1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Dexamethasone (with Ethanol) Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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

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
Important symptoms and outlines of the emergency assumed:
Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

Version 2.8  Revision Date: 09/13/2019  SDS Number: 752037-00010  Date of last issue: 2019/04/24
Date of first issue: 2016/06/14

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-202</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td></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 cir-
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 dyeing or other appropriate containment to keep material from spreading. If dyed 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**: 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.

Avoidance of contact: Oxidizing agents

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.

Storage


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

Threshold limit value and permissible exposure limits for each component in the work environment

<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>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>Further information: Skin</td>
<td>Wipe limit 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: Chemical-resistant gloves

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).

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Color : 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
**SAFETY DATA SHEET**

**Dexamethasone (with Ethanol) 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>
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<tr>
<td>2.8</td>
<td>09/13/2019</td>
<td>752037-00010</td>
<td>2019/04/24</td>
<td>2016/06/14</td>
</tr>
</tbody>
</table>

- **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

### 10. STABILITY AND REACTIVITY

- **Reactivity:** Not classified as a reactivity hazard.
- **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.
- **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
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
  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

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: \( \geq 0.062 \) 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

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:**
Dexamethasone (with Ethanol) Formulation

Partition coefficient: n-octanol/water

Dexamethasone:
Partition coefficient: n-octanol/water

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Designated Flammable Substances, Flammable liquid, (2 cubic metre)
Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law
Harmful Substances Prohibited from Manufacture
Not applicable
Harmful Substances Required Permission for Manufacture
Not applicable
Substances Prevented From Impairment of Health
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable
Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>61</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>61</td>
</tr>
</tbody>
</table>
Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Specially Controlled Industrial Waste

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)
ACGIH / STEL : Short-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; ICS0 - Half maximal inhibitory con-
centration; 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 Organization for Standardization; 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 - 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.

JP / EN