

Material Safety Data Sheet

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

CLOBETASOLI PROPIONAS

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 21/03/2022

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Version: 01



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

1.1 Product identifier

Product name:	Clobetasol propionate Clobetasoli propionas Clobetasolpropionaat Clobétasol (propionate de) Clobetasolpropionat
N° CAS:	25122-46-7
N° EC:	246-634-3

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.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s):
Attention
Irritant

Hazard statements:

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



CLOBETASOLI PROPIONAS

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P271	Use only outdoors or in a well-ventilated area.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P501	Dispose of this substance and its container to a special or hazardous waste collection point in accordance with local, regional, national and/or international regulations.
Additional applicable label elements:	

2.3 Other hazards

The substance does not meet the criteria to be identified as a PBT or vPvB according to Annex XIII of the REACH Regulation.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Clobetasol propionate
IUPAC name:	21-Chloro-9-fluoro-11 β -hydroxy-16 β -methyl-3,20-dioxopregna-1,4-dien-17-yl propanoate
Synonyms:	Clobetasol 17-propionate Dermovate
N° CAS:	25122-46-7
N° EC:	246-634-3
Molecular Formula:	C ₂₅ H ₃₂ ClFO ₅
Content:	97.0 per cent to 102.0 per cent (dried substance)

3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



CLOBETASOLI PROPIONAS

After eye contact:

Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.

After ingestion:

Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.

If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation and skin irritation. May cause respiratory tract irritation.

4.3 Indication of any immediate medical attention and special treatment needed

In cases of doubt, or when symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:

Foam, dry powder, carbon dioxide, sand, water mist.

Neighbouring fires (containers exposed to fire): Water spray or fog.

Unsuitable extinguishing media:

Direct water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

5.3 Advice for firefighters

Surrounding fires:

Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.

Protection against fire:

Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8.

Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

For emergency responders

For exposure control and personal protective measures, see section 8.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



CLOBETASOLI PROPIONAS

Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

6.2 Environmental precautions

Prevent product from entering sewers, surface and ground water.

6.3 Methods and material for containment and cleaning up

Collect spilled product and place in containers for recovery or disposal. Ensure sufficient ventilation of the leak site. Avoid dust formation.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Wash thoroughly after handling.

Use only outdoors or in a well-ventilated area.

Avoid breathing dust, fumes, gas, mist, vapours or aerosol.

Personal protection:

Not available.

Technical protective measures:

Ensure good ventilation of the processing area to avoid formation of vapour.

Handling:

Wash thoroughly after handling

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Keep container tightly closed.

Keep only in the original container in a cool, well-ventilated place protected from direct sunlight.

Storage – away from:

Store protected from light.

Store containers away from incompatible materials, see section 10.

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

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must bear the CE marking attesting to compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



CLOBETASOLI PROPIONAS

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

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: Characteristic.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 196 °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, sparingly soluble in ethanol (96 per cent), soluble in chloroform, practically insoluble in diethyl ether.

Solubility in water: Practically insoluble in water.

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature: Not available.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



CLOBETASOLI PROPIONAS

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 466.98 g/mol

Density (20 °C): 0.272 g/mL

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not established.

10.4 Conditions to avoid

Direct sunlight.

Extremely high or extremely low temperatures.

10.5 Incompatible materials

Strong bases. Strong acids. Sources of ignition.

10.6 Hazardous decomposition products

Fumes: carbon oxides (CO and CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD₅₀, rat): > 3 g/kg
Acute intraperitoneal toxicity (LD₅₀, rat): 351 mg/kg

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye irritation.

Respiratory/skin sensitisation: May cause respiratory irritation.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the

CMR properties:

STOT-single exposure: Not available.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



CLOBETASOLI PROPIONAS

STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Signs and Symptoms of Exposure: Increased susceptibility to infection, alterations in electrolyte balance manifested by salt and water retention leading to oedema, hypertension, hyperglycaemia, increased appetite, delayed wound healing, suppression of the suprarenal axis and hypothalamic pituitary; loss of collagen, subcutaneous atrophy, acneiform eruptions, burning, itching, erythema, dermatitis and hyperpigmentation; corneal ulcers and reduced visual range; full moon face, hirsutism, buffalo back, hot flushes, hair growth and acne and sometimes leads to full-blown Cushing's syndrome. N° RTECS: GZ2230000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation.
Skin contact:	Harmful if absorbed through skin. May cause skin irritation.
Inhalation:	Harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

The substance does not meet the criteria to be identified as a PBT or vPvB according to Annex XIII of the REACH Regulation.

12.6 Other adverse effects

Avoid release to the environment.

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



CLOBETASOLI PROPIONAS

Contaminated container: Dispose of as unused product.

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) : It is not dangerous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.6 Special precautions for user

It is not dangerous in transport.

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

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant

Risk phrases:

R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S28 After contact with skin, wash immediately with plenty of soap and water.

S51 Use only in well-ventilated areas.

S56 Dispose of this material and its container at hazardous or special waste collection point.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



CLOBETASOLI PROPIONAS

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

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

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

Material Safety Data Sheet

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

CLOBETASOLI PROPIONAS

EN

FORM-06-14-01 (V00)

Page 10/9

Publication: 21/03/2022

Revision: 27/12/2024

Version: 01



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16.8 Department issuing MSDS

Quality Department

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