1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone (0.085%) Formulation

Manufacturer or supplier’s details
Company : MSD
Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance : suspension
Colour : No data available
Odour : No data available

Not a hazardous substance or mixture.

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Physical and chemical hazards
Not classified based on available information.

Health hazards
Not classified based on available information.

Environmental hazards
Not classified based on available information.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Components
Dexamethasone (0.085%) Formulation

Version 1.3
Revision Date: 09/13/2019
SDS Number: 2708637-00004
Date of last issue: 2019/04/24
Date of first issue: 2018/04/13

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

- **If inhaled**: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
- **In case of skin contact**: Wash with water and soap as a precaution. Get medical attention if symptoms occur.
- **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 if symptoms occur. Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**

**Protection of first-aiders**

No special precautions are necessary for first aid responders.

**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
  Metal 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**: Wear self-contained breathing apparatus for firefighting if necessary.
  Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

- **Personal precautions, protective equipment and emergency procedures**: 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 containment).
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 certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Storage

Conditions for safe storage: Keep in properly labelled containers. 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

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>Dexamethasone</td>
<td>50-02-2</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
</tr>
</tbody>
</table>

Further information: Skin

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-
less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

**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**: Organic vapour type
- **Eye/face 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.

**Hand protection**
- Material: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**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**: suspension
- **Colour**: No data available
- **Odour**: No data available
- **Odour Threshold**: No data available
## 10. STABILITY AND REACTIVITY

**Reactivity**

Not classified as a reactivity hazard.
Dexamethasone (0.085%) Formulation

1.3

Revision Date: 09/13/2019

SDS Number: 2708637-00004

Date of last issue: 2019/04/24

Date of first issue: 2018/04/13

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

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Product:

Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Benzyl alcohol:
Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Dexamethasone:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
LD50 (Mouse): > 6,500 mg/kg

Acute toxicity (other routes of administration): LD50 (Rat): 14 mg/kg
Application Route: Subcutaneous

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

Components:

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Dexamethasone (0.085%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>09/13/2019</td>
<td>2708637-00004</td>
<td>2019/04/24</td>
<td>2018/04/13</td>
</tr>
</tbody>
</table>

Result : No skin irritation

**Dexamethasone:**
Species : Rabbit
Result : Mild skin irritation

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

**Components:**

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

**Dexamethasone:**
Species : Rabbit
Result : Mild eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Benzy alcohol:**
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

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

**Components:**

**Benzy alcohol:**
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative
Dexamethasone (0.085%) Formulation

Version: 1.3  Revision Date: 09/13/2019  SDS Number: 2708637-00004  Date of last issue: 2019/04/24  Date of first issue: 2018/04/13

Dexamethasone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  Result: negative
Test Type: in vitro assay  Test system: mouse lymphoma cells  Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse  Application Route: Oral  Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Benzyl alcohol:
Species: Mouse  Application Route: Ingestion
Exposure time: 103 weeks  Method: OECD Test Guideline 451  Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

Benzyl alcohol:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat  Application Route: Ingestion  Result: negative  Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse  Application Route: Ingestion  Result: negative

Dexamethasone:
Effects on foetal development: Test Type: Development
Species: Mouse  Application Route: Subcutaneous  Developmental Toxicity: LOAEL: 6 mg/kg body weight  Result: Specific developmental abnormalities, Cleft palate
Species: Rabbit  Application Route: Intramuscular  Developmental Toxicity: NOAEL: 0.025 mg/kg body weight
### Dexamethasone (0.085%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>09/13/2019</td>
<td>2708637-00004</td>
<td>2019/04/24</td>
<td>2018/04/13</td>
</tr>
</tbody>
</table>

Result: Specific developmental abnormalities

**Species:** Rabbit  
**Application Route:** Intramuscular  
**Developmental Toxicity:** LOAEL: >= 0.062 mg/kg body weight  
**Result:** Specific developmental abnormalities

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: >= 0.02 mg/kg body weight  
Result: Skeletal and visceral variations, Retardations

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

**STOT - single exposure**  
Not classified based on available information.

**STOT - repeated exposure**  
Not classified based on available information.

**Components:**

**Dexamethasone:**
- **Exposure routes:** Oral  
- **Target Organs:** Adrenal gland, Immune system, thymus gland  
- **Assessment:** May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Benzyl alcohol:**
- **Species:** Rat  
- **NOAEL:** 1.072 mg/l  
- **Application Route:** inhalation (dust/mist/fume)  
- **Exposure time:** 28 Days  
- **Method:** OECD Test Guideline 412

**Dexamethasone:**
- **Species:** Rat  
- **NOAEL:** 0.0015 mg/kg  
- **Application Route:** Oral  
- **Exposure time:** 7 d  
- **Target Organs:** Liver  
- **Remarks:** Significant toxicity observed in testing

Species: Rat  
LOAEL: 0.003 mg/kg  
Application Route: Oral  
Exposure time: 90 d  
Target Organs: Blood, Adrenal gland, thymus gland  
Remarks: Significant toxicity observed in testing
Dexamethasone (0.085%) Formulation

Species: Rat
LOAEL: 0.125 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Target Organs: Adrenal gland
Remarks: Significant toxicity observed in testing

Species: Rat
LOAEL: 0.4 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Immune system
Remarks: Significant toxicity observed in testing

Species: Dog
LOAEL: 8 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Immune system
Remarks: Significant toxicity observed in testing

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Dexamethasone:
Ingestion: Target Organs: Immune system
Target Organs: Adrenal gland
Target Organs: Bone
Symptoms: muscle weakness

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzy alcohol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Dexamethasone (0.085%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>09/13/2019</td>
<td>2708637-00004</td>
<td>2019/04/24</td>
<td>2018/04/13</td>
</tr>
</tbody>
</table>

**NOEC** (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

**Dexamethasone**:  
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 56 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

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

**Toxicity to microorganisms**: EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Persistence and degradability**

**Components**:

**Benzyl alcohol**: Biodegradability: Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

**Dexamethasone**: Biodegradability: Result: Not readily biodegradable.  
Biodegradation: 50 %
Dexamethasone (0.085%) Formulation

Bioaccumulative potential

**Components:**

**Benzyl alcohol:**
- Partition coefficient: n-octanol/water: log Pow: 1.05

**Dexamethasone:**
- Partition coefficient: n-octanol/water: log Pow: 1.83

**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**
- Not regulated as a dangerous good

**IATA-DGR**
- Not regulated as a dangerous good

**IMDG-Code**
- Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
- Not applicable for product as supplied.

**National Regulations**

**GB 6944/12268**
- Not regulated as a dangerous good

**Special precautions for user**
- Not applicable
Dexamethasone (0.085%) Formulation

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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: 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; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for 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 - Trans-
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Dexamethasone (0.085%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>09/13/2019</td>
<td>2708637-00004</td>
<td>2019/04/24</td>
<td>2018/04/13</td>
</tr>
</tbody>
</table>

portation 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

Disclaimer
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.

CN / EN