

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Dexamethasone (with Ethanol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.10	09/30/2023	752027-00018	Date of first issue: 06/14/2016

SECTION 1. IDENTIFICATION

Product name : Dexamethasone (with Ethanol) Formulation
Other means of identification : No data available

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.
Storage:
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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Ethanol#	Ethyl alcohol	64-17-5	$\geq 5 - < 10$
Dexamethasone	No data available	50-02-2	$\geq 0.1 - < 1$ *

Voluntarily-disclosed substance

* Actual concentration or concentration range 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

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Unsuitable extinguishing media	:	Carbon dioxide (CO ₂) Dry chemical 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 (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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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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
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m ³	CA AB OEL
		STEL	1,000 ppm	CA BC OEL
		STEV	1,000 ppm	CA QC OEL
		STEL	1,000 ppm	ACGIH
Dexamethasone	50-02-2	TWA	10 µg/m ³ (OEB 3)	Internal
Further information: Skin				
		Wipe limit	100 µg/100 cm ²	Internal

- Engineering measures : Minimize workplace exposure concentrations.
If sufficient ventilation is unavailable, use with local exhaust ventilation.

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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). |
| 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 |
| 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 | : | 68 °C |

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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 size	:	No data available

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:

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

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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:

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

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Dexamethasone:

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

Test Type: in vitro test
Test system: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

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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.

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Repeated dose toxicity

Components:

Ethanol:

Species	: Rat
NOAEL	: 1,280 mg/kg
LOAEL	: 3,156 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

Dexamethasone:

Species	: Rat
NOAEL	: 0.0015 mg/kg
Application Route	: Oral
Exposure time	: 7 d
Target Organs	: Liver
Remarks	: Significant toxicity observed in testing

Species	: Rat
LOAEL	: 0.003 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Target Organs	: Blood, Adrenal gland, thymus gland
Remarks	: Significant toxicity observed in testing

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

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

Species	: Dog
LOAEL	: 8 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Immune system
Remarks	: Significant toxicity observed in testing

Aspiration toxicity

Not classified based on available information.

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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:

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
plants Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
Exposure time: 72 h

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 9.6 mg/l
aquatic invertebrates (Chronic toxicity) Exposure time: 9 d

Toxicity to microorganisms : EC50 (Pseudomonas putida): 6,500 mg/l
Exposure time: 16 h

Dexamethasone:

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 56 mg/l
aquatic invertebrates Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2
plants 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

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Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Ethanol:

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

Dexamethasone:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 3.54 d
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 : Do not dispose of waste into sewer.
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

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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

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

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / STEL	:	Short-term exposure limit
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / STEL	:	short-term exposure limit
CA QC OEL / STEV	:	Short-term exposure value

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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 System; GLP - Good Laboratory Practice; 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 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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/>

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Date format : mm/dd/yyyy

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.

CA / Z8