## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product name**: Betamethasone Liquid Formulation

**Manufacturer or supplier's details**

<table>
<thead>
<tr>
<th>Company</th>
<th>MSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>Briahnager - Off Pune Nagar Road</td>
</tr>
<tr>
<td></td>
<td>Wagholi - Pune - India 412 207</td>
</tr>
<tr>
<td>Telephone</td>
<td>908-740-4000</td>
</tr>
<tr>
<td>Emergency phone</td>
<td>1-908-423-6000</td>
</tr>
<tr>
<td>E-mail address</td>
<td><a href="mailto:EHSDATASTEWARD@msd.com">EHSDATASTEWARD@msd.com</a></td>
</tr>
<tr>
<td>Telefax</td>
<td>908-735-1496</td>
</tr>
</tbody>
</table>

**Recommended use of the chemical and restrictions on use**

| Recommended use | Pharmaceutical                           |

## 2. HAZARDS IDENTIFICATION

### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

**Classification**

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

### GHS Classification

- **Reproductive toxicity**: Category 1B
- **Specific target organ toxicity - repeated exposure**: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
- **Long-term (chronic) aquatic hazard**: Category 1

### GHS label elements

- **Hazard pictograms**
- **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.
  - H410 Very toxic to aquatic life with long lasting effects.
**Precautionary statements**

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe 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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.3 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>&gt;= 0.0025 - &lt; 0.025</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.
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Most important symptoms and effects, both acute and delayed: Get medical attention. Rinse mouth thoroughly with water. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

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

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: 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).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and 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-
mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</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></td>
</tr>
</tbody>
</table>

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

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
Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection

Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

9. 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

Flammability (solid, gas): Not applicable

Flammability (liquids): 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: > 10 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:**
- **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
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Date of first issue: 15.07.2016

Remarks: Based on data from similar materials

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

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

Genotoxicity in vivo:
Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: positive

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
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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: 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 study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
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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.

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
  - 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

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

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

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

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 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 (passen-
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ger aircraft)
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 IMO instruments
Not applicable for product as supplied.

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

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

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

16. OTHER INFORMATION

Further information

Date format : dd.mm.yyyy

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;
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.

IN / EN