1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone Liquid Formulation

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

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : ☐ ☐
Signal word : Danger
Hazard statements : H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
H402 Harmful to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
SAFETY DATA SHEET
Betamethasone Liquid Formulation

Version 4.0  Revision Date: 2020/03/23  SDS Number: 805315-00012  Date of last issue: 2019/09/13
Date of first issue: 2016/07/15

P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.3 - &lt; 1</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>&gt;= 0.0025 - &lt; 0.025</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

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

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

Notes to physician: Treat symptomatically and supportively.

## 5. FIREFIGHTING MEASURES

| Suitable extinguishing media | Water spray  
|                             | Alcohol-resistant foam  
|                             | Carbon dioxide (CO2)  
|                             | Dry chemical  
| Unsuitable extinguishing media | None known.  
| Specific hazards during firefighting | Exposure to combustion products may be a hazard to health.  
| Hazardous combustion products | No hazardous combustion products are known  
| Specific extinguishing methods | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
|                             | Use water spray to cool unopened containers.  
|                             | Remove undamaged containers from fire area if it is safe to do so.  
|                             | Evacuate area.  
| Special protective equipment for firefighters | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. 

## 6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protective equipment and emergency procedures | Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.  
| Environmental precautions | Discharge into the environment must be avoided.  
|                           | Prevent further leakage or spillage if safe to do so.  
|                           | Prevent spreading over a wide area (e.g. by containment or oil barriers).  
| Methods and materials for containment and cleaning up | Soak up with inert absorbent material.  
|                                                           | For large spills, provide drying 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.
7. HANDLING AND STORAGE

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe 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.

Avoidance of contact:
- Oxidizing agents

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

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

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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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></td>
<td>Wipe limit 10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
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

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter type</td>
<td>: Particulates type</td>
</tr>
<tr>
<td>Hand protection</td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>: Chemical-resistant gloves</td>
</tr>
<tr>
<td>Remarks</td>
<td>: Consider double gloving.</td>
</tr>
<tr>
<td>Eye protection</td>
<td>: 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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>: 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.</td>
</tr>
</tbody>
</table>

### 9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical state       | : liquid                                                                                       |
| Colour               | : colourless                                                                                   |
| Odour                | : No data available                                                                           |
| Odour Threshold      | : No data available                                                                           |
| Melting point/freezing point | : No data available                                                                 |
| Boiling point, initial boiling point and boiling range | : No data available                                                                 |
| Flammability (solid, gas) | : Not applicable                                                                              |
| Flammability (liquids) | : No data available                                                                            |
| Lower explosion limit and upper explosion limit / flammability limit | : No data available                                                                           |
| Upper explosion limit / Upper flammability limit | : No data available                                                                           |
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : 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): 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
  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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>Rabbit</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>Rabbit</td>
<td>Irreversible effects on the eye</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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Weak sensitizer</td>
</tr>
<tr>
<td>benzalkonium chloride</td>
<td>Skin contact</td>
<td>Humans</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
<th>Germ cell mutagenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative</td>
<td>Weight of evidence does not support classification as a germ</td>
</tr>
<tr>
<td>benzalkonium chloride</td>
<td>Test Type: Chromosome aberration test in vitro Result: positive</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Oral Result: equivocal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Assessment 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 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

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:**

Effects on foetal develop- Species: Rabbit
SAFETY DATA SHEET

Betamethasone Liquid Formulation

Version 4.0 Revision Date: 2020/03/23 SDS Number: 805315-00012 Date of last issue: 2019/09/13 Date of first issue: 2016/07/15

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.

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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Components:

betamethasone:
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.

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 days
- **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 days
  - **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
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

**Betamethasone:**
- Toxidity to daphnia and other aquatic invertebrates:
  - EC50 (Americamysis): > 50 mg/l
  - Exposure time: 96 h

- Toxidity 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

- Toxidity to fish (Chronic toxicity):
  - NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

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

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

- M-Factor (Chronic aquatic toxicity): 1,000

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

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

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

- M-Factor (Acute aquatic toxicity): 100

- Toxidity to fish (Chronic toxicity):
  - NOEC (Pimephales promelas (fathead minnow)): 0.032 mg/l
  - Exposure time: 34 d

**Betamethasone:**
- Toxidity to daphnia and other aquatic invertebrates:
  - EC50 (Americamysis): > 50 mg/l
### Aquatic Invertebrates

**Exposure time:** 96 h

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 32 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td>NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 219 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 229</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 8 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

**M-Factor (Chronic aquatic toxicity):** 1,000

### Persistence and Degradability

**Components:**

#### Benzalkonium chloride:

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Readily biodegradable. Method: OECD Test Guideline 301D</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Bioaccumulative Potential

**Components:**

#### betamethasone:

<table>
<thead>
<tr>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow: 2.11</th>
</tr>
</thead>
</table>

#### Benzalkonium chloride:

<table>
<thead>
<tr>
<th>Bioaccumulation</th>
<th>Species: Lepomis macrochirus (Bluegill sunfish)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bioconcentration factor (BCF): &lt; 500</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>log Pow: 1.692</td>
</tr>
<tr>
<td></td>
<td>Remarks: Calculation</td>
</tr>
</tbody>
</table>
14. TRANSPORT INFORMATION

International Regulations

**UNRTDG**
- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9

**IATA-DGR**
- **UN/ID No.**: UN 3082
- **Proper shipping name**: Environmentally hazardous substance, liquid, n.o.s. (betamethasone)
- **Class**: 9
- **Packing group**: III
- **Labels**: Miscellaneous
- **Packing instruction (cargo aircraft)**: 964
- **Packing instruction (passenger aircraft)**: 964
- **Environmentally hazardous**: yes

**IMDG-Code**
- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9
- **EmS Code**: F-A, S-F
- **Marine pollutant**: yes
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

**National Regulations**
Refer to section 15 for specific national regulation.

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

### 15. REGULATORY INFORMATION

**Related Regulations**

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

**Chemical Substance Control Law**
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**
Not applicable

**Harmful Substances Required Permission for Manufacture**
Not applicable

**Substances Prevented From Impairment of Health**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**
Not applicable

**Substances Subject to be Notified Names**
Not applicable

**Substances Subject to be Indicated Names**
Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**
Not applicable

**Ordinance on Prevention of Lead Poisoning**
Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**
Not applicable
16. OTHER INFORMATION

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-
SAFETY DATA SHEET
Betamethasone Liquid Formulation

Version 4.0   Revision Date: 2020/03/23   SDS Number: 805315-00012   Date of last issue: 2019/09/13

SDS Number: 805315-00012

Date of last issue: 2019/09/13

Date of first issue: 2016/07/15


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

Date format yyyy/mm/dd

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; ICS0 - 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 Standardisation; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

JP / EN