

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 08/09/2021

Revision: 23/08/2024

Version: 01



BETAMETHASONI VALERAS

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

1.1 Product identifier

Product name: Betamethasone valerate
Betamethasoni valeras
Betamethasonvaleraat
Bétaméthasone (valérate de)
Betamethasonvalerat

N° CAS: 2152-44-5

N° EC: 218-439-3

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

Reproductive toxicity (category 2) H361D
STOT RE (category 2) H373

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H361D Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/9

BETAMETHASONI VALERAS

Publication: 08/09/2021

Revision: 23/08/2024

Version: 01



Precautionary statements:

P201	Obtain special instructions before use.
P260	Do not breathe dust/fumes/gas/mist/vapours/spray.
P281	Use personal protective equipment as required.
P308+P313	If exposed: Call a POISON CENTER or doctor/physician.
P314	Get medical advice/attention if you feel unwell.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local / regional / national / international regulation.

Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Betamethasone valerate
IUPAC name:	[(8S,9R,10S,11S,13S,14S,16S,17R)-9-fluoro-11-hydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl-3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl] pentanoate
Synonyms:	Betamethasone 17-valerate, Betnovate, Betaderm
N° CAS:	2152-44-5
N° EC:	218-439-3
Molecular Formula:	C ₂₇ H ₃₇ FO ₆
Content:	97.0 per cent to 103.0 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 doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	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

It is suspected that it damages the unborn child. Causes organ damage.

Material Safety Data Sheet

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

BETAMETHASONI VALERAS

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 08/09/2021

Revision: 23/08/2024

Version: 01



4.3 Indication of any immediate medical attention and special treatment needed

Consult a physician in case of obvious or suspected exposure. Do not give 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.

Unsuitable extinguishing media: Direct stream of water.

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 avoid decomposition of the product and the development of potential health hazards. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second current regulations.

Protection against fire: Always wear full fire protection. Helmet with visor, flame retardant clothing (jacket and trousers with suspenders around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with a face mask covering all in front of the operator or the car (self-protective) in the 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 individual protection measures, see section 8. Equip cleaning personnel with the appropriate means of protection. Ventilate the area. Evacuate unnecessary personnel.

For emergency responders

For exposure control and individual protection measures, see section 8. Equip cleaning personnel with the appropriate means of protection. Ventilate the area. Evacuate unnecessary personnel.

6.2 Environmental precautions

Prevent it from entering sewers and water lines. If the product reaches drains or public water pipes, notify the authorities.

6.3 Methods and material for containment and cleaning up

Store away from other materials. If it is on the ground, sweep or collect (shovel or similar) to deposit in appropriate containers. Limit dust production.

6.4 Reference to other sections

For exposure control and individual protection measures, see section 8.

For waste disposal, follow the recommendations in section 13.

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: 08/09/2021

Revision: 23/08/2024

Version: 01



BETAMETHASONI VALERAS

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking, and leaving work.
Personal protection:	For personal protection, see section 8.
Technical protective measures:	Provide good ventilation in the processing area to avoid vapour formation.
Handling:	Obtain special instructions before use. Handle with adequate industrial hygiene precautions.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep container closed when you are not using.
Conditions for safe storage, including any incompatibilities:	Keep only in the original container in a cool, well-ventilated place.
Storage – away from:	Keep away from strong acids and bases, sources of ignition and direct sunlight.

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 must always take precedence over personal protective equipment, ensure good ventilation in the workplace through effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Provide an emergency shower with a viscoelastic tray.

Individual protection measures

Eye/face protection:	Protective masks and safety glasses according to EN166.
Skin protection:	Choose protection for the body according to the amount and concentration of the dangerous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of the EU Directive 89/686/CEE and the standard EN 374 derived from it. Handle with adequate industrial hygiene precautions, and respect safety practices. Wash your hands before breaks and after the end of the workday.
Respiratory protection:	Where risk assessment shows that air purifying respirators are appropriate, wear type N95 (USA) or type P1 (EN 143) dust mask. 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.

Material Safety Data Sheet

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

BETAMETHASONI VALERAS

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 08/09/2021

Revision: 23/08/2024

Version: 01



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Slightly characteristic.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
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:	0.210 g/mL (20 °C)
Relative density:	Not available.
Solubility:	Freely soluble in acetone and in methylene chloride, soluble in ethanol (96%).
Solubility in water:	Practically insoluble in water (< 1mg/L (20 °C)).
Partition coefficient (n-octanol/water):	3.909
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular mass: 476.58 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

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

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

The product does not present the possibility of hazardous reactions.

Material Safety Data Sheet

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

BETAMETHASONI VALERAS

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 08/09/2021

Revision: 23/08/2024

Version: 01



10.4 Conditions to avoid

Avoid any type of incorrect handling: high pressures and/or temperatures. Direct sunlight.

10.5 Incompatible materials

Strong acids and bases.

10.6 Hazardous decomposition products

Carbon oxide fumes (CO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not available.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	No component of this product, which exhibits levels greater than or equal to 0.1%, is identified as a probable, possible, or confirmed human carcinogen.
Reproductive toxicity:	It is suspected that it damages the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	May cause damage to organs through prolonged or repeated exposure.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	May cause damage to organs through prolonged or repeated exposure.
Ingestion:	May cause damage to organs through prolonged or repeated exposure.
Aspiration:	May cause damage to organs through prolonged or repeated exposure.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

Material Safety Data Sheet

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

BETAMETHASONI VALERAS

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 08/09/2021

Revision: 23/08/2024

Version: 01



12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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

Contaminated packaging: Discard 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), Not classified.
IATA/ICAO (Air) :

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

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

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.

14.8 Additional transport information

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

Material Safety Data Sheet

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

BETAMETHASONI VALERAS

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 08/09/2021

Revision: 23/08/2024

Version: 01



SECTION 15: REGULATORY INFORMATION

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

N/A

15.2 Chemical safety assessment

A chemical safety assessment 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.

Material Safety Data Sheet

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

BETAMETHASONI VALERAS

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 08/09/2021

Revision: 23/08/2024

Version: 01



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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be