

Material Safety Data Sheet

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

EN

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

1.1 Product identifier

Product name: Latanoprost
Latanoprostum
Latanoprost
Latanoprost
Latanoprost
N° CAS: 130209-82-4
N° EC: 634-172-9

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. 3	H301
Repr. 2	H361d

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s):
Danger
Harmful
Toxic

Hazard statements:

H301	Toxic if swallowed.
H361d	Suspected of damaging the unborn child.

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Precautionary statements:

P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P330	Rinse mouth.
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:	Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Latanoprost
IUPAC name:	(5Z)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptanoic acid 1-methylethyl ester
Synonyms:	Xalatan Latanoprost, ethanol solution
N° CAS:	130209-82-4
N° EC:	634-172-9
Molecular Formula:	C ₂₆ H ₄₀ O ₅
Content:	94.0 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:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give 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. Remove 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, including 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.

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4.2 Most important symptoms and effects, both acute and delayed

Severe abdominal and stomach pain, possible respiratory tract infection, blurred vision, foreign body sensation, burning or stinging, itching, dryness, superficial keratitis.

4.3 Indication of any immediate medical attention and special treatment needed

In cases of doubt, or when 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: Foam, dry powder, carbon dioxide, sand, water mist.
Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

Emits toxic fumes in case of fire.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from entering sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a face mask with full face shield covering the operator or the car (self protective) in 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 personal protective measures, see section 8. In general, evacuate the area. Wear self-contained breathing apparatus, boots and heavy rubber gloves.

For emergency responders

For exposure control and personal protective measures, see section 8. In general, evacuate the area. Wear self-contained breathing apparatus, boots and heavy rubber gloves.

6.2 Environmental precautions

Product not classified as dangerous for the environment, avoid spillage as far as possible.

6.3 Methods and material for containment and cleaning up

Collect dry, bag and retain for subsequent disposal as waste in accordance with local and/or national authority legislation. Avoid raising dust.
Ventilate the room and wash the spill site after complete removal.

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6.4 Reference to other sections

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

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: For personal protection, see section 8.

Personal protection: Not available.

Technical protective measures: Not available.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In a well-closed, light-resistant container.

Conditions for safe storage, including any incompatibilities: Store in a refrigerator or a freezer.
Store at a temperature of 2°C to 8°C.
The product does not require special storage measures.
Keep containers tightly closed in a dry place.

Storage – away from: Protect from moisture and sunlight.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Safety shower and eye bath.
Avoid all contact with eyes, skin and clothing.
Avoid prolonged or repeated exposure.
Wash hands and skin thoroughly after handling.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with appropriate industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after breaks and after the end of the working day.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

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Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Clear, colourless or yellow, viscous, oily liquid.

Odour: Odourless.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: Not available.

Initial boiling point: 538.8 °C

Boiling range: Not available.

Flash point: 188.3 °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: Very soluble in acetonitrile.
Freely soluble in anhydrous ethanol.

Solubility in water: Practically insoluble in water.

Partition coefficient (n-octanol/water): LogPow 4.276 (25 °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

Molecular weight: 432.59 g/mol

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions. Stable under the recommended handling and storage conditions (see section 7).

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Avoid improper handling: high pressures, humidity and temperatures.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

If heated by sunlight, decomposes to form fumes of carbon oxides (CO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD ₅₀ , rat): > 50 mg/kg Acute intravenous toxicity (LD ₅₀ , rat): > 2 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	May cause eye irritation.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	No components of this product have been identified as probable, possible or confirmed human carcinogens at levels greater than or equal to 0.1%.
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:	May cause eye irritation.
Skin contact:	Harmful if absorbed through skin. May cause skin irritation.
Inhalation:	Harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Harmful if swallowed. Toxic if swallowed.
Aspiration:	Not available.

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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.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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

Contaminated container: 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) : UN2810

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Toxic liquid, organic, N.E.G., 6.1, III
Toxic liquid, organic, N.O.S., 6.1, III
Toxic liquid, organic, n.o.s., 6.1, III

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : 6.1 Toxic substances
6.1 Toxic substances



14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No

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14.6 Special precautions for user

Warning: Toxic substances
Danger code: 60
EMS Number: F-A, S-A
Stowage Category: A
Stowage Code: SW2 Clear of living quarters

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

Not applicable.

14.8 Additional transport information

UN2810, Toxic liquid, organic, N.O.S., 6.1, III

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful Toxic

Risk phrases:

R25 Toxic if swallowed.
R63 Possible risk of harm to the unborn child.

Safety phrases:

S1 Keep locked up.
S20/21 When using do not eat, drink or smoke.
S46 If swallowed, seek medical advice immediately and show this container or label.

15.2 Chemical safety assessment

A chemical safety assessment of the product 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

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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

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