SECTIO1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Betamethasone Liquid 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: H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1: H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
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>CAS-No.</th>
<th>EC-No. Index-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>378-44-9 206-825-4</td>
<td></td>
<td>Acute Tox.2; H330 Repr. 1B; H360D STOT RE1; H372 Aquatic Chronic1; H410</td>
<td>&gt;= 0.3 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1.000</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td></td>
<td>Acute Tox.4; H302 Acute Tox.2; H330 Skin Corr. 1B; H314 Eye Dam.1; H318 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 0.0025 - &lt; 0.025</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1</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 fire-fighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: No hazardous combustion products are known

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 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.

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.
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.

6.3 Methods and material for containment and cleaning up
Methods for 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.

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 breathe vapours or spray mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.

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>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td>Skin</td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**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**

**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**
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.
Filter type: Particulates type (P)

**SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

- **Appearance**: liquid
- **Colour**: colourless
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: 6.8 - 7.2
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: 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: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: 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:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:

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

Components:

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

Benzalkonium chloride:

Acute oral toxicity:
- LD50 (Rat): 344 mg/kg
- Remarks: Based on data from similar materials

Acute inhalation toxicity:
- LC50 (Rat): 0.25 mg/l
- Exposure time: 4 h
- Test atmosphere: dust/mist
- Method: OECD Test Guideline 403
- Assessment: Corrosive to the respiratory tract.
- Remarks: Based on data from similar materials

Acute dermal toxicity:
- LD50 (Rabbit): 3.412 mg/kg
- Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

betamethasone:
Betamethasone Liquid Formulation

Species : Rabbit
Result : Mild skin irritation

Benzalkonium chloride:
Species : Rabbit
Result : Corrosive after 3 minutes to 1 hour of exposure
Remarks : Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:
betamethasone:
Species : Rabbit
Result : No eye irritation

Benzalkonium chloride:
Species : Rabbit
Result : Irreversible effects on the eye
Remarks : Based on data from similar materials

Respiratory or skin sensitisisation

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

Benzalkonium chloride:
Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

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 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.

**Benzalkonium chloride:**

**Genotoxicity in vitro:**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Method: OECD Test Guideline 471
  - 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: Ingestion
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

**Carcinogenicity:**
Not classified based on available information.

**Components:**

**Benzalkonium chloride:**
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Method: OECD Test Guideline 453
- Result: negative
- Remarks: Based on data from similar materials

**Reproductive toxicity:**
May damage the unborn child.

**Components:**

**Betamethasone:**
- Effects on foetal development
  - Species: Rabbit
  - Application Route: Intramuscular
## Developmental Toxicity

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.05 mg/kg body weight</td>
<td>Fetotoxicity, Malformations were observed.</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LOAEL: 0.05 mg/kg body weight</td>
<td>Malformations were observed.</td>
</tr>
<tr>
<td>0.42 mg/kg body weight</td>
<td>Malformations were observed.</td>
<td>Mouse</td>
<td>Intramuscular</td>
<td>LOAEL: 0.42 mg/kg body weight</td>
<td>Malformations were observed.</td>
</tr>
<tr>
<td>1 mg/kg body weight</td>
<td>Malformations were observed.</td>
<td>Mouse</td>
<td>Intramuscular</td>
<td>LOAEL: 1 mg/kg body weight</td>
<td>Malformations were observed.</td>
</tr>
</tbody>
</table>

### Reproductive toxicity - Assessment

Clear evidence of adverse effects on development, based on animal experiments.

## Benzalkonium chloride

### Effects on fertility

- **Test Type:** Two-generation study
- **Species:** Rat
- **Application Route:** Ingestion
- **Method:** OECD Test Guideline 416
- **Result:** negative
- **Remarks:** Based on data from similar materials

### Effects on foetal development

- **Test Type:** Embryo-foetal development
- **Species:** Rabbit
- **Application Route:** Ingestion
- **Method:** OECD Test Guideline 414
- **Result:** negative
- **Remarks:** Based on data from similar materials

## 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:

**betamethasone:**

- **Species:** Rabbit
- **LOAEL:** 0.05 %
- **Application Route:** Skin contact
## Betamethasone Liquid Formulation

**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

**Benzalkonium chloride**:  
**Species**: Dog  
**NOAEL**: 50 mg/kg  
**Application Route**: Ingestion  
**Exposure time**: 13 Weeks  
**Method**: OECD Test Guideline 409  
**Remarks**: Based on data from similar materials

### Aspiration toxicity
Not classified based on available information.

### 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:**

**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: 0.052 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

NOEC: 0.07 µg/l
Exposure time: 219 d
Species: Oryzias latipes (Japanese medaka)
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

Benzalkonium chloride:
Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.85 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)): 0.016 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.049 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): 0.009 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 10

Toxicity to microorganisms : EC50 : 7.75 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: > 32.2 mg/l
Exposure time: 34 d
Species: Pimephales promelas (fathead minnow)
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.0125 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1

12.2 Persistence and degradability

Components:

Benzalkonium chloride:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 95.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

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

Benzalkonium chloride:
Partition coefficient: n-octanol/water : log Pow: 0.004
Remarks: Based on data from similar materials

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

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>:</td>
<td>:</td>
<td>:</td>
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<tr>
<td>UN 3082</td>
<td>UN 3082</td>
<td>UN 3082</td>
<td>UN 3082</td>
<td>UN 3082</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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</thead>
<tbody>
<tr>
<td>:</td>
<td>:</td>
<td>:</td>
<td>:</td>
<td>:</td>
</tr>
<tr>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (betamethasone)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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<tr>
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<tr>
<td>9</td>
<td>9</td>
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</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group: III</td>
</tr>
<tr>
<td>Classification Code: M6</td>
</tr>
<tr>
<td>Hazard Identification Number: 90</td>
</tr>
<tr>
<td>Labels: 9</td>
</tr>
</tbody>
</table>
Betamethasone Liquid Formulation

**14.5 Environmental hazards**

<table>
<thead>
<tr>
<th>Mode</th>
<th>Environmentally hazardous</th>
<th>ADR</th>
<th>Environmentally hazardous</th>
<th>yes</th>
<th>ADR</th>
<th>Environmentally hazardous</th>
<th>yes</th>
<th>RID</th>
<th>Environmentally hazardous</th>
<th>yes</th>
<th>IMDG</th>
<th>Marine pollutant</th>
<th>yes</th>
<th>IATA (Passenger)</th>
<th>Environmentally hazardous</th>
<th>yes</th>
<th>IATA (Cargo)</th>
<th>Environmentally hazardous</th>
<th>yes</th>
</tr>
</thead>
</table>

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

Betamethasone Liquid Formulation

Version: 4.2  Revision Date: 09/13/2019  SDS Number: 809716-00011  Date of last issue: 24.04.2019
Date of first issue: 15.07.2016

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): Conditions of restriction for the following entries should be considered:
Number on list 3

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 (EC) No 850/2004 on persistent organic pollutants:
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 ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 t</td>
<td>200 t</td>
<td></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

H302: Harmful if swallowed.
Betamethasone Liquid Formulation

Version: 4.2  Revision Date: 09/13/2019  SDS Number: 809716-00011  Date of last issue: 24.04.2019

H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.
H330 : Fatal if inhaled.
H360D : May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
STOT RE : Specific target organ toxicity - repeated exposure

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; 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 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; 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
Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
Betamethasone Liquid Formulation

Classification of the mixture:

Repr. 1B  H360D  Calculation method
STOT RE 1  H372  Calculation method
Aquatic Chronic 1  H410  Calculation method

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.

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