

**CLOBETASONI BUTYRAS**

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

**1.1 Product identifier**

Product name:	EN: Clobetasone butyrate
	LAT: Clobetasoni butyras
	NL: Clobetasonbutyraat
	FR: Clobétasone (butyrate de)
	DE: Clobetasonbutyrat
N° CAS:	25122-57-0
N° EC:	246-635-9

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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**1.3 Details of the supplier of the safety data sheet**

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk 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.centreatipoisons.be

**SECTION 2: HAZARDS IDENTIFICATION**

**2.1 Classification of the substance/mixture**

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

Carc. 2	H351
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**2.2 Label elements**

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

Hazard pictogram(s):



Signal word(s): Attention.

Hazard statements:

H351 Suspected of causing cancer.

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Precautionary statements:

P281

Use personal protective equipment as required.

Additional applicable label elements:



**2.3 Other hazards**

Not available.

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

**3.1 Substances**

Product name:	Clobetasone butyrate
IUPAC name:	[(8S,9R,10S,13S,14S,16S,17R)-17-(2-chloroacetyl)-9-fluoro-10,13,16-trimethyl-3,11-dioxo-7,8,12,14,15,16-hexahydro-6H-cyclopenta[a]phenanthren-17-yl] butanoate
Synonyms:	Emovate Eumovate
N° CAS:	25122-57-0
N° EC:	246-635-9
Molecular Formula:	C <sub>26</sub> H <sub>32</sub> ClFO <sub>5</sub>
Content:	97.0 per cent to 102.0 per cent (dried substance)

**3.2 Mixtures**

Not applicable.

**SECTION 4: FIRST AID MEASURES**

**4.1 Description of first aid measures**

General notes:	Consult a physician. Show this safety data sheet to the doctor in attendance.
After inhalation:	If breathed in, move person into fresh air. If not breathing give artificial respiration Consult a physician.
After skin contact:	Wash off with soap and plenty of water. Consult a physician.
After eye contact:	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
After ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

Refer section 2.2 for symptoms and effects.

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

Get medical advice/attention. If possible, show this safety data sheet, if not available show packaging or label. Active agent. Pharmaceutical.

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**SECTION 5: FIREFIGHTING MEASURES**

**5.1 Extinguishing media**

Suitable extinguishing media:	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media:	Do not use a heavy water stream.

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

Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

**5.3 Advice for firefighters**

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained breathing apparatus for firefighting if necessary.
Hazardous combustion products:	Not available.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

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

**For non-emergency personnel**

Remove ignition sources. Evacuate area. Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

**For emergency responders**

Remove ignition sources. Evacuate area. Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

**6.2 Environmental precautions**

Do not let product enter drains.

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

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

**6.4 Reference to other sections**

For disposal, see section 13.

**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

Precautions for safe handling:	Avoid contact with skin and eyes. Normal measures for preventive fire protection.
Personal protection:	Not available.
Technical protective measures:	Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
Handling:	Not available.

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

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Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store in a place between 15 °C an 30 °C. Keep container tightly closed in a dry and well-ventilated place.
Storage – away from:	Store protected from light.

**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**

Keep in a well-ventilated room. Use only in an exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter). Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

**Individual protection measures**

Eye/face protection: Safety glasses with side-shields

Skin protection: Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hand protection: Handle with gloves.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate, use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls.

If the respirator is the sole means of protection, use a full-face supplied air respirator.

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US).

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 powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

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Melting/freezing point:	About 178 °C.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in acetone and in methylene chloride, slightly soluble in ethanol (96 per cent).
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

**9.2 Other information**

Not available.

**SECTION 10: STABILITY AND REACTIVITY**

**10.1 Reactivity**

Stable under normal conditions.

**10.2 Chemical stability**

Stable.

**10.3 Possibility of hazardous reactions**

Not available.

**10.4 Conditions to avoid**

Heat.  
Direct sunlight.

**10.5 Incompatible materials**

Not available.

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**10.6 Hazardous decomposition products**

Hazardous decomposition products formed under fire conditions.  
Carbon oxides, hydrogen chloride gas.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

Acute toxicity:	Oral LD50 (rat): > 6.000 mg/kg Remarks: Behavioural: Somnolence (general depressed activity). Blood: Changes in spleen. Skin and Appendages: Other: Hair.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Limited evidence of carcinogenicity in animal studies. IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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:	RTECS: TU4154083

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

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 Toxicity**

General: Hazardous waste. Use suitable disposal containers.

**12.2 Persistence and degradability**

Not available.



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### 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

Product: Observe all federal, state and local environmental regulations.

Contaminated packaging: Dispose container at hazardous or special waste collection point.

Special precautions: Avoid release to the environment as it has hazardous components.

## 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 dangerous goods.

#### 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) : No hazard identified.

#### 14.6 Special precautions for user

Not available.

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

Not available.

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**14.8 Additional transport information**

Not available.

**SECTION 15: REGULATORY INFORMATION**

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

Hazard symbol:



Risk phrases:

R40 Limited evidence of a carcinogenic effect.

Safety phrases:

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

**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)
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**





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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.

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#### 16.8 Department issuing MSDS

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