test Type: Reproduction/Developmental toxicity screening test
    - Species: Rat
SAFETY DATA SHEET

Betamethasone Ointment Formulation

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

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.

Repeated dose toxicity

Components:

Petrolatum:
Species:
: Rat
NOAEL:
: 5,000 mg/kg
Application Route:
: Ingestion
Exposure time:
: 2 yr
### Paraffin oil:
- **Species**: Rat, female
- **LOAEL**: 161 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days

### 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.

### 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

### betamethasone:
- **Inhalation**: Target Organs: Adrenal gland
- **Skin contact**: Symptoms: Redness, pruritis, Irritation
## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

**Petrolatum:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203 Remarks: Based on data from similar materials</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 10,000 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</td>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Paraffin oil:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LL50 (Scophthalmus maximus (turbot)): &gt; 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</td>
<td>EL50 (Acartia tonsa): &gt; 100 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</td>
<td>EL50 (Skeletonema costatum (marine diatom)): &gt; 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</td>
<td>NOELR (Skeletonema costatum (marine diatom)): &gt; 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Americamysis): &gt; 50 mg/l</td>
</tr>
</tbody>
</table>
### aquatic invertebrates

**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)

**M-Factor**: 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

### Bioaccumulative potential

### Components:

#### Paraffin oil:

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

#### 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

<table>
<thead>
<tr>
<th>UNRTDG</th>
<th>UN number</th>
<th>UN 3077</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IATA-DGR</th>
<th>UN/ID No.</th>
<th>UN 3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>Environmentally hazardous substance, solid, n.o.s. (betamethasone)</td>
<td></td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>Labels</td>
<td>Miscellaneous</td>
<td></td>
</tr>
<tr>
<td>Packing instruction (cargo aircraft)</td>
<td>956</td>
<td></td>
</tr>
<tr>
<td>Packing instruction (passenger aircraft)</td>
<td>956</td>
<td></td>
</tr>
<tr>
<td>Environmentally hazardous</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>

IMDG-Code

| UN number | UN 3077 |
| Proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (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
Designated Flammable Substances, Flammable solid, (3000 kilogram)

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>
</tr>
</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

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable
Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

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

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

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

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

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance(Category Y)
Pack transportation : Classified as marine pollutant

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.

JP / EN