

DESOXIMETASONUM

Publication: 26/08/2024
Revision: 03/11/2024
Version: 01

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

1.1 PRODUCT IDENTIFIER

Product name: EN: Desoximetasone
LAT: Desoximetasolum
NL: Desoximetason
FR: Désoximétasone
DE: Desoximetason
N° CAS: 382-67-2
N° EC: 206-845-3

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE/MIXTURE AND USES ADVISED AGAINST

Identified uses: Active Pharmaceutical Ingredient.

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

Acute Tox. 4	H302
Acute Tox. 4	H312
Skin Irrit. 2	H315
Skin Sens. 1	H317
Eye Irrit. 2	H319
Acute Tox. 4	H332
STOT SE 3	H335
Carc. 2	H351
Repr. 2	H361d

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning

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Hazard statements:

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H361d	Suspected of damaging the unborn child.

Precautionary statements:

P201	Obtain special instructions before use.
P203	Obtain, read and follow all safety instructions before use.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264+P265	Wash hands [and ...] thoroughly after handling. Do not touch eyes.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P317	IF SWALLOWED: Get medical help.
P302+P352	IF ON SKIN: wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P317	Get emergency medical help.
P318	If exposed or concerned, get medical advice.
P319	Get medical help if you feel unwell.
P321	Specific treatment (see section 4 on this label).
P330	Rinse mouth.
P332+P317	If skin irritation occurs: Get medical help.
P333+P317	If skin irritation or rash occurs: Get medical help.
P337+P317	If eye irritation persists: Get medical help.
P362+P364	Take off contaminated clothing and wash it before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to a waste disposal plant in accordance with local, regional, national and/or international regulations.

Additional applicable label elements:



2.3 OTHER HAZARDS

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative (vPvB).

The substance does not have endocrine disrupting properties.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Product name:	Desoximetasone
IUPAC name:	(8S,9R,10S,11S,13S,14S,16R,17S)-9-fluoro-11-hydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl-7,8,11,12,14,15,16,17-octahydro-6H-cyclopenta[a]phenanthren-3-one
Synonyms:	9-Fluoro-11beta,21-dihydroxy-16alpha-methylpregna-1,4-diene-3,20-dione Topicort Flubason
N° CAS:	382-67-2
N° EC:	206-845-3
Molecular Formula:	C ₂₂ H ₂₉ FO ₄
Content:	Desoximetasone contains NLT 97.0% and NMT 103.0% of desoximetasone (C ₂₂ H ₂₉ FO ₄), calculated on the dried basis.

3.2 MIXTURES

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

After inhalation:	Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
After skin contact:	Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
After eye contact:	Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
After ingestion:	Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media:	The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
Unsuitable extinguishing media:	Water jet

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

Hazards caused by exposure in the event of fire: Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

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5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires:	Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
Protection against fire:	Normal firefighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).
Hazardous combustion products:	Carbon monoxide (CO), Carbon dioxide (CO ₂)

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

FOR NON-EMERGENCY PERSONNEL

If there are no contraindications, spray powder with water to prevent the formation of dust.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

FOR EMERGENCY RESPONDERS

If there are no contraindications, spray powder with water to prevent the formation of dust.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2 ENVIRONMENTAL PRECAUTIONS

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.
Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in section 13.

6.4 REFERENCE TO OTHER SECTIONS

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling:	Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.
Personal protection:	Not available.
Technical protective measures:	Not available.

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Handling: Not available.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Storage: In well-closed, airtight container.

Conditions for safe storage, including any incompatibilities: Store only in the original container. Store the containers sealed, in a well-ventilated place. Store at room temperature.

Storage – away from: Store the containers away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3 SPECIFIC END USE(S)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate not otherwise classified (PNOC respirable fraction: 3 mg/m³; PNOC inhalable fraction: 10 mg/m³). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

8.2 EXPOSURE CONTROLS

APPROPRIATE ENGINEERING CONTROL

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

INDIVIDUAL PROTECTION MEASURES

Eye/face protection: Wear airtight protective goggles (see standard EN 166).
In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

Skin protection: Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

Hand protection: In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

Respiratory protection: Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

Thermal hazards: Not determined.

ENVIRONMENTAL EXPOSURE CONTROL

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White or off-white, crystalline powder.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	> 206 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	276 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	This material is combustible, but will not ignite readily
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	1.15E ⁻⁰⁹ mmHg
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in alcohol, in acetone and in chloroform.
Solubility in water:	Insoluble in water.
Partition coefficient (n-octanol/water):	2.2 (Remark: QSAR)
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 weight: 376.51 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

There are no particular risks of reaction with other substances in normal conditions of use.

10.2 CHEMICAL STABILITY

The product is stable in normal conditions of use and storage.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

The powders are potentially explosive when mixed with air.

10.4 CONDITIONS TO AVOID

Avoid environmental dust build-up.

10.5 INCOMPATIBLE MATERIALS

Oxidisers.

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10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity:	LD ₅₀ (oral): 1469 mg/kg (rat) Acute toxicity, category 4. Harmful if swallowed.
Skin corrosion/irritation:	Does not meet the classification criteria for this hazard class.
Serious eye damage/irritation:	Does not meet the classification criteria for this hazard class.
Respiratory/skin sensitisation:	Does not meet the classification criteria for this hazard class.
Germ cell mutagenicity:	Does not meet the classification criteria for this hazard class.
Carcinogenicity:	Does not meet the classification criteria for this hazard class.
Reproductive toxicity:	Suspected of damaging the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Does not meet the classification criteria for this hazard class.
STOT-repeated exposure:	Does not meet the classification criteria for this hazard class.
Aspiration Hazard:	Does not meet the classification criteria for this hazard class.
Other:	Based on the available data, the substance is not listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

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

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1 TOXICITY

Not available.

12.2 PERSISTENCE AND DEGRADABILITY

Solubility in water: 10 - 100 (QSAR) mg/l
NOT rapidly degradable.

12.3 BIOACCUMULATIVE POTENTIAL

Partition coefficient: n-octanol/water: 2.2 Log Kow
BCF: 84 (QSAR)

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12.4 MOBILITY IN SOIL

Partition coefficient: soil/water: 2.26 l/kg (QSAR)

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative (vPvB).

12.6 OTHER ADVERSE EFFECTS

Endocrine disrupting properties: Based on the available data, the substance is not listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Contaminated packaging: Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN NUMBER

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

14.2 UN PROPER SHIPPING NAME

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

14.3 TRANSPORT HAZARD CLASS(ES)

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

14.4 PACKING GROUP

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

14.5 ENVIRONMENTAL HAZARDS

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

14.6 SPECIAL PRECAUTIONS FOR USER

Not applicable.

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

Information not relevant.

14.8 ADDITIONAL TRANSPORT INFORMATION

Not available.

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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:

R22 Harmful if swallowed.

R63 Possible risk of harm to the unborn child.

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

Has not been performed / is not yet available a chemical safety assessment for the substance.

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

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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

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