

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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Publication: 16/04/2022

Revision: XX/XX/XXXX

Version: 00



TRETINOINUM

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

1.1 Product identifier

Product name: Tretinoin
Tretinoinum
Tretinoïne
Trétinoïne
Tretinoin
N° CAS: 302-79-4
N° EC: 206-129-0

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: 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

Acute Tox. 4	H302
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Muta. 2	H341
Repr. 2	H361d
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

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Hazard statements:

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.
H361d	Suspected of damaging the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Use personal protective equipment as required.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321	Specific treatment (see on this label).
P405	Store locked up.
P501	Dispose of contents/container in accordance with applicable laws.

Additional applicable label elements:



2.3 Other hazards

Under normal conditions of use and in its original form, the product has no other negative effects on health and the environment. Additional hazard information: For professional users only.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Tretinoin
IUPAC name:	(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethylcyclohexen-1-yl)nona-2,4,6,8-tetraenoic acid
Synonyms:	All-trans-Retinoic acid Vitamin A acid Airol Retin-A Vesanoid ATRA
N° CAS:	302-79-4
N° EC:	206-129-0
Molecular Formula:	C ₂₀ H ₂₈ O ₂
Content:	98.0 per cent to 102.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	If in doubt, or if symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to an unconscious person.
After inhalation:	Place the casualty in the open air, keep warm and at rest, if breathing is irregular or stops, give artificial respiration. Do not administer anything by mouth. If unconscious, place in a suitable position and seek medical help.
After skin contact:	Remove contaminated clothing. Wash skin vigorously with soap and water or a suitable skin cleanser. NEVER use solvents or thinners.
After eye contact:	If contact lenses are worn, remove them. Flush eyes thoroughly with clean, cool water for at least 10 minutes, pulling up the eyelids and seek medical attention.
After ingestion:	If accidentally swallowed, seek medical attention immediately. Keep at rest. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Irritant product. Repeated or prolonged contact with skin or mucous membranes may cause redness, blistering or dermatitis, inhalation of spray mist or airborne particles may cause respiratory tract irritation, some symptoms may not be immediate. Allergic reactions may occur.

Toxic product, in case of accidental contact may cause severe respiratory distress, central nervous system disturbance and in extreme cases unconsciousness. Immediate medical attention is required.

4.3 Indication of any immediate medical attention and special treatment needed

If in doubt, or if symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Extinguishing powder or CO ₂ . In case of more serious fires also alcohol-resistant foam and water spray.
Unsuitable extinguishing media:	Do not use direct water jet for extinguishing.

5.2 Special hazards arising from the substance/mixture

Fire may produce thick black smoke. As a result of thermal decomposition, hazardous products may be formed: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products may be harmful to health.

The product does not present any particular risk in case of fire.

5.3 Advice for firefighters

Surrounding fires:	Cool tanks, cisterns or containers near the source of heat or fire with water. Take wind direction into account. Prevent products used in fire-fighting from entering drains, sewers or watercourses.
Protection against fire:	Depending on the size of the fire, heat protection suits, self-contained breathing apparatus, gloves, goggles or face masks and boots may be required.
Hazardous combustion products:	Not available.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

For emergency responders

For exposure control and personal protective measures, see section 8.

6.2 Environmental precautions

Environmentally hazardous product, in case of large spills or if the product contaminates lakes, rivers or sewers, inform the competent authorities according to local legislation. Avoid contamination of drains, surface or ground water as well as soil.

6.3 Methods and material for containment and cleaning up

The contaminated area must be cleaned immediately with a suitable decontaminant. Pour the decontaminant on the debris and leave it for several days until no reaction occurs, in an unsealed container.

Collect and prepare for disposal without causing dust. Store in suitable, closed containers for disposal.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Never use pressure to empty containers, they are not pressure resistant containers. Smoking, eating and drinking must be prohibited in the application area. Comply with occupational health and safety legislation. Keep the product in containers made of material identical to the original.

Personal protection:

For personal protection, see section 8.

Technical protective measures:

Avoid formation of dust and aerosols. Adequate extraction must be provided where dust is formed. Normal fire safety precautions.

Handling:

Comply with occupational health and safety legislation.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

In an airtight container.

Conditions for safe storage, including any incompatibilities:

Under inert gas, in an airtight container.

It is recommended that the contents of an opened container be used as soon as possible and any unused part be protected by an atmosphere or inert gas.

Store in accordance with local legislation. Observe label instructions. Store containers between 5 and 35 °C, in a dry, well-ventilated place. Do not smoke. Keep away from unauthorised persons. After opening, containers should be carefully resealed and placed upright to prevent spillage.

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Classification and threshold storage quantity according to Annex I of Directive 2012/18/EU (SEVESO III):

Threshold quantity (tonnes) for the application of ...

Code	Description	Threshold quantity (tonnes) for the application of ...	
		lower tier requirements	higher tier requirements
P5b	FLAMMABLE LIQUIDS	50	200

Storage – away from:

Store away from heat sources and direct sunlight. Keep away from sources of ignition. Keep away from oxidizing agents and strongly acidic or alkaline materials. Keep away from unauthorised persons.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does NOT contain substances with Occupational Environmental Exposure Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls

Appropriate engineering control

Provide adequate ventilation, which can be achieved through good local exhaust ventilation and a good general exhaust system.

Hygiene measures: Handle with appropriate industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after work.

Individual protection measures

Eye/face protection:	PPE:	Particle impact protection goggles.
	Characteristics:	CE marked Category II. Eye protection against dust and fumes.
	CEN standards:	EN 165, EN 166, EN 167, EN 168.
	Maintenance:	The visibility through the eyepieces must be optimal, for which these elements must be cleaned daily, the protectors must be disinfected periodically following the manufacturer's instructions.
Skin protection:	Remarks:	Indicators of deterioration can be: yellowing of the eyepieces, surface scratches on the eyepieces, tears, etc.
	PPE:	Chemical protective clothing
	Characteristics:	CE-marked Category III. The clothing must have a good fit. The level of protection must be set according to a test parameter called "Breakthrough Time" (BT. Breakthrough Time) which indicates the time it takes for the chemical to pass through the material.
	CEN standards:	EN 464, EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034.

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	Maintenance:	Washing and care instructions provided by the manufacturer should be followed to ensure unchanging protection.
	Remarks:	The design of the protective clothing should facilitate its correct positioning and its permanence without displacement, during the intended period of use, taking into account environmental factors, together with the movements and postures that the user may adopt during his activity.
	PPE:	Safety footwear against chemical products and with antistatic properties.
	Characteristics:	CE marked Category III. The list of chemicals against which the footwear is resistant must be checked.
	CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345.
	Maintenance:	For the correct maintenance of this type of safety footwear, it is essential to follow the instructions specified by the manufacturer. Footwear should be replaced at any sign of deterioration.
	Remarks:	Footwear should be cleaned regularly and dried when damp but not placed too close to a heat source to avoid sudden temperature change.
	Hand protection:	
	PPE:	Non-disposable chemical protective gloves.
	Characteristics:	CE marking Category III. The list of chemicals against which the glove has been tested should be reviewed.
	CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420
	Maintenance:	A schedule for periodic replacement of gloves should be established to ensure that gloves are changed before they are permeated by contaminants. The use of contaminated gloves can be more dangerous than non-use, as the contaminant can accumulate in the glove component material.
	Remarks:	They shall be replaced whenever breaks, cracks or deformations are observed and when external soiling may reduce their resistance.
	Material:	PVC (Polyvinyl Chloride)
	Penetration time:	> 480 min.
	Material thickness:	0.35 mm
	Respiratory protection:	If the recommended technical measures are complied with, no personal protective equipment is necessary. Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (US) or type P1 (EN 143) Use respirators and components tested and approved under appropriate governmental 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:	Yellow or light orange, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	180 - 181 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	> 60 °C
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:	Sparingly soluble in methylene chloride, slightly soluble in ethanol (96 per cent) and in chloroform.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	6.7 (= Log P(o/w))
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: 300.44 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product presents no hazards due to its reactivity.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

The product does not present the possibility of hazardous reactions.

10.4 Conditions to avoid

Avoid any kind of incorrect handling. Light.

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10.5 Incompatible materials

Keep away from oxidizing agents and strongly alkaline or acidic materials in order to avoid exothermic reactions.

10.6 Hazardous decomposition products

Carbon oxides. No decomposition if used as intended.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (rat): 2,000 mg/kg Cutaneous LD ₅₀ (rabbit): > 2,500 mg/kg
Skin corrosion/irritation:	Product classified: Skin irritant, Category 2: Causes skin irritation.
Serious eye damage/irritation:	Eye - rabbit - Non-irritating to eyes.
Respiratory/skin sensitisation:	Inconclusive data for classification.
Germ cell mutagenicity:	Negative.
Carcinogenicity:	IARC: No component of this product is identified at levels greater than or equal to 0.1% as a probable, possible or confirmed human carcinogen by the International Agency for Research on Carcinogens (IARC).
Reproductive toxicity:	Product classified: Toxic for reproduction, Category 1A: May impair fertility or harm the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Inconclusive data for classification.
STOT-repeated exposure:	Inconclusive data for classification.
Aspiration Hazard:	Inconclusive data for classification.
Other:	Signs and Symptoms of Exposure: Based on our information, we believe that the chemical, physical and physical properties of the product have not been adequately investigated. Chemical, physical and toxicological properties have not been adequately investigated. RTECS: VH6475000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation. Splashes in the eyes may cause irritation and reversible damage.
Skin contact:	May be harmful if absorbed through skin. Causes skin irritation. Repeated or prolonged contact with the product may cause removal of oil from the skin, resulting in non-allergic contact dermatitis and absorption of the product through the skin.
Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish LC₅₀ - *Danio rerio* (zebrafish) - 4.64 mg/l - 96 h

Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

Biodegradability: Result: > 60 % - Readily biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

No information on mobility in soil is available.

The product must not be allowed to enter sewers or watercourses. Avoid penetration into the soil.

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: For disposal of this product, contact an authorised professional service. Dissolve or mix product with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all state and local environmental protection regulations.

Contaminated containers: Dispose of 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),
IATA/ICAO (Air) : UN3077

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : ADR: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(CONTAINS TRETINOIN), 9, GE III, (E)
IMDG: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(CONTAINS TRETINOIN), 9, GE/E III, MARINE POLLUTANT
ICAO: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(CONTAINS TRETINOIN), 9, GE III

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : 9

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14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Marine pollutant: Yes
IATA/ICAO (Air) : Dangerous for the environment

14.6 Special precautions for user

Labels: 9
Hazard number: 90
ADR limited quantity: 5 kg
IMDG limited quantity: 5 kg
ICAO limited quantity: 30 kg B
Provisions for carriage in bulk in ADR:
VC1 Bulk transport in wrapped vehicles, wrapped containers or wrapped bulk containers is permitted.
VC2 Carriage in bulk in covered vehicles, closed containers or closed bulk containers is permitted.
Transport by ship, FEm - Emergency sheets (F - Fire, S - Spillage): F-A,S-F
Act according to point 6.

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

The product is not affected by bulk transport on ships.

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:



Harmful Harmful to the environment
Irritant

Risk phrases:

R22 Harmful if swallowed.
R36/38 Irritating to eyes and respiratory system.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R63 Possible risk of harm to the unborn child.
R68 Possible risk of irreversible effects.

Safety phrases:

S1 Keep locked up.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

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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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be