SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Betamethasone Ointment Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Betamethasone Ointment Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

   Classification (REGULATION (EC) No 1272/2008)
   Reproductive toxicity, Category 1B
   Specific target organ toxicity - repeated exposure, Category 1
   Long-term (chronic) aquatic hazard, Category 1

   Hazard statements:
   H360D: May damage the unborn child.
   H372: Causes damage to organs through prolonged or repeated exposure.
   H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : ![Hazard Pictograms]
   Signal word : Danger
   Hazard statements : H360D  May damage the unborn child.
                      H372  Causes damage to organs through prolonged or repeated exposure.
                      H410  Very toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P264 Wash skin thoroughly after handling.
- 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.

**Hazardous components which must be listed on the label:**
betamethasone

**2.3 Other hazards**
None known.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>8012-95-1</td>
<td>232-384-2</td>
<td></td>
<td>Asp. Tox.1; H304</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>378-44-9</td>
<td>206-825-4</td>
<td></td>
<td>Acute Tox.2; H330 Refr.1B; H360D STOT RE1; H372 Aquatic Chronic1; H410 M-Factor (Chronic aquatic toxicity): 1.000</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
</tr>
<tr>
<td>betamethasone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.

**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).
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.

4.2 Most important symptoms and effects, both acute and delayed
Risks: May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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

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

Specific extinguishing methods: Use extinguishing measures that are appropriate to local cir-
Betamethasone Ointment Formulation

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Vapour)</td>
<td>50 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Vapour)</td>
<td>50 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m³</td>
<td>FOR-2011-12-06-1358</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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Short-term exposure</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
</tbody>
</table>

**8.2 Exposure controls**

**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**

**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.

**Hand protection**

- Material: Chemical-resistant gloves
- Remarks: Consider double gloving.

**Skin and body protection**

- Material: 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.

**Respiratory protection**

- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Equipment should conform to NS EN 14387 Filter type: Combined particulates and organic vapour type (A-P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

- Appearance: ointment
- Colour: No data available
- Odour: No data available
- Odour Threshold: No data available
- pH: No data available
- Melting point/freezing point: No data available
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

None known.

**10.5 Incompatible materials**

Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

### SECTION 11: Toxicological information

**11.1 Information on toxicological effects**

**Information on likely routes of exposure**

- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:**

- **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:**

- **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:

<table>
<thead>
<tr>
<th>Paraffin oil:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>No eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>betamethasone:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>No eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

betamethasone:

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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 cyogenetic 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.

Reproductive toxicity
May damage the unborn child.

Components:

**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 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:

**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

Components:

betamethasone:
Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritis, Irritation

SECTION 12: Ecological information

12.1 Toxicity

Components:

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: EL50 (Acartia tonsa): > 3.193 mg/l
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<table>
<thead>
<tr>
<th>aquatic invertebrates</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>EL50 (Skeletonema costatum (marine diatom)): &gt; 3.200 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>NOELR (Skeletonema costatum (marine diatom)): 993 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>EC50 (Americamysis): &gt; 50 mg/l</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 32 d</td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>NOEC: 0.052 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>NOEC: 8 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

| NOEC: 0.07 µg/l                                                       |

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 219 d</td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>NOEC: 0.07 µg/l</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>NOEC: 8 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.000</td>
<td></td>
</tr>
</tbody>
</table>

**12.2 Persistence and degradability**

**Components:**

- **Paraffin oil:**
  - Biodegradability: Result: Readily biodegradable.
12.3 Bioaccumulative potential

**Components:**

- **betamethasone:**
  - Partition coefficient: n-octanol/water: \( \log P_{ow} = 2.11 \)

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- **Product:** Dispose of in accordance with local regulations.
  - According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **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.

SECTION 14: Transport information

14.1 UN number

- **ADN:** UN 3077
- **ADR:** UN 3077
- **RID:** UN 3077
- **IMDG:** UN 3077
- **IATA:** UN 3077

14.2 UN proper shipping name

- **ADN:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
- **ADR:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
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RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)

IATA : Environmentally hazardous substance, solid, n.o.s. (betamethasone)

14.3 Transport hazard class(es)

  ADN : 9
  ADR : 9
  RID : 9
  IMDG : 9
  IATA : 9

14.4 Packing group

  ADN
  Packing group : III
  Classification Code : M7
  Hazard Identification Number : 90
  Labels : 9 (ENVIROM.)

  ADR
  Packing group : III
  Classification Code : M7
  Hazard Identification Number : 90
  Labels : 9 (ENVIROM.)
  Tunnel restriction code : (-)

  RID
  Packing group : III
  Classification Code : M7
  Hazard Identification Number : 90
  Labels : 9 (ENVIROM.)

  IMDG
  Packing group : III
  Labels : 9 (ENVIROM.)
  EmS Code : F-A, S-F

  IATA (Cargo)
  Packing instruction (cargo aircraft) : 956
  Packing instruction (LQ) : Y956
  Packing group : III
  Labels : Miscellaneous,

  IATA (Passenger)
  Packing instruction (passenger aircraft) : 956
  Packing instruction (LQ) : Y956
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14.5 Environmental hazards

**ADN**
Environmentally hazardous : yes

**ADR**
Environmentally hazardous : yes

**RID**
Environmentally hazardous : yes

**IMDG**
Marine pollutant : yes

**IATA (Passenger)**
Environmentally hazardous : yes

**IATA (Cargo)**
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

**REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)** : Not applicable

**REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).** : Not applicable

**REACH - List of substances subject to authorisation (Annex XIV)** : Not applicable

**Regulation (EC) No 1005/2009 on substances that deplete the ozone layer** : Not applicable

**Regulation (EU) 2019/1021 on persistent organic pollutants (recast)** : Not applicable

**Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals** : Not applicable


<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

**Other regulations:**
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

The components of this product are reported in the following inventories:

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### 15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

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

**Full text of H-Statements**

- **H304**: May be fatal if swallowed and enters airways.
- **H330**: Fatal if inhaled.
- **H360D**: May damage the unborn child.
- **H372**: Causes damage to organs through prolonged or repeated exposure.
- **H410**: Very toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

- **Acute Tox.**: Acute toxicity
- **Aquatic Chronic**: Long-term (chronic) aquatic hazard
- **Asp. Tox.**: Aspiration hazard
- **Repr.**: Reproductive toxicity
- **STOT RE**: Specific target organ toxicity - repeated exposure
- **FOR-2011-12-06-1358**: Norway. Occupational Exposure limits
- **FOR-2011-12-06-1358 / TWA**: Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Chemicals.
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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

- Calculation method

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

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.

NO / EN