1. PRODUCT AND COMPANY IDENTIFICATION

**Product name**: Betamethasone (0.05%) Liquid Formulation

**Manufacturer or supplier's details**

- **Company**: MSD
- **Address**: Briahnager - Off Pune Nagar Road
  Wagholi - Pune - India 412 207
- **Telephone**: 908-740-4000
- **Emergency telephone number**: 1-908-423-6000
- **E-mail address**: EHSDATASTEWARD@msd.com
- **Telefax**: 908-735-1496

**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**: ![Pictogram](image)
- **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:**
P203 Obtain, read and follow all safety instructions before use.
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:**
P318 IF exposed or concerned, get medical advice.
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>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>

#: Voluntarily-disclosed non-hazardous substance

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 and effects, both acute and delayed:
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:
Carbon oxides

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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
Avoid release to the environment.
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.

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 determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding
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 mist or vapours.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Do not eat, drink or smoke when using this product.
- 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 (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>TWA</td>
<td>1,000 ppm 1,900 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td>Wipe limit 10 µg/100 cm²</td>
<td>Internal</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 expo- |


Filter type
Hand protection : Combined particulates and organic vapour type

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 : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

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
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.

Components:

**Ethanol:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 401
- Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
  Exposure time: 4 h
  Test atmosphere: vapour

**Betamethasone:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  LD50 (Mouse): > 4,500 mg/kg
- Acute inhalation toxicity: LC50 (Rat): 0.4 mg/l
  Exposure time: 4 h

Skin corrosion/irritation
Not classified based on available information.

Components:

**Ethanol:**
- Species: Rabbit
  Method: OECD Test Guideline 404
  Result: No skin irritation

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

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

Components:

**Ethanol:**
- Species: Rabbit
  Method: OECD Test Guideline 405
  Result: Irritation to eyes, reversing within 21 days

**Betamethasone:**
- Species: Rabbit
  Result: No eye irritation
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>Ethanol:</th>
<th>Test Type: Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure routes: Skin contact</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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

Germ cell mutagenicity
Not classified based on available information.

Components:

- Ethanol:
  - Genotoxicity in vitro
    - Test Type: In vitro mammalian cell gene mutation test
    - Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative

  - Genotoxicity in vivo
    - Test Type: Rodent dominant lethal test (germ cell) (in vivo)
    - Species: Mouse
    - Application Route: Ingestion
    - Result: equivocal

- 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
SAFETY DATA SHEET

Betamethasone (0.05%) Liquid Formulation

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
May damage the unborn child.

Components:

Ethanol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Betamethasone:
Effects on foetal development: Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
Result: Malformations were observed.

Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (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:**

**Ethanol:**
- Species: Rat
- NOAEL: 1,280 mg/kg
- LOAEL: 3,156 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days

**betamethasone:**
- Species: Rabbit
- NOAEL: 0.05 %
- Application Route: Skin contact
- Exposure time: 10 - 30 d
- Target Organs: Pituitary gland, Immune system, muscle

**Species:**
- Rat
- NOAEL: 0.05 %
- Application Route: Skin contact
- Exposure time: 8 Weeks
- Target Organs: thymus gland

**Species:**
- Mouse
- NOAEL: 0.1 %
- Application Route: Skin contact
- Exposure time: 8 Weeks
- Target Organs: thymus gland

**Species:**
- Dog
- NOAEL: 0.05 mg/kg
- Application Route: Oral
- Exposure time: 28 d
- Target Organs: Blood, thymus gland, Adrenal gland

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

**Components:**

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

**Ethanol:**
### Toxicity to Fish
- **LC50**: Pimephales promelas (fathead minnow); > 1,000 mg/l
- Exposure time: 96 h

### Toxicity to Daphnia and Other Aquatic Invertebrates
- **EC50**: Ceriodaphnia (water flea); > 1,000 mg/l
- Exposure time: 48 h

### Toxicity to Algae/Aquatic Plants
- **ErC50**: Chlorella vulgaris (Fresh water algae); 275 mg/l
  - Exposure time: 72 h
- **EC10**: Chlorella vulgaris (Fresh water algae); 11.5 mg/l
  - Exposure time: 72 h

### Toxicity to Microorganisms
- **EC50**: Pseudomonas putida; 6,500 mg/l
  - Exposure time: 16 h

### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)
- **NOEC**: 9.6 mg/l
  - Exposure time: 9 d
  - Species: Daphnia magna (Water flea)

### 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
12. PERSISTENCE AND DEGRADABILITY

**Components:**

- **Ethanol:**
  - Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 84 %
  - Exposure time: 20 d

**Bioaccumulative potential**

**Components:**

- **Ethanol:**
  - Partition coefficient: n-octanol/water
    - log Pow: -0.35

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

**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)

<table>
<thead>
<tr>
<th>Class</th>
<th>Packing group</th>
<th>Labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>III</td>
<td>9</td>
</tr>
</tbody>
</table>

**IATA-DGR**

- UN/ID No.: UN 3082
- Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (betamethasone)

<table>
<thead>
<tr>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Betamethasone (0.05%) Liquid Formulation

<table>
<thead>
<tr>
<th>Packing group</th>
<th>III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labels</td>
<td>Miscellaneous</td>
</tr>
<tr>
<td>Packing instruction (cargo aircraft)</td>
<td>964</td>
</tr>
<tr>
<td>Packing instruction (passenger aircraft)</td>
<td>964</td>
</tr>
<tr>
<td>Environmentally hazardous</td>
<td>yes</td>
</tr>
</tbody>
</table>

**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
- AICS: not determined

**16. OTHER INFORMATION**

**Further information**

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

Date format: dd.mm.yyyy

Full text of other abbreviations
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.