SAFETY DATA SHEET

Dexamethasone (0.085%) Formulation

SECTION 1. IDENTIFICATION

Product name : Dexamethasone (0.085%) Formulation

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
          Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 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>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>&lt; 0.1</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.
            Get medical attention if symptoms occur.
In case of skin contact : Wash with water and soap as a precaution.
                        Get medical attention if symptoms occur.
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 if symptoms occur.
               Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : None known.

Protection of first-aiders : No special precautions are necessary for first aid responders.

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:
- None known.

Specific hazards during firefighting:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Metal 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:
- Wear self-contained breathing apparatus for firefighting if necessary.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- 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:
- Soak up with inert absorbent material.
- 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.

Advice on safe handling: Use only with adequate ventilation.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled containers.
Store in accordance with the particular national regulations.

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

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>Benzyl alcohol</td>
<td>100-51-6</td>
<td>TWA</td>
<td>10 ppm</td>
<td>US WEEL</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>
</tbody>
</table>

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

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material: Chemical-resistant gloves
Remarks

Eye protection : Consider double gloving.
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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension
Color : No data available
Odor : No data available
Odor Threshold : No data available
pH : 7.0 - 7.8
No data available
Melting point/freezing point : Not applicable
Initial boiling point and boiling range : No data available
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
### 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 reac-</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>tions</td>
<td></td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</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>

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

- **Inhalation**
- **Skin contact**
- **Ingestion**
- **Eye contact**

#### Acute toxicity

Not classified based on available information.

**Product:**

- **Acute oral toxicity**: Acute toxicity estimate: > 5,000 mg/kg  
  Method: Calculation method
Acute inhalation toxicity: Acute toxicity estimate: > 200 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Method: Calculation method

Components:

Benzyl alcohol:
Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Method: OECD Test Guideline 403

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:

Benzyl alcohol:
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:

Benzyl alcohol:
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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Benzyl alcohol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

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.

Components:

Benzyl alcohol:
Species: Mouse
Application Route: Ingestion
Exposure time: 103 weeks
Dexamethasone (0.085%) Formulation

Method: OECD Test Guideline 451
Result: negative

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:

Benzyl alcohol:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
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:

Benzy alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Benzyl alcohol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2
Dexamethasone (0.085%) Formulation

Persistence and degradability

Components:

Benzyl alcohol:
Biodegradability: Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d

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

Bioaccumulative potential

Components:

Benzyl alcohol:
Partition coefficient: n-octanol/water: log Pow: 1.05

Dexamethasone:
Partition coefficient: n-octanol/water: log Pow: 1.83

Mobility in soil
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. 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.

**Domestic regulation**
- **49 CFR**: Not regulated as a dangerous good

### SECTION 15. REGULATORY INFORMATION

**EPCRA - Emergency Planning and Community Right-to-Know**

**CERCLA Reportable Quantity**
This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**
This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**
This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards**
- No SARA Hazards

**SARA 313**
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

**Pennsylvania Right To Know**
- **Water**: 7732-18-5
SAFETY DATA SHEET

Dexamethasone (0.085%) Formulation

Version: 2.2  Revision Date: 09/13/2019  SDS Number: 2708663-00004
Date of last issue: 04/24/2019  Date of first issue: 04/13/2018

Benzyl alcohol  100-51-6

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

NFPA 704:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "∗∗∗" represents a chronic hazard, while the """" represents the absence of a chronic hazard.

Full text of other abbreviations

US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA: 8-hr TWA

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECX - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCxx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - 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 Organisation 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-

Revision Date: 09/13/2019

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.

US / Z8