

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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BECLOMETHASONI DIPROPIONAS

Publication: 26/08/2022

Revision: 23/08/2024

Version: 01



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

1.1 Product identifier

Product name: Beclometasone dipropionate
Beclomethasoni dipropionas
Beclomethasondipropionaat
Béclométhasone (dipropionate de)
Beclometasondipropionat

N° CAS: 5534-09-8

N° EC: 226-886-0

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: 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

Repr. 1B	H360
STOT RE 2	H373

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H360	May damage fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

P201	Obtain special instructions before use.
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P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P281	Use personal protective equipment as required.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P314	Get medical advice/attention if you feel unwell.
P405	Store locked up.
P501	Dispose of contents/container at hazardous or special waste collection point.
Additional applicable label elements:	

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Beclometasone dipropionate
IUPAC name:	[2-[[[8S,9R,10S,11S,13S,14S,16S,17R)-9-chloro-11-hydroxy-10,13,16-trimethyl-3-oxo-17-propanoyloxy-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl]-2-oxoethyl] propanoate
Synonyms:	Aldecin Beclacin Beclovent Vancenase
N° CAS:	5534-09-8
N° EC:	226-886-0
Molecular Formula:	C ₂₈ H ₃₇ ClO ₇
Content:	96.0 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.

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4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after ingestion: Symptoms may include dizziness, headache, nausea and loss of coordination.

4.3 Indication of any immediate medical attention and special treatment needed

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

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: Avoid (reject) fire-fighting water to enter environment. Prevent entry to sewers and public waters.

Protection against fire: Wear self contained breathing apparatus for fire fighting if necessary.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

General: Remove ignition sources. Evacuate area.

For non-emergency personnel

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

For emergency responders

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so.

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 refer section 13.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	Not available.
Technical protective measures:	Avoid formation of dust and aerosols. Avoid exposure – obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store in 15 °C to 30 °C place. Keep container tightly closed in a dry and well-ventilated place.
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

Keep in a well-ventilated room. Use only in an exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

Hygiene measures: Provide local exhaust or general room ventilation. Material should be handled in a laboratory hood whenever possible.

Individual protection measures

Eye/face protection:	Safety glasses with side-shields conforming to EN166.
Skin protection:	Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hand protection:	The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves.
Respiratory protection:	When 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 back up 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) or CEN (EU).
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Around 200 °C to 210 °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%).
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

Moisture.

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10.5 Incompatible materials

Strong oxidizers

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions.

- Carbon dioxides, hydrogen chloride gas.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	LD ₅₀ oral (rat): > 3.750 mg/kg Endocrine disorders. May produce irregular heart beat and nervous symptoms. Oedema. Gastrointestinal disorders.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	IARC: No component of this product presents at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	May cause congenital malformation in the fetus. Presumed human reproductive toxicant. May cause reproductive disorder.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Signs and Symptoms of Exposure: Exposure to corticosteroids can cause infection of the throat and mouth or hoarseness and disturbances of electrolyte balance manifested by corticosteroids can cause moon face, hirsutism, buffalo hump, flushing, increased bruising and acne, sometimes leading to a fully developed Cushing syndrome. RTECS: TU3805000

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

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General: Hazardous waste. Use suitable disposal containers.

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

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. This product contains hazardous components for the environment. Avoid release to the environment.

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

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:

R48 Danger of serious damage to health by prolonged exposure.

R60 May impair fertility.

R61 May cause harm to the unborn child.

Safety phrases:

S1 Keep locked up.

S23 Do not breathe dust/fume/gas/mist/vapours/spray.

S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

S53 Avoid exposure - obtain special instructions before use.

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

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.

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<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.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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