

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 1/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



## DEXAMETHASONUM

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name: Dexamethasone  
Dexamethasonum  
Dexamethason  
Dexaméthason  
Dexamethason

N° CAS: 50-02-2

N° EC: 200-003-9

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

#### 1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV  
Oostmalsebaan 1c (unit 5)  
2960 Sint-Lenaarts  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Skin irritation (category 2)	H315
Eye irritation (category 2)	H319
Skin sensitization (category 1)	H317
	H360
STOT SE (category 3)	H335

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H315 Causes skin irritation.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



## DEXAMETHASONUM

H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H360	May damage fertility or the unborn child
H335	May cause respiratory irritation
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Use personal protective equipment as required.
P321	Specific treatment
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P362	Take off contaminated clothing.
Additional applicable label elements:	

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Dexamethasone
IUPAC name:	(8S,9R,10S,11S,13S,14S,16R,17R)-9-fluoro-11,17-dihydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-3-one
Synonyms:	Dexamethazone
N° CAS:	50-02-2
N° EC:	200-003-9
Molecular Formula:	C <sub>22</sub> H <sub>29</sub> FO <sub>5</sub>
Content:	97.0% -103.0% (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Remove immediately all contaminated clothing.
After inhalation:	Supply fresh air, give respiratory aid if necessary, heat. If the symptoms persist, consult a doctor.
After skin contact:	Immediately wash with water and soap and rinse thoroughly.
After eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor
After ingestion:	Rinse out mouth and then drink plenty of water

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## DEXAMETHASONUM

EN

FORM-06-14-01 (V00)

Page 3/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



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

Not available.

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

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing media: Powerful water jet.

### 5.2 Special hazards arising from the substance/mixture

Hydrogen fluoride (HF). Carbon monoxide (CO).

### 5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained respiratory protective device and protective clothing to prevent contact with skin and eyes.

Hazardous combustion products: Emits toxic fumes under fire conditions.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Wear protective equipment. Keep unprotected persons away.

#### For emergency responders

Wear protective equipment. Keep unprotected persons away.

### 6.2 Environmental precautions

No special measures required.

### 6.3 Methods and material for containment and cleaning up

Dispose contaminated material as waste according to section 13. Ensure adequate ventilation.

### 6.4 Reference to other sections

See sections 7, 8 and 13 for information on safe handling, personal protection equipment and disposal information.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling: Prevent formation of dust.

Personal protection: Not available.

Technical protective measures: Provide good ventilation / exhaustion at the workplace.

Handling: Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 4/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



## DEXAMETHASONUM

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in cool, dry conditions in well-sealed receptacles.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Not available.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Not available.

#### Individual protection measures

Eye/face protection:	Tightly sealed goggles.
Skin protection:	Use protective suit.
Hand protection:	The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Respiratory protection:	Filter P3. In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
Thermal hazards:	Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Odorless
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	250 °C – 253 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



## DEXAMETHASONUM

Evaporation rate:	Not available.
Flammability (solid/gas):	Prproduct is not flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Sparingly soluble in anhydrous ethanol, slightly soluble in methylene chloride.
Solubility in water:	Practically insoluble in water .
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	> 250 °C
Viscosity:	Not available.
Explosive properties:	Product does not present an explosion hazard.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Not available.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Strong oxidizing agents. Light.

### 10.6 Hazardous decomposition products

Hydrogen fluoride (HF). Carbon monoxide (CO).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral: LD50 > 3000 mg/kg (rat).
Skin corrosion/irritation:	Irritant to skin and mucous membranes
Serious eye damage/irritation:	Irritating effect.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



## DEXAMETHASONUM

Respiratory/skin sensitisation:	Sensitization possible through skin contact.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Irritation.
Skin contact:	Sensitization, irritation.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

EC50 (daphnia magna, 24 h): > 100 mg/L.  
EC50 (activated sludge, 3 h): > 320 mg/L.

### 12.2 Persistence and degradability

Biological elimination: 0%. Not degradable in biological waste water treatment plant.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Must be specially treated adhering to official regulations. Must not be disposed of together with household garbage.  
Do not allow product to reach sewage system.  
Uncleaned packaging disposal must be made according to official regulations.

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## DEXAMETHASONUM

EN

FORM-06-14-01 (V00)

Page 7/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.6 Special precautions for user

Not classified.

##### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not classified.

##### 14.8 Additional transport information

Not classified.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not available.

Risk phrases: Not available.

Safety phrases: Not available.

#### 15.2 Chemical safety assessment

Not available.

### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

#### 16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 8/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



## DEXAMETHASONUM

EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

[info@magis-pharma.be](mailto:info@magis-pharma.be)