

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Dexamethasone (with Ethanol) Formulation

Version 5.2      Revision Date: 09/28/2024      SDS Number: 752043-00021      Date of last issue: 06/24/2024  
Date of first issue: 06/14/2016

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### SECTION 1. IDENTIFICATION

Product name : Dexamethasone (with Ethanol) Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
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  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Flammable liquids : Category 4  
Reproductive toxicity : Category 1B

#### GHS label elements

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.  
P202 Do not handle until all safety precautions have been read and understood.  
P210 Keep away from heat, sparks, open flame and hot surfaces. No smoking.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.  
**Storage:**  
P403 + P235 Store in a well-ventilated place. Keep cool.  
P405 Store locked up.

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### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

Vapors may form explosive mixture with air.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Polyethylene glycol	25322-68-3	$\geq 50 - < 70$
Ethanol#	64-17-5	$\geq 5 - < 10$
Benzyl alcohol	100-51-6	$\geq 0.1 - < 1$
Dexamethasone	50-02-2	$\geq 0.1 - < 1$

# Voluntarily-disclosed substance

Actual concentration is withheld as a trade secret

## 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 (CO<sub>2</sub>)

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- 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.
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### 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 (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/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

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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, 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.
- 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  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m <sup>3</sup>	US WEEL
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m <sup>3</sup>	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m <sup>3</sup>	OSHA Z-1
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
Dexamethasone	50-02-2	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				

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		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
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**Engineering measures** : Minimize workplace exposure concentrations.  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

### 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** : 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).

**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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : liquid

**Color** : clear

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Odor	:	No data available
Odor 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	:	154 °F / 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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition 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 characteristics Particle size	:	No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Combustible liquid. Vapors 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.

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### 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:

##### **Polyethylene glycol:**

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: Based on data from similar materials

##### **Ethanol:**

Acute oral toxicity	:	LD50 (Rat): 10,470 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC50 (Rat, male): 116.9 mg/l Exposure time: 4 h Test atmosphere: vapor
Acute dermal toxicity	:	LD50 (Rabbit): > 15,800 mg/kg

##### **Benzyl alcohol:**

Acute oral toxicity	:	LD50 (Rat): 1,200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403

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Assessment: The substance or mixture has no acute inhalation toxicity

### 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:

#### Polyethylene glycol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

#### Ethanol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

#### 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:

#### Polyethylene glycol:

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

#### Ethanol:

Species : Rabbit



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Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

### **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:**

#### **Polyethylene glycol:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

#### **Ethanol:**

Test Type : Mouse ear swelling test (MEST)  
Routes of exposure : Skin contact  
Species : Mouse  
Result : negative

#### **Benzyl alcohol:**

Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Species : Humans  
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Polyethylene glycol:**

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Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

### Ethanol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Result: negative

### 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.

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### Components:

#### **Benzyl alcohol:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 103 weeks  
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**

May damage the unborn child.

### Components:

#### **Ethanol:**

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

#### **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.

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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:

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:

Species : Rat  
NOAEL : 1,730 mg/kg  
LOAEL : 3,200 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

#### Benzyl 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

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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

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Polyethylene glycol:**

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

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### Ethanol:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 5,012 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 fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l  
Exposure time: 100 d
- 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 (Protozoa): 5,800 mg/l  
Exposure time: 4 h

### 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 plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l

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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

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:

##### **Polyethylene glycol:**

Biodegradability : Result: rapidly degradable  
Remarks: Based on data from similar materials

##### **Ethanol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 84 %  
Exposure time: 20 d

##### **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:

##### **Polyethylene glycol:**

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Partition coefficient: n-octanol/water : log Pow: < 3

### Ethanol:

Partition coefficient: n-octanol/water : log Pow: -0.35

### 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

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations. Do not dispose of waste into sewer.

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.

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## 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

UN/ID/NA number : NA 1993  
Proper shipping name : Combustible liquid, n.o.s.

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# SAFETY DATA SHEET

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## Dexamethasone (with Ethanol) Formulation

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(Ethanol)

Class	: CBL
Packing group	: III
Labels	: NONE
ERG Code	: 128
Marine pollutant	: no
Remarks	: Above applies only to containers over 119 gallons or 450 liters. Not regulated if shipped in packages less than or equal to 119 gallons (450 liters).

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

### 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** : Flammable (gases, aerosols, liquids, or solids)  
Reproductive toxicity

**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

Polyethylene glycol	25322-68-3
Water	7732-18-5
Ethanol	64-17-5

#### California List of Hazardous Substances

Ethanol	64-17-5
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#### California Permissible Exposure Limits for Chemical Contaminants

Ethanol	64-17-5
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### The ingredients of this product are reported in the following inventories:

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

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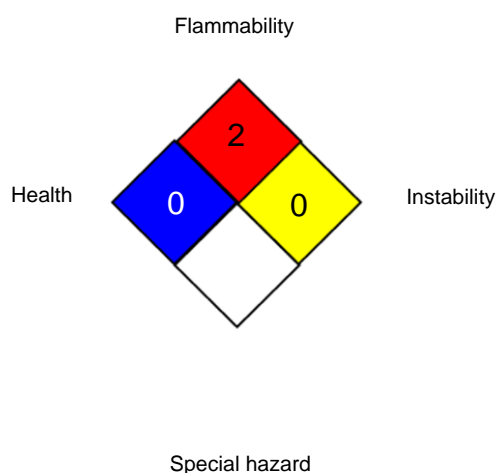
## Dexamethasone (with Ethanol) Formulation

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### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	0
FLAMMABILITY		2
PHYSICAL HAZARD		0

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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)  
ACGIH / STEL : Short-term exposure limit  
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
OSHA Z-1 / TWA : 8-hour time weighted average  
US WEEL / TWA : 8-hr TWA

AllC - Australian Inventory of Industrial Chemicals; 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); ErCx - 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; 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 Organisation for Standardization; KECI - Korea Existing Chemi-

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icals 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 Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/28/2024

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.

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