

Dexamethasone (with Ethanol) Formulation

Version 4.1 Revision Date: 10.10.2020 SDS Number: 752026-00012 Date of last issue: 23.03.2020
Date of first issue: 14.06.2016

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

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

GHS label elements in accordance with ABNT NBR 14725 Standard

Signal Word : Warning
Hazard Statements : H227 Combustible liquid.
Precautionary Statements : **Prevention:**
P210 Keep away from heat/ sparks/ open flames/ hot surfaces.
No smoking.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Other hazards which do not result in classification

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Ethanol#	64-17-5	Flammable liquids, Category 2 Eye irritation, Category 2A	>= 5 -< 10

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Dexamethasone	50-02-2	Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Oral) (Adrenal gland, Immune system, thymus gland), Category 2 Long-term (chronic) aquatic hazard, Category 1	$\geq 0,1$ - $< 0,25$
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Voluntarily-disclosed non-hazardous substance

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 : None known.
- 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.

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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 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.

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- 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.
- 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.
- Conditions for safe storage : Wash contaminated clothing before re-use.
 Keep in properly labeled containers.
 Keep tightly closed.
 Keep in a cool, well-ventilated place.
 Store in accordance with the particular national regulations.
- Materials to avoid : Keep away from heat and sources of ignition.
 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	LT	780 ppm 1.480 mg/m ³	BR OEL
	Further information: Degree of harmfulness: minimum			
		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.

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

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- 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).
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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
- 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

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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.

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

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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

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)

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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

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

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

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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:

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

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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:

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

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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) : 1

Toxicity to microorganisms : EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Ethanol:

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

Dexamethasone:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 3,54 d

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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

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**ANTT**

Not regulated as a dangerous good

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SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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**

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/>

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

AIC - 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

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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; 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

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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