

## Dexamethasone Formulation

Version 2.9      Revision Date: 30.09.2023      SDS Number: 1842879-00012      Date of last issue: 04.04.2023  
Date of first issue: 20.07.2017

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone 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

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 1B

Long-term (chronic) aquatic hazard : Category 3

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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**Storage:**

P405 Store locked up.

**Other hazards which do not result in classification**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Benzyl alcohol	100-51-6	Acute toxicity (Oral), Category 4 Acute toxicity (Inhalation), Category 4 Eye irritation, Category 2A	1,04
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	0,3

**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 : May damage the unborn child.

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and effects, both acute and delayed

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.

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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : 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 : 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 : 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 : 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

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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.  
 Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
 When using do not eat, drink or smoke.  
 Wash contaminated clothing before re-use.
- Conditions for safe storage : Keep in properly labeled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- 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
Dexamethasone	50-02-2	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				
		Wipe limit	100 µg/100 cm <sup>2</sup>	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.

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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. 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. 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	:	white to off-white
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	7,0 - 7,8
Melting point/freezing point	:	No data available
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
Vapor pressure	:	No data available
Relative vapor density	:	No data available

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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

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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	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
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
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**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: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

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### 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.

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### 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  
Method                                    : OECD Test Guideline 451  
Result                                     : negative



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### Reproductive toxicity

May damage the unborn child.

### 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.

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**Repeated dose toxicity****Components:****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  
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

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## 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 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 tox- : NOEC (Pimephales promelas (fathead minnow)): 0,033 mg/l

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icity)      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:

##### **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

##### **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

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handling site for recycling or disposal.  
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

##### ANTT

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

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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

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

AICS : not determined

DSL : not determined

IECSC : not determined

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### SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023  
Date format : dd.mm.yyyy

#### 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/>

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### Full text of other abbreviations

AllC - 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; TECl - 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

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