SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone (with Ethanol) Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Flammable liquids : Category 4
Reproductive toxicity : Category 1B

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H227 Combustible liquid.
H360D May damage the unborn child.

Precautionary Statements :
Prevention:
P201 Obtain special instructions before use.
P210 Keep away from heat/sparks/open flames/hot surfaces.
No smoking.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

Storage:
P405 Store locked up.

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>Flammable liquids, Category 2</td>
<td>&gt;= 5 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye irritation, Category 2A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>Reproductive toxicity, Category 1B</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific target organ toxicity - repeated exposure (Oral) (Adrenal gland, Immune system, thymus gland), Category 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term (chronic) aquatic hazard, Category 1</td>
<td></td>
<td></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:
- May damage the unborn child.
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. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- High volume water jet

Specific hazards during fire fighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapors 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 fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

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/vapors/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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 vapors 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.

#### Conditions for safe storage
Keep in properly labeled 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 Organic peroxides Explosives Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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>LT</td>
<td>780 ppm 1.480 mg/m³</td>
<td>BR OEL</td>
</tr>
</tbody>
</table>

Further information: Degree of harmfulness: minimum

| STEL       | 1.000 ppm | ACGIH |
Dexamethasone (with Ethanol) Formulation

<table>
<thead>
<tr>
<th>Dexamethasone</th>
<th>50-02-2</th>
<th>TWA</th>
<th>10 µg/m³ (OEB 3)</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
<td></td>
<td></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 vapor type
- Hand protection: Material: Chemical-resistant gloves

**Remarks**
- Choose gloves to protect hands against chemicals depending on the concentration 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**

<table>
<thead>
<tr>
<th>Appearance</th>
<th>liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>clear</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>4,9</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Property</td>
<td>Value</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Flash point</td>
<td>68 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**SECTION 10. STABILITY AND REACTIVITY**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Combustible liquid. Vapors may form explosive mixture with air. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

SECTION 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: vapor

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
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

Version: 3.2  
Revision Date: 09/13/2019  
SDS Number: 752026-00010  
Date of last issue: 24.04.2019  
Date of first issue: 14.06.2016

Dexamethasone:
Species: Rabbit  
Result: Mild eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Ethanol:
Test Type: Local lymph node assay (LLNA)  
Routes of exposure: 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: 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 test  
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
May damage the unborn child.

Components:

Ethanol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Dexamethasone:
Effects on fetal 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:
Routes of exposure : 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:
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Dexamethasone (with Ethanol) Formulation

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
NOAEL: 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
NOAEL: 0.125 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Target Organs: Adrenal gland
Remarks: Significant toxicity observed in testing

Species: Rat
NOAEL: 0.4 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Immune system
Remarks: Significant toxicity observed in testing

Species: Dog
NOAEL: 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
SAFETY DATA SHEET

Dexamethasone (with Ethanol) Formulation

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
- M-Factor (Chronic aquatic toxicity):
  - 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
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

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
SECTION 15. REGULATORY INFORMATION

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

International Regulations

The ingredients of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information


Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- BR OEL: Brazil. NR 15 - Unhealthy activities and operations
- ACGIH / STEL: Short-term exposure limit
- BR OEL / LT: Up to 48 hours /week

Abbreviations:
- 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
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