

Material Safety Data Sheet

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

DIFLUCORTOLONI VALERAS

EN

FORM-06-14-01 (V00)

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Version: 00



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

1.1 Product identifier

Product name: Diflucortolone valerate
Diflucortoloni valeras
Diflucortolonvaleraat
Diflucortolone (valérate de)
Diflucortolonvalerat

N° CAS: 59198-70-8

N° EC: 261-655-8

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

Repr. 2 H361fd

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

Precautionary statements:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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If exposed: Call a POISON CENTER or doctor/physician.

Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Diflucortolone valerate
IUPAC name:	[2-[(6S,8S,9R,10S,11S,13S,14S,16R,17S)-6,9-difluoro-11-hydroxy-10,13,16-trimethyl-3-oxo-7,8,11,12,14,15,16,17-octahydro-6H-cyclopenta[a]phenanthren-17-yl]-2-oxoethyl] pentanoate
Synonyms:	Nerisona Nerisone Texmeten Temetex
N° CAS:	59198-70-8
N° EC:	261-655-8
Molecular Formula:	C ₂₇ H ₃₆ F ₂ O ₅
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

After inhalation:	Remove to fresh air. If symptoms persist, call a physician.
After skin contact:	Wash off immediately with soap and plenty of water. If symptoms persist, call a physician.
After eye contact:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediate medical attention is required.
After ingestion:	Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician or poison control centre immediately.
Self-protection of the first aider:	Use personal protective equipment as required.

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

Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48h after the accident is recommended.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray (fog), carbon dioxide (CO₂), foam, extinguishing powder, sand.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Thermal decomposition can lead to release of irritating and toxic gases and vapours.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Use personal protective equipment as required.
Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For indoors, ensure sufficient ventilation process until the end of the work.

Prevent unnecessary access for anyone other than the persons concerned by using, for example, a rope.

During work, wear suitable protective equipment to prevent sticking to the skin or inhaling the gas.

Work from windward and retract the people downwind.

For emergency responders

Prevent unnecessary access for anyone other than the persons concerned by using, for example, a rope.

Work from windward, and retract the people downwind.

6.2 Environmental precautions

To be careful not discharged to the environment without being properly handled waste water contaminated.

6.3 Methods and material for containment and cleaning up

Sweep up and gather scattered particles, and collect it in an empty airtight container.

Secondary disaster prevention measures: Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Do not handle containers roughly, such as knocking them over, dropping them, shocking them or dragging them.
Prevent leakage, overflow and scattering.

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	Do not generate steam and dust in vain. Seal the container after use. Wash hands and face after use and then gargle. Do not smoke, eat or drink in places other than those specified. Do not bring contaminated protective equipment and gloves to rest areas.
Personal protection:	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
Technical protective measures:	Avoid contact with oxidising agents. Use with local exhaust ventilation.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep container tightly closed.
Conditions for safe storage, including any incompatibilities:	Store in a cool place (-20°C).
Storage – away from:	Store protected from light. Store away from foodstuffs. Incompatible substances: Strong oxidising agents.

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

In case of indoor workplace, seal the source or use a local exhaust system.
Provide the safety shower facility, and hand- and eye-wash facility. And display their position clearly.
Handle in accordance with good industrial hygiene and safety practice.

Individual protection measures

Eye/face protection:	Protective eyeglasses or chemical safety goggles.
Skin protection:	Long-sleeved work clothes, protective boots.
Hand protection:	Protection gloves.
Respiratory protection:	Dust mask.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

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Appearance:	A white to creamy white, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	195.0 °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 dichloromethane and in 1,4-dioxan. Slightly soluble in methanol. Sparingly soluble in ether.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Product is not selfigniting.
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

Not available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

None under normal processing.

10.4 Conditions to avoid

Extremes of temperature and direct sunlight.

10.5 Incompatible materials

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Strong oxidising agents.

10.6 Hazardous decomposition products

Carbon monoxide (CO), carbon dioxide (CO₂), halides.

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

Not available.

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12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste from residues: Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated container and contaminated packaging: Disposal should be in accordance with applicable regional, national and local laws and regulations.

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 available.

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

Not available.

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:

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

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Safety phrases: S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S53 Avoid exposure – obtain special instructions before use.

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.

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16.8 Department issuing MSDS

Quality Department

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