

Material Safety Data Sheet

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

EN

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Version: 00



TRIAMCINOLONI ACETONIDUM

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

1.1 Product identifier

Product name: Triamcinolone acetonide
Triamcinoloni acetonidum
Triamcinolonacetonide
Triamcinolone (acétonide de)
Triamcinolonacetonid

N° CAS: 76-25-5

N° EC: 200-948-7

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	H361d
Muta. 2	H341
Acute Tox. 4	H302
Acute Tox. 4	H312
Acute Tox. 4	H332

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention
Warning

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Hazard statements:

H361d	Suspected of damaging the unborn child.
H341	Suspected of causing genetic defects.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.

Precautionary statements:

P280	Wear protective gloves, protective clothing, eye protection, face protection.
P261	Avoid breathing dust, fume, gas, mist, vapours, spray.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P304+P340	IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

Additional applicable label elements:



2.3 Other hazards

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Triamcinolone acetonide
IUPAC name:	(1S,2S,4R,8S,9S,11S,12R,13S)-12-fluoro-11-hydroxy-8-(2-hydroxyacetyl)-6,6,9,13-tetramethyl-5,7-dioxapentacyclo[10.8.0.0.2,9.0.4,8.0.13,18]icosa-14,17-dien-16-one
Synonyms:	Azmacort Kenalog Triacort Vetalog
N° CAS:	76-25-5
N° EC:	200-948-7
Molecular Formula:	C ₂₄ H ₃₁ FO ₆
Content:	97.5 per cent to 102.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	If exposed or concerned: get medical advice. Never give anything by mouth to an unconscious person.
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After inhalation:	Remove to fresh air and keep at rest in a position comfortable for breathing. Assure fresh air breathing. Allow the victim to rest. Call a POISON CENTER or doctor if you feel unwell.
After skin contact:	Immediately call a POISON CENTER or doctor. Specific measures (see on this label). Wash with plenty of soap and water. Wash contaminated clothing before reuse. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
After eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
After ingestion:	Do NOT induce vomiting. Rinse mouth. Obtain emergency medical attention. Call a POISON CENTER or doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms relating to use: Repeated exposure to this material can result in absorption through skin causing significant health hazard. Danger of serious damage to health by prolonged exposure through inhalation. Swallowing a small quantity of this material will result in serious health hazard. Suspected of damaging the unborn child. Suspected of causing genetic defects.

4.3 Indication of any immediate medical attention and special treatment needed

General information: If exposed or concerned: get medical advice. Never give anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam. Dry powder. Carbon dioxide. Water spray. Sand. Surrounding fires: Use water spray or fog for cooling exposed containers.
Unsuitable extinguishing media:	Do not use a heavy water stream.

5.2 Special hazards arising from the substance/mixture

Hazardous combustion products : Under fire conditions, hazardous fumes will be present.

5.3 Advice for firefighters

Surrounding fires:	Use water spray or fog for cooling exposed containers. Special procedures: Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.
Protection against fire:	Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Evacuate unnecessary personnel.

For emergency responders

Equip clean-up crew with proper protection. Ventilate area.

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6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Store away from other materials. On land, sweep or shovel into suitable containers. Minimise generation of dust.

6.4 Reference to other sections

See section 8: Exposure controls/personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Use only outdoors or in a well-ventilated area. Avoid breathing dust, fume, gas, mist, vapours, spray. Do not eat, drink or smoke when using this product. Obtain special instructions before use.
Personal protection:	Use personal protective equipment as required.
Technical protective measures:	Provide good ventilation in process area to prevent 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 only in the original container in a cool, well ventilated place. Keep container closed when not in use.
Storage – away from:	Strong bases. Strong acids. Sources of ignition. 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

Avoid all unnecessary exposure. When using, do not eat, drink or smoke.

Individual protection measures

Eye/face protection:	Chemical goggles or safety glasses.
Skin protection:	Not determined.
Hand protection:	Wear protective gloves.
Respiratory protection:	In case of insufficient ventilation, wear suitable respiratory equipment.
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:	Characteristic.
Odour threshold:	Not available.
pH:	Not applicable.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not applicable.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	Non flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not applicable.
Solubility:	Sparingly soluble in ethanol (96 per cent).
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	2.53 (20 °C)
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

Not established.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Not established.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

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10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Fumes. Carbon monoxide. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Inhalation: Harmful if inhaled. Dermal: Harmful in contact with skin. Ingestion: Harmful if swallowed. Oral LD ₅₀ (rat): 1451 mg/kg
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory/skin sensitisation:	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Suspected of causing genetic defects.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Suspected of damaging the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	RTECS nr: TU3920000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Harmful in contact with skin.
Inhalation:	Harmful if inhaled.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not established.

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

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12.4 Mobility in soil

Not established.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects

Environmental precautions: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

General: Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Avoid release to the environment. Dispose in a safe manner in accordance with local/national 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 regulated.

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SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful
Irritant

Risk phrases:

R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

R63: Possible risk of harm to the unborn child.

R68: Possible risks of irreversible effects.

Safety phrases:

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

S36/37: Wear suitable protective clothing and gloves.

S53: Avoid exposure - obtain special instructions before use.

63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

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.

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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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