1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone / Salicylic Acid Ointment Formulation

Supplier’s company name, address and phone number

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

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irritation : Category 1
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 : ![Pictogram] (Danger, Eye Irritation, Reproductive Toxicity)

Signal word : Danger

Hazard statements : H318 Causes serious eye damage. 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 protection/ face protection.

Response:
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>86.93</td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>3</td>
<td>3-1640</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>0.064</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 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:
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.

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:
Causes serious eye damage.
May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders:
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:
Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media:
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media:
None known.

Specific hazards during firefighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant 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 swallow.
- Do not get in eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact:
  - Oxidizing agents
Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
</table>

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## SAFETY DATA SHEET

### Betamethasone / Salicylic Acid Ointment Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>OEL (Mist)</th>
<th>JP OEL JSOH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Salicylic acid</td>
<td>69-72-7</td>
<td>100 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>1 µg/m³</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

### 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

**Material**: Chemical-resistant gloves

#### 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...

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9. PHYSICAL AND CHEMICAL PROPERTIES

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>ointment</td>
</tr>
<tr>
<td>Colour</td>
<td>white, translucent</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
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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>
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</tr>
<tr>
<td>pH</td>
<td>4.6 - 5.3</td>
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<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
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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>
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.
Molecular weight: No data available
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: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
   Skin contact
   Ingestion
   Eye contact

Acute toxicity
Not classified based on available information.

Product:
  Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
                     Method: Calculation method
  Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
                             Exposure time: 4 h
                             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
Betamethasone / Salicylic Acid Ointment Formulation

 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

Salicylic acid:
Acute oral toxicity: LD50 (Mouse): 480 mg/kg
LD50 (Rat): 891 mg/kg
LD50 (Rabbit): 1,300 mg/kg
Acute inhalation toxicity: LC50 (Rat): 0.9 mg/l
Exposure time: 1 h
Acute dermal toxicity: LD50 (Rat): 2,000 mg/kg
LD50 (Rabbit): 10,000 mg/kg

Betamethasone:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 4,500 mg/kg
Acute inhalation toxicity: LC50 (Rat): 0.4 mg/l
Exposure time: 4 h

Skin corrosion/irritation
Not classified based on available information.

Components:

Petrolatum:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Paraffin oil:
Species: Rabbit
### Result:

<table>
<thead>
<tr>
<th>Component</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salicylic acid:</td>
<td>Skin irritation</td>
</tr>
<tr>
<td>Betamethasone:</td>
<td>Mild skin irritation</td>
</tr>
</tbody>
</table>

### Serious eye damage/eye irritation

Causes serious eye damage.

### 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

#### Salicylic acid:

- **Species**: Rabbit
- **Remarks**: Severe 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
salicylic acid:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Result: negative

betamethasone:
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

salicylic acid:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Mammalian bone marrow sister chromatid exchange
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Test Type: Sister chromatid exchange analysis in spermatogonia
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative
SAFETY DATA SHEET
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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

Salicylic acid:
Species: Mouse
Application Route: Skin contact
Exposure time: 1 Years
NOAEL: 2 mg/cm2
Result: negative

Reproductive toxicity
May damage the unborn child.

Components:

Petrolatum:
Effects on fertility
Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development
Test Type: Embryo-foetal development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Salicylic acid:
Effects on foetal development
Test Type: Embryo-foetal development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 380 mg/kg body weight
Result: Maternal toxicity observed, Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 80 mg/kg body weight
Result: No effects on foetal development

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

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

_salicylic acid:
Species: Rat
NOAEL: 50 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Species: Rat
LOAEL: 500 mg/kg
Application Route: Oral
Exposure time: 3 d
Target Organs: Liver

_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

**Components:**

**salicylic acid:**
- **Skin contact**: Symptoms: Skin irritation
- **Eye contact**: Symptoms: Severe irritation
- **Ingestion**: Symptoms: Gastrointestinal discomfort, hearing loss, Dizziness, electrolyte imbalance

**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
### Paraffin oil:

**Toxicity to fish**
- LL50 (Scophthalmus maximus (turbot)): > 1,028 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): > 3,193 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)): > 3,200 mg/l
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

### salicylic acid:

**Toxicity to fish**
- LC50 (Pimephales promelas (fathead minnow)): 1,380 mg/l
- Exposure time: 96 h
- Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): 870 mg/l
- Exposure time: 48 h

**Toxicity to algae/aquatic plants**
- EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): 10 mg/l
- Exposure time: 21 d

### 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

**Paraffin oil:**
Biodegradability : Result: Readily biodegradable.
  Biodegradation: 82 %
  Exposure time: 24 d
  Method: OECD Test Guideline 301F
  Remarks: Based on data from similar materials

**Bioaccumulative potential**

**Components:**

**salicylic acid:**
Partition coefficient: n-octanol/water : log Pow: 2.25

**betamethasone:**
Partition coefficient: n-octanol/water : log Pow: 2.11

**Mobility in soil**
No data available

**Hazardous to the ozone layer**
Not applicable
Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class : 9
Packing group : III
Labels : 9

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

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class : 9
Subsidiary risk : ENVIRONM.
Packing group : III
Labels : 9 (ENVIRONM.)
EmS Code : F-A, S-F
Marine pollutant : yes

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

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

15. REGULATORY INFORMATION

Related Regulations

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

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,2,4,6,6-Pentamethylheptane</td>
<td>212</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>
</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
Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
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 use.
intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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