1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Dexamethasone Solid Formulation

Supplier’s company name, address and phone number
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
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
Long-term (chronic) aquatic hazard: Category 3

GHS label elements
Hazard pictograms: None
Signal word: None
Hazard statements: H412 Harmful to aquatic life with long lasting effects.
Precautionary statements: Prevention:
P273 Avoid release to the environment.
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: Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 - &lt; 40</td>
<td>8-98</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>&gt;= 0.25 - &lt; 0.3</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: If in eyes, rinse well with water. 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: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. 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
## 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Safety Measure</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personal precautions, protective equipment and emergency procedures</strong></td>
<td>Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
</tr>
<tr>
<td><strong>Environmental precautions</strong></td>
<td>Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.</td>
</tr>
<tr>
<td><strong>Methods and materials for containment and cleaning up</strong></td>
<td>Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.</td>
</tr>
</tbody>
</table>

## 7. HANDLING AND STORAGE

### Handling

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>If sufficient ventilation is unavailable, use with local exhaust ventilation.</td>
</tr>
<tr>
<td>Advice on safe handling</td>
<td>Do not get on skin or clothing. Do not breathe dust. 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. Minimize dust generation and accumulation. Keep container closed when not in use. 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.</td>
</tr>
</tbody>
</table>
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.

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.

Storage:

Conditions for safe storage:

Keep in properly labelled containers.

Keep tightly closed.

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

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>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</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></td>
<td>Wipe limit</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 100 µg/100 cm² Internal

Engineering measures:

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:

Particulates type

Hand protection:

Material:

Chemical-resistant gloves

Remarks:

Consider double gloving.

Eye 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: powder
Colour: white
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): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available

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: Not applicable
Decomposition temperature: No data available
pH: No data available
Evaporation rate: Not applicable
Auto-ignition temperature: No data available
Viscosity
Viscosity, kinematic: Not applicable

Solubility(ies)
Water solubility: No data available
Partition coefficient: n-
octanol/water

Vapour pressure : Not applicable

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
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
May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

Conditions to avoid
Heat, flames and sparks.
Avoid dust formation.

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:

Starch:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

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:**

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

**Starch:**
Species: Rabbit
Result: No eye irritation

**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:**

**Starch:**
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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

**Components:**

**Starch:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Dexamethasone Solid Formulation

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:

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:

Starch:

- **Species**: Rat
- **NOAEL**: >= 2,000 mg/kg
- **Application Route**: Skin contact
- **Exposure time**: 28 Days
- **Method**: OECD Test Guideline 410

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:
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:**

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

Bioaccumulative potential

**Components:**

**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. 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
Not applicable to dangerous materials / designated flammables.

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
Not applicable

Substances Subject to be Indicated Names
Not applicable

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
SAFETY DATA SHEET

Dexamethasone Solid Formulation

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 : Not classified as noxious liquid substance
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
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 / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; 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 Sys-
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