SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Dexamethasone (with Ethanol) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 26 Talavera Road, Talavera Corp Centre, Macquarie Park New South Wales, 2113 Australia
Telephone: (61)-02-8988-8000
Emergency telephone number: (61)-02-8988-8000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Flammable liquids: Category 4

GHS label elements
Hazard pictograms: None
Signal word: Warning
Hazard statements: H227 Combustible liquid.
Precautionary statements: Prevention:
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.

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

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

Version 2.8  Revision Date: 09/13/2019  SDS Number: 752024-00010  Date of last issue: 24.04.2019

Date of first issue: 14.06.2016

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>&lt; 0.3</td>
</tr>
</tbody>
</table>

SECTION 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.

SECTION 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.
SECTION 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 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:
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.

SECTION 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.

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.


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

### SECTION 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, 1,880 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</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).

SECTION 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: No data 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

SECTION 10. STABILITY AND REACTIVITY

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

Conditions to avoid : Heat, flames and sparks.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : 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
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Ethanol:
Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rodent dominant lethal test (germ cell) (in vivo)</td>
<td>equivocal</td>
<td>Mouse</td>
<td>Ingestion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Micronucleus test</td>
<td>negative</td>
<td>Mouse</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two-generation reproduction toxicity study</td>
<td>negative</td>
<td>Mouse</td>
<td>Ingestion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development</td>
<td>Specific developmental abnormalities, Cleft palate</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Specific developmental abnormalities</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Specific developmental abnormalities</td>
</tr>
<tr>
<td>Development</td>
<td>NOAEL: 0.025 mg/kg body weight</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Specific developmental abnormalities</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Specific developmental abnormalities</td>
</tr>
<tr>
<td>Development</td>
<td>LOAEL: &gt;= 0.062 mg/kg body weight</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Specific developmental abnormalities</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>Specific developmental abnormalities</td>
</tr>
<tr>
<td>Development</td>
<td>LOAEL: 6 mg/kg body weight</td>
<td>Mouse</td>
<td>Ingestion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Genotoxicity in vitro**

**Genotoxicity in vivo**

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**Ethanol:**

**Effects on fertility**

**Dexamethasone:**

**Effects on foetal 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: \( \geq 0.02 \) 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
Application Route
: Ingestion
Exposure time
: 90 Days

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
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

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

SECTION 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

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
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 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.

SECTION 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.

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements: There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
SECTION 16. OTHER INFORMATION

Further information
Revision Date: 09/13/2019
Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA, ACGIH Threshold Limit Values (TLV)
AU OEL: Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / STEL: Short-term exposure limit
AU OEL / TWA: Exposure standard - time weighted average

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.

AU / EN