



Safety Data Sheet

Cat. # API-04

Dexamethasone [10mM]

Size: 1ml





dexamethasone

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Revision date: 5/11/2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Substance
Substance name	: dexamethasone
EC-No.	: 200-003-9
CAS-No.	: 50-02-2
Product code	: 115D
Type of product	: Pharmaceutical, The data relate to the active substance, Pure substance
Formula	: C22H29FO5
Synonyms	: (11beta, 16alpha)-9-fluoro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione / 16-alpha-methyl-9-alpha-fluoro-1,4-pregnadiene-11-beta,17-alpha,21-triol-3,20-dione / 16-alpha-methyl-9-alpha-fluoro-11-beta,17-alpha,21-trihydroxypregna-1,4-diene-3,20-dione / 16-alpha-methyl-9-alpha-fluoro-1-dehydrocortisol / 16-alpha-methyl-9-alpha-fluoro-delta(*1)hydrocortisone / 16-alpha-methyl-9-alpha-fluoroprednisolone / 1-dehydro-16-alpha-methyl-9-alpha-fluorohydrocortisone / 4-alpha-fluoro-16-alpha-methyl-11-beta,17,21-trihydroxypregna-1,4-diene-3,20-dione / 9-alpha-fluoro-11-beta,17-alpha,21-trihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione / 9-alpha-fluoro-16-alpha-methyl-1,4-pregnadiene-11-beta,17-alpha,21-triol-3,20-dione / 9alpha-fluoro-16alpha-methyl-11beta,17alpha,21trihydroxy-1,4-pregnadiene-3,20-dione / 9-alpha-fluoro-16-alpha-methylprednisolone / 9-fluoro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione / 9-fluoro-11-beta,17,21-trihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione / 9-fluoro-11beta,17alpha,21-trihydroxy-16alpha-methylpregna-1,4-diene-3,20-dione / aereoseb-D / aereoseb-DEX / anaflogistico / aphtasolon / azium / calonat / corson / corsone / cortisumman / decacortin / decaderm / decadron / decalix / decasone / decaspray / dectancyl / dekacort / delta(*1)-9-alpha-fluoro-16-alpha-methylcortisol / deltafluorene / dergramin / deronil / desidrene / desametasone / desamethasone / desameton / deseronil / dexa / dexacort / dexacortal / dexa-cortidelt / dexacortin / dexa-cortisyl / dexadeltone / dexafarm / dexafarma / dexalona / dexa-mamallet / dexameth / dexamethasone alcohol / dexamethazone / dexapolcort / dexapos / dexaprol / dexa-scheroson / dexa-sine / dexason / dexasone / dex-ide / dextrinolon / dextrinoral / dexmethason vetranal / dexone / dextelan / dezone / dinormon / DXMS (= dexamethasone) / fluormone / fluorocort / fortecortin / gammacorten / hexadecadrol / hexadrol / HL-DEX / isopto-dex / lokalison F / loverine / luxazone / maxidex / mexidex / millicorten / MK 125 / ocu-trol / oradexon / pet derm III / policort / prednisolon F / prednisolone F / pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11beta,16alpha)- / pregna-1,4-diene-3,20-dione, 9-fluoro-11-beta,17,21-trihydroxy-16-alpha-methyl- / SK-dexamethasone / spoloven / superprednol / visumetazone
Product group	: Raw material
BIG No	: 16180

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture	: Pharmaceutical product: active ingredient Veterinary medicine: active ingredient
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1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Geno Technology, Inc./ G-Biosciences
9800 Page Avenue
63132-1429 Saint Louis - United States
T 800-628-7730 - F 314-991-1504
technical@GBiosciences.com - www.GBiosciences.com

1.4. Emergency telephone number

Emergency number : Chemtrec **1-800-424-9300** (USA/Canada), **+1-703-527-3887** (Intl)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
dexamethasone	(CAS-No.) 50-02-2 (EC-No.) 200-003-9	100	Not classified

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Check the vital functions. Unconscious: maintain adequate airway and respiration. Respiratory arrest: artificial respiration or oxygen. Cardiac arrest: perform resuscitation. Victim conscious with laboured breathing: half-seated. Victim in shock: on his back with legs slightly raised. Vomiting: prevent asphyxia/aspiration pneumonia. Prevent cooling by covering the victim (no warming up). Keep watching the victim. Give psychological aid. Keep the victim calm, avoid physical strain. Depending on the victim's condition: doctor/hospital.
First-aid measures after inhalation	: Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.
First-aid measures after skin contact	: Rinse with water. Soap may be used. Take victim to a doctor if irritation persists.
First-aid measures after eye contact	: Rinse with water. Do not apply neutralizing agents. Take victim to an ophthalmologist if irritation persists.
First-aid measures after ingestion	: Rinse mouth with water. Call Poison Information Centre (www.big.be/antigif.htm). Consult a doctor/medical service if you feel unwell. Ingestion of large quantities: immediately to hospital. Take the container/vomit to the doctor/hospital.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : See patient information on package leaflet.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Alcohol-resistant foam. Polymer foam. ABC powder. Carbon dioxide.
Unsuitable extinguishing media : No unsuitable extinguishing media known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : DIRECT FIRE HAZARD: No data available on direct fire hazard. INDIRECT FIRE HAZARD: No data available on indirect fire hazard.
Explosion hazard : DIRECT EXPLOSION HAZARD: No data available on direct explosion hazard. INDIRECT EXPLOSION HAZARD: No data available on indirect explosion hazard.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Precautionary measures fire : Exposure to fire/heat: keep upwind. Exposure to fire/heat: consider evacuation. Exposure to fire/heat: have neighbourhood close doors and windows.
Firefighting instructions : Dilute toxic gases with water spray.
Protection during firefighting : Heat/fire exposure: compressed air/oxygen apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Gloves. Protective clothing.
Emergency procedures : Mark the danger area. No naked flames. Wash contaminated clothes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

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6.2. Environmental precautions

Prevent spreading in sewers.

6.3. Methods and material for containment and cleaning up

For containment : Contain released product. Dam up the solid spill.
Methods for cleaning up : Scoop solid spill into closing containers. Carefully collect the spill/leftovers. Clean contaminated surfaces with an excess of water. Wash clothing and equipment after handling.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Comply with the legal requirements. Clean contaminated clothing. Do not discharge the waste into the drain. Avoid raising dust. Keep away from naked flames/heat. Observe normal hygiene standards. Keep container tightly closed. Carry operations in the open/under local exhaust/ventilation or with respiratory protection.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.
Heat and ignition sources : KEEP SUBSTANCE AWAY FROM: heat sources.
Information on mixed storage : KEEP SUBSTANCE AWAY FROM: oxidizing agents. (strong) acids.
Storage area : Store in a dry area. Store in a dark area. Meet the legal requirements.
Special rules on packaging : SPECIAL REQUIREMENTS: closing. opaque. correctly labelled. meet the legal requirements. Secure fragile packagings in solid containers.
Packaging materials : SUITABLE MATERIAL: No data available. MATERIAL TO AVOID: No data available.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Materials for protective clothing:

GIVE EXCELLENT RESISTANCE: No data available. GIVE GOOD RESISTANCE: No data available. GIVE LESS RESISTANCE: No data available. GIVE POOR RESISTANCE: No data available

Hand protection:

Gloves

Eye protection:

Safety glasses. In case of dust production: protective goggles

Skin and body protection:

Protective clothing

Respiratory protection:

Dust production: dust mask with filter type P1

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Crystalline solid. Crystalline powder. May be present in various forms.
Molecular mass : 392.47 g/mol
Colour : White.
Odour : No data available on odour.

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Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 262 °C
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: < 0.1 hPa (20 °C)
Relative vapour density at 20 °C	: No data available
Relative density	: Not applicable
Solubility	: Insoluble in water. Soluble in ethanol. Soluble in acetone. Soluble in chloroform. Water: 0.01 g/100ml (25 °C)
Log Pow	: 1.83 (Experimental value)
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: Not applicable

9.2. Other information

VOC content : 0 %

SECTION 10: Stability and reactivity

10.1. Reactivity

On burning: release of toxic and corrosive gases/vapours (hydrofluoric acid, carbon monoxide - carbon dioxide).

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

dexamethasone (50-02-2)

LD50 oral rat	> 3000 mg/kg (Rat)
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Ecology - air	: Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009). TA-Luft Klasse 5.2.1.
Ecology - water	: Mild water pollutant (surface water). Maximum concentration in drinking water: 1.5 mg/l (fluoride) (Directive 98/83/EC). No data available on ecotoxicity.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

12.2. Persistence and degradability

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Persistence and degradability	Biodegradability in water: no data available.
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12.3. Bioaccumulative potential

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Log Pow	1.83 (Experimental value)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Waste treatment methods.
Product/Packaging disposal recommendations	: Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals. Dissolve or mix with a combustible solvent. Remove to an authorized incinerator equipped with an afterburner and a flue gas scrubber with energy recovery. Do not discharge into the sewer.
Additional information	: LWCA (the Netherlands): KGA category 04. Hazardous waste according to Directive 2008/98/EC.
European List of Waste (LoW) code	: 07 05 13* - solid wastes containing dangerous substances

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: Not applicable
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IMDG

Transport hazard class(es) (IMDG)	: Not applicable
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IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Transport regulations (ADR) : Not subject

Transport by sea

Transport regulations (IMDG) : Not subject

Air transport

Transport regulations (IATA) : Not subject

Inland waterway transport

No data available

Rail transport

Transport regulations (RID) : Not subject

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

dexamethasone is not on the REACH Candidate List

dexamethasone is not on the REACH Annex XIV List

dexamethasone is not subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

dexamethasone is not subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

VOC content : 0 %

15.1.2. National regulations

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Safety Data Sheet applicable for regions : GB - United Kingdom

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.