Betamethasone Liquid Formulation

SECTION 1: 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
   National Poison Control Center (UZEM): 114
   Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification T.R. SEA No 28848
   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 T.R. SEA No 28848
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H360D May damage the unborn child.
                     H372 Causes damage to organs through prolonged or re-
Betamethasone Liquid Formulation

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

peated 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.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>206-825-4</td>
<td></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></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></td>
<td></td>
<td>Acute Tox.3; H301 Acute Tox.2; H330 Acute Tox.3; H311 Skin Corr.1; H314 Eye Dam.1; H318 Aquatic Acute1; H400 Aquatic Chronic2; H411</td>
<td>&gt;= 0.0025 - &lt; 0.025</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute</td>
<td></td>
</tr>
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</table>
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Betamethasone Liquid Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 2050079-00006 Date of last issue: 13.09.2019 Date of first issue: 07.10.2017

| aquatic toxicity: | 100 |

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
Betamethasone Liquid Formulation

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting : 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 deter-
Betamethasone Liquid Formulation

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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</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></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></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
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 TS EN 143

Filter type
Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: liquid
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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>colourless</td>
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<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
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<tr>
<td>pH</td>
<td>6.8 - 7.2</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
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</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
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<tr>
<td>flammability limit</td>
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</tr>
<tr>
<td>Vapour pressure</td>
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<td>Relative vapour density</td>
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<tr>
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<tr>
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<tr>
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<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<tr>
<td>Auto-ignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
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</tr>
<tr>
<td>Viscosity, kinematic</td>
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</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
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</table>

9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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:
**SAFETY DATA SHEET**

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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<td>07.10.2017</td>
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</tbody>
</table>

**Acute oral toxicity**
LD50 (Rat): 240 mg/kg

**Acute inhalation toxicity**
LC50 (Rat, male): > 0.05 - 0.5 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

**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 (Rat, female): 704 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

- **Betamethasone**
  - Species: Rabbit
  - Result: Mild skin irritation

- **Benzalkonium chloride**
  - Species: Human
  - Result: Corrosive after 4 hours or less of exposure

**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

**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
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Result : Weak sensitizer

Benzalkonium chloride:
Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Species : Humans
Result : negative

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)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
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
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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

Species : Mouse
Application Route: Skin contact
Exposure time: 80 weeks
Result: negative

Species : Rabbit
Application Route: Skin contact
Exposure time: 90 weeks
Result: negative

Reproductive toxicity
May damage the unborn child.

Components:

betamethasone:
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.
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**Benzalkonium chloride:**
- **Effects on fertility**
  - Test Type: Two-generation reproduction toxicity 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.

**Benzalkonium chloride:**
- **Assessment**
  - No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

**Repeated dose toxicity**

**Components:**

**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
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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: Rat
NOAEL: >= 100 mg/kg
Application Route: Ingestion
Exposure time: 12 Weeks

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 tox-: NOEC: 0.052 mg/l
SAFETY DATA SHEET
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</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
- **NOEC:** 8 mg/l
- **Exposure time:** 219 d
- **Species:** Oryzias latipes (Japanese medaka)
- **Method:** OECD Test Guideline 229

**Toxicity to fish:**
- **LC50 (Pimephales promelas (fathead minnow)):** 0.28 mg/l
- **Exposure time:** 96 h

**Toxicity to daphnia and other aquatic invertebrates:**
- **EC50 (Daphnia magna (Water flea)):** 0.0056 mg/l
- **Exposure time:** 48 h

**Toxicity to algae/aquatic plants:**
- **ErC50 (Chlorella pyrenoidosa (aglae)):** 0.09 mg/l
- **Exposure time:** 72 h

**M-Factor (Acute aquatic toxicity):**

**M-Factor (Chronic aquatic toxicity):** 1.000

**Benzalkonium chloride:**

**Biodegradability:**
- **Result:** Readily biodegradable.
- **Method:** OECD Test Guideline 301D
- **Remarks:** Based on data from similar materials

**12.2 Persistence and degradability**

**Components:**

**Benzalkonium chloride:**

**12.3 Bioaccumulative potential**

**Components:**

**betamethasone:**
- **Partition coefficient: n-octanol/water:** \( \log \text{Pow}: 2.11 \)

**Benzalkonium chloride:**
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Bioaccumulation:
- Species: Lepomis macrochirus (Bluegill sunfish)
  - Bioconcentration factor (BCF): < 500
  - Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water:
- log Pow: 1.692
  - Remarks: Calculation

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 3082
- ADR: UN 3082
- RID: UN 3082
- IMDG: UN 3082
- IATA: UN 3082

14.2 UN proper shipping name:
- ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
- ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
- RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
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</tbody>
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IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)

IATA: Environmentally hazardous substance, liquid, 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**: M6  
- **Hazard Identification Number**: 90  
- **Labels**: 9

### ADR

- **Packing group**: III  
- **Classification Code**: M6  
- **Hazard Identification Number**: 90  
- **Labels**: 9  
- **Tunnel restriction code**: (-)

### RID

- **Packing group**: III  
- **Classification Code**: M6  
- **Hazard Identification Number**: 90  
- **Labels**: 9

### IMDG

- **Packing group**: III  
- **Labels**: 9  
- **EmS Code**: F-A, S-F

### IATA (Cargo)

- **Packing instruction (cargo aircraft)**: 964
- **Packing instruction (LQ)**: Y964
- **Packing group**: III  
- **Labels**: Miscellaneous

### IATA (Passenger)

- **Packing instruction (passenger aircraft)**: 964  
- **Packing instruction (LQ)**: Y964  
- **Packing group**: III
Betamethasone Liquid Formulation

Version 2.3  Revision Date: 23.03.2020  SDS Number: 2050079-00006  Date of last issue: 13.09.2019  Date of first issue: 07.10.2017

Labels: Miscellaneous

14.5 Environmental hazards

<table>
<thead>
<tr>
<th>Label</th>
<th>Environmentally hazardous</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>yes</td>
</tr>
<tr>
<td>ADR</td>
<td>yes</td>
</tr>
<tr>
<td>RID</td>
<td>yes</td>
</tr>
<tr>
<td>IMDG</td>
<td>yes</td>
</tr>
<tr>
<td>IATA (Passenger)</td>
<td>yes</td>
</tr>
<tr>
<td>IATA (Cargo)</td>
<td>yes</td>
</tr>
</tbody>
</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

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

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Conditions of restriction for the following entries should be considered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)</td>
<td>Number on list 3</td>
</tr>
<tr>
<td>Regulation on Persistent Organic Pollutants (Number 30595)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation on prevention of major industrial accidents. Reg number 30702</td>
<td></td>
</tr>
<tr>
<td><strong>E1</strong></td>
<td><strong>ENVIRONMENTAL HAZARDS</strong></td>
</tr>
<tr>
<td>Quantity 1</td>
<td>Quantity 2</td>
</tr>
<tr>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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The components of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

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
- H301: Toxic if swallowed.
- H311: Toxic in contact with skin.
- 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.
- H411: Toxic to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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; 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; IG50 - Half maximal inhibitory concentra-
Betamethasone Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
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<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Further information


Classification of the mixture:

<table>
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<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>H360D</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
<tr>
<td>H372</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
<tr>
<td>H410</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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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