1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Dexamethasone (with Ethanol) Formulation

Supplier’s company name, address and phone number

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 of chemical product
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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Substance / Mixture: Mixture
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

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>

# 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: 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.

6. ACCIDENTAL RELEASE MEASURES

- **Personal precautions, protective equipment and emergency procedures:**
  - Remove all sources of ignition.
  - 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:**
  - 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**
  - **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, hot surfaces, sparks, open flames and
other ignition sources. No smoking.
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
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

Packaging material: Unsuitable material: None known.

**8. EXPOSURE CONTROLS/PERSOAL 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.

<table>
<thead>
<tr>
<th>Filter type</th>
<th>Combined particulates and organic vapour type</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Hand protection</th>
<th>Material</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical-resistant gloves</td>
<td>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,</td>
<td></td>
</tr>
</tbody>
</table>
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

Physical state: liquid
Colour: clear
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Boiling point, initial boiling point and boiling range: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): Not applicable
Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: 68 °C
Decomposition temperature: No data available
pH: 4.9
Evaporation rate: No data available
Auto-ignition temperature: No data available
Viscosity
Viscosity, kinematic: No data available
Solubility(ies)
Dexamethasone (with Ethanol) Formulation

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  
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
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
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

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
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
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

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>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

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
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.