SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

Version: 2.8  Revision Date: 2019/09/13  SDS Number: 752034-00010  Date of last issue: 2019/04/24
Date of first issue: 2016/06/14

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Dexamethasone (with Ethanol) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
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: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
Vapours may form explosive mixture with air.

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>&lt; 10</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>&gt;= 0.025 -&lt; 0.25</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 and effects, both acute and delayed: None known.

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: High volume water jet

Specific hazards during firefighting: Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. 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: Remove all sources of ignition. 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
Methods and materials for containment and cleaning up:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- 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

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.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.
- Keep away from heat and sources of ignition.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Components with workplace control parameters</th>
<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>
</table>

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Ethanol

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Exposure Limit</th>
<th>ID OEL</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>1,000 ppm</td>
<td>NAB</td>
<td>Upper respiratory tract irritation</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures

Minimize workplace exposure concentrations.
If sufficient ventilation is unavailable, use with local exhaust ventilation.

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: Combined particulates and organic vapour type

Hand protection

Material: Chemical-resistant gloves

Remarks

Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Take note that the product is flammable, which may impact the selection of hand protection. Wash hands before breaks and at the end of workday.

Eye protection

Wear the following personal protective equipment:
Safety glasses

Skin and body protection

Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Wear the following personal protective equipment:
If assessment demonstrates that there is a risk of explosive atmospheres or flash fires, use flame retardant antistatic protective clothing.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Colour: clear

Odour: No data available
## Odour Threshold
- No data available

## pH
- 4.9

## Melting point/freezing point
- No data available

## Initial boiling point and boiling range
- No data available

## Flash point
- 68 °C

## Evaporation rate
- No data available

## Flammability (solid, gas)
- Not applicable

## Flammability (liquids)
- Not applicable

## Upper explosion limit / Upper flammability limit
- No data available

## Lower explosion limit / Lower flammability limit
- No data available

## Vapour pressure
- No data available

## Relative vapour density
- No data available

## Density
- No data available

## Solubility(ies)
- Water solubility: No data available

## Partition coefficient: n-octanol/water
- Not available

## Auto-ignition temperature
- No data available

## Decomposition temperature
- No data available

## Viscosity
- Viscosity, kinematic: No data available

## Explosive properties
- Not explosive

## Oxidizing properties
- The substance or mixture is not classified as oxidizing.

## Molecular weight
- No data available

## Particle size
- No data available

### 10. STABILITY AND REACTIVITY

**Reactivity**: Not classified as a reactivity hazard.
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Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- Combustible liquid.
- Vapours may form explosive mixture with air.
- Can react with strong oxidizing agents.

Conditions to avoid:
- Heat, flames and sparks.
- Oxidizing agents

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

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:

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

Dexamethasone:
- Species: Rabbit
- Result: Mild skin irritation
Serious eye damage/eye irritation
Not classified based on available information.

Components:

Ethanol:
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:

Ethanol:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

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

Genotoxicity in vivo: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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.

## Reproductive toxicity
Not classified based on available information.

### Components:

#### Ethanol:
- **Effects on fertility**
  - **Test Type:** Two-generation reproduction toxicity study
  - **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
  - **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:**

**Ethanol:**

| Species | Rat |
| NOAEL | 1,280 mg/kg |
| LOAEL | 3,156 mg/kg |

**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 |

| 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:**

**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 daphnia and other aquatic invertebrates (Chronic toxicity)
  - NOEC (Daphnia magna (Water flea)): 9.6 mg/l
  - Exposure time: 9 d

- Toxicity to microorganisms
  - EC50 (Pseudomonas putida): 6,500 mg/l
  - Exposure time: 16 h

**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:

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

Dexamethasone:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 3.54 d
Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

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

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.
Empty containers retain residue and can be dangerous.
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources
of ignition. They may explode and cause injury and/or death. 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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Ethanol
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / STEL: Short-term exposure limit
ID OEL / NAB: Long term exposure limit

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 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; TCIS - 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.

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