	SAFETY DATA SHEET	**SS DT 0302 03** **LAT0002N**
	LATANOPROST	Edition : 03 Revision: 02 Data: 22/04/2013

In accordance with Regulation (EC) 1907/2006, (EC) 1272/2008 and (UE) 453/2010 (Annex I)

SECTION 1.
IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1. Substance identifier

Substance name:	**LATANOPROST**
Other names (if available): Name in Annex VI-CLP: Name reported in the inventory of harmonized classification and labelling:	Isopropyl (Z)-7-((1R,2R,3R,5S)-3,5-dihydroxy-2-((3R)-3-hydroxy-5-phenylpentyl)cyclopentyl)-5-heptenoate 5-Heptenoic acid, 7-[3,5-dihydroxy-2-(3-hydroxy-5- phenylpentyl) cyclopentyl]- , 1-methylethyl ester, [1R[1α(Z),2β(R*), 3α,5α]]- 5-Heptenoic acid, 7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-, 1-methylethyl ester, (5Z)- Not present in Annex VI-CLP Substance not listed in the Inventory
CAS number	130209-82-4
IUPAC name (if CAS is not available)	Propan-2-yl (Z)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]hept-5-enoate
REACH registration number, if given	Substance not subject to REACH registration for its use

1.2. Relevant identified uses of the substance and uses advised against

Relevant use(s)	Active Pharmaceutical Ingredient. Antiglaucoma agent
Uses advised against	Other uses are not expected.

1.3. Details of the supplier of the safety data sheet

Identification of the company (supplier): Newchem S.p.A.
Address: Via Roveggia, 47
37136 Verona - ITALY
Telephone number: +39 045 504922
Fax: +39 045 8201568

Competent person for MSDS: segreteria@newchemspa.it

1.4. Emergency telephone number

Factory: Address**:** Via Roveggia, 47 - 37136 Verona - ITALY

EMERGENCY TELEPHONE NUMBER: +39 045 504922 (08.00-18.30).

SECTION 2
HAZARDS IDENTIFICATION

2.1 Classification of the substance

- **Classification of the substance in accordance with Regulation (EC) n. 1272/2008:**

Hazard class	Class code and hazard category	Hazard statement	Hazard warning
Acute toxicity	**Acute Tox. Cat. 3**	**H301**	**H301 -** Toxic if swallowed
Reproductive toxicity	**Repr. Tox. Cat. 2**	**H361d**	**H361d** - Suspected of damaging the unborn child

- **Classification in accordance with Directive 67/548/EEC :**

Classification	Hazard symbol	Risk phrases
T; R25	 **T - Toxic**	**R25 –** Toxic if swallowed
Repr.Cat.3: R63	 **Xn-Harmful**	**R63** - Possible risk of harm to the unborn child.

Main adverse effects
Physico-chemical effects: There are no known physical-chemical effects related to this substance.
Health effects: Ingestion: intense abdominal and stomach pain.
Suspected of damaging the unborn child.
Environmental effects: Dangers about the environment are not known.
See also sections from 9 to 12

2.2 Label elements

- **Labelling in accordance with regulation n. 1272/2008/EC**

Pictograms		
Signal Word	**Danger**	**Warning**
Hazard Statements[*]	**H301**	**H361d**
Safety statements (P)[*]		
- *Prevention*	**P264 -** Wash thoroughly after handling.	

	P270 - Do not eat, drink or smoke when using this product.
- *Response*	**P301+P310 –** IF swallowed: Immediately call a poison center or doctor/physician. **P330 -** Rinse mouth.
- *Storage*	**P405 -** Store locked up.
- *Disposal*	**P501**- Dispose of contents/container in accordance with local/regional/national/ international regulation.

[*] For the meaning of the Hazard and Safety Advices: See Section 16

2.3 Other hazards (which do not results in the classification)

The substance satisfies the PBT criteria	YES	NO
- PBT		X
- vPvB		X

- Health hazards: Ingestion: strong abdominal and stomach pain.
Inhalation exposure: possible irritation of mucous membranes and upper breathing intakes.
Contact with skin: may irritate the skin.
Contact with eyes: may be irritating.

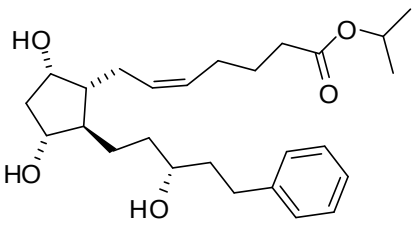
- Environmental hazards: Dangers about the environment are not known.

- Physical-chemical hazards: No smoking. Substance emits toxic fumes in case of fire.

- Specific effects: Specific effects related to this substance are not known.

SECTION 3
COMPOSITION/INFORMATION ON INGREDIENTS

Description:

Name of the component:	Latanoprost
Concentration	Pure substance
Structural formula	
Chemical formula	$C_{26}H_{40}O_5$
Molecular weight	432,59 [g/mol]
Substance with Community OEL	NO
CAS name	5-Heptenoic acid, 7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-, 1-methylethyl ester, (5Z)
CAS number	130209-82-4
IUPAC name	Propan-2-yl (Z)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R) -3-hydroxy-5-phenylpentyl]cyclopentyl]hept-5-enoate
EC number	Not found after bibliographic research
Index number	Not found after bibliographic research

Impurity/ies (if classified)	There are no impurities
Additive/es (if classified)	There are no additives

SECTION 4
FIRST AID MEASURES

4.1 Description of the first aid measures

- *Eye contact:* Wash immediately with large amounts of water or normal saline solution. Keep eyelids open with the finger. Get medical advice in case adverse symptoms appear.
- *Skin contact:* Remove contaminated clothes and shoes. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical advice immediately and show the label to the doctor.
- *Ingestion:* If swallowed wash mouth with water provided the person is conscious. Get medical advice immediately and show container or label.
- *Inhalation:* In case of hazardous vapors formation, remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms will appear.

4.2 Most important symptoms and effects (acute and delayed)

- *Acute effects:* Ingestion: intense abdominal and stomach pain.
Inhalation exposure: possible respiratory tract infection.
Contact with eyes: blurred vision, foreign body sensation, burning or stinging, itching, dryness, superficial keratitis.

- *Delayed effects and symptoms:* The most frequently reported effects have been the iris increased pigmentation, periorbital tissue (eyelid) and eyelashes, and growth of eyelashes. The most common adverse systemic events were represented by upper respiratory tract infection/cold/flu (incidence 4%). Chest pain/angina, back pain/muscles/joints, and rash/allergic skin reactions (incidence 1-2%). The substance may cause allergic skin reactions. Suspected to cause harm to the fetus.

4.3 Indications of any immediate medical attention and special treatment needed

- *Medical monitoring:* Foreseen on the base of the classification of the substance.
- *Antidotes, if known:* Unknown
- *Contraindications:* Unknown
- *Immediate treatment at workplace:* Not foreseen

SECTION 5
FIREFIGHTING MEASURES

5.1 Extinguishing media

- *Suitable extinguishing media:* Nebulised water, chemical powder, foam, CO_2
- *Unsuitable extinguishing media:* Unsuitable extinguishing media aren't known

5.2 Special hazards arising from the substance

- *Hazardous combustion products:* Thermal decomposition and combustion may produce toxic fumes containing COx.
- *Other special hazards:* Special dangers are not known.

5.3 Advice for firefighters

- *Technical actions for protection:*	Don't try to extinguish the fire without an autonomous respiratory device (SCBA) and suitable protective clothes.
- *Special protective equipment for firefighters:*	Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria and used in the maximum conditions of protection on the basis of the information reported in the previous sub-sections.

SECTION 6
ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

- *Eye:*	Wear suitable protected devices. (see section 8)
- *Skin:*	Wear suitable clothes with full body protection.
- *Inhalation:*	In case of fire and/or explosions avoid to breathe smokes and vapors. Use an autonomous respiratory device (SCBA) and suitable protective clothes. The vapors can be eliminated with nebulized water.

In case of accidental release (not in normal use conditions), it is advised to use personal protective equipment, according to EN criteria.

For emergency responders

- *Eye:*	see section 8
- *Skin:*	see section 8
- *Inhalation:*	see section 8

6.2 Environmental precautions

In case of accidental release in the environment, avoid that the substance can reach drains, surface water and ground water.

6.3 Methods and material for containment and cleaning up

- *Containment procedures:*	Collect all the material scattered on the ground with suitable protective equipment. Ventilate the contaminated area of leak or spill. Keep out strangers and unprotected from the area of the spill. Wear appropriate personal protective equipment as specified in Section 8.
- *Cleaning up procedures:*	Recover the substance by suction or other mechanic means and wash the area with plenty of water and cleanings. Store the recovered product in wait of the skilled disposal society. If the effusion happened in highway or in a public place, suitable espedients should be adopted in order to protect people from any risks. Absorb the substance with vermiculite or similar absorbing agent and collect the residues into an appropriate container for disposal

6.4 Reference to other sections

See also section 8 and 13

SECTION 7
HANDLING AND STORAGE

7.1. Precautions for safe handling

- *Recommendations for handling:*	Handle away from sparkles and flames - sources of ignition Handle in a well ventilated place Avoid contact with incompatible materials Do not breathe vapours/gases Wear suitable Personal Protection Equipment (see section 8) Keep the substance away from drains, surface or ground waters
- *Recommendations for personal hygiene:*	Do not eat, drink and smoke in the working areas Wash hands after handling the substance Remove contaminated clothing and protective equipment before entering eating areas

7.2. Conditions for safe storage including any incompatibilities

The risk management procedures described in this section are consistent with the physical and chemical properties reported in section 9.
The substance is not classified for any physical and chemical properties and no risk management is foreseen.

Risk Management measures related to :

- *Potential ignition sources:*	Don't expose to heat sources.

Procedure to control other effects

- *Weather conditions:*	Do not expose to elevated temperatures.
- *Ambient pressure:*	No procedure of restriction is expected.
- *Temperature:*	Store at +2/+8°C.
- *Sunlight:*	Don't expose to the direct light of the sun.
- *Humidity*	Don't store in a damp place.
- *Vibration:*	No procedure of restriction is expected.

The adoption of the Risk Management procedure related to the physical and chemical properties is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.

Material to keep the integrity of the substance

- *Stabilisers:*	Use of stabilisers is not expected
- *Antioxidants:*	Use of antioxidants is not expected

Other advice

- *Ventilation requirements*	Requested on the base of the storage of the substance
- *Specific design of storage rooms*	Not requested on the base of the classification
- *Quantity limits for storage*	Not requested on the base of the classification
- *Packaging compatibilities*	See also 10.5

7.3. Specific end use(s)

- Recommendation for specific final use(s)

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X
- Industry or sector specific guidance available and attached		X

SECTION 8
EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

- National/ European Occupational Exposure Limits	< 1 µg/m^3 (calculated using qualitative approach)
- Other National/ European Occupational Exposure Limits	Not present in databases consulted
- National/ European Biological Limits (BEI):	Not present in databases consulted
- Other National/ European Biological Limits (BEI):	Not present in databases consulted
- Recommended monitoring procedures	The measurement of substances in the workplace should be performed with standardized methods (*eg* UNI EN 689:1997: Atmosphere at work - Guidance on assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy, UNI EN 482:2006: atmospheres in the workplace - General requirements for performance of procedures for the measurement of chemical agents) or, in their absence, with appropriate methods.
- DNEL values (components)	Chemical Safety Report has not been performed
- PNEC values (components)	Chemical Safety Report has not been performed

8.2. Exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X
- Accordance with the controlled conditions of use. Only for intermediates registered under art. 17 to 18		X

8.2.1. Appropriate engineering controls

The adoption of the most appropriate engineering controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario described in the Reach registration Dossier is not available.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

The adoption of the most appropriate Personal Protective Equipment is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.
If the results of such risk evaluation done in accordance with Directive 98/24/EEC showed that the collective and general risk management measures are not sufficient to reduce the risks and, if the exposure to the substance cannot be

reduced by other containment means, appropriate PPE must be adopted in compliance with technical EN guidance indication.

a) Eye and Face protection	Safety goggles as for EN 166; facial shield
b) Skin protection	
- *Hands protection*	Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/EEC. The gloves material must be waterproof and stable against the substance content. Select the glove material on the basis of the type of the material, typical or minimal breakdown times, permeability ranges, thickness. Material: nitrile (nitrile rubber), hypoallergenic Thickness: not inferior to 0.12 mm
- *Other, body protection*	Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 14605 in case of spurts.
c) Respiratory protection	When the risk evaluation foresees the need to use respiratory devices, use antigas or combined filters (EN 141). Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).
d) Thermal hazards	Not foreseen in the standard use of the substance. Assess possible Personal Protection Equipment on the basis of specific uses of the substance.

8.2.3 Environmental exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 9
PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Colorless or pale yellow oil
Odor:	Odourless
pH:	Not found after bibliographic research
Flash point:	188.3 °C (predicted using ACS/Lab). [1]
Melting point/freezing point:	Not found after bibliographic research
Initial boiling point and boiling range:	583.8 °C at 760 mmHg (predicted using ACS/Lab). [1]
Vapour tension:	43.4 dyne/cm (predicted using ACS/Lab). [1]
Vapour pressure:	$1.79x10^{-14}$ mmHg at 25°C (predicted using ACS/Lab). [1]
Density:	1.093 g/cm^3 (predicted using ACS/Lab). [1]
Water solubility:	Practically insoluble.[6]
Solubility in organic solvents:	Very soluble in acetonitrile and freely soluble in acetone, in ethanol, in ethyl acetate, in isopropanol, in methanol, and in octanol.[6]
Partition coefficient Octanol/water (Log Kow):	4.276 ± 0.338 (Temp: 25 °C, calculated). [5]
Ignition temperature:	Not found after bibliographic research.
Viscosity:	Not found after bibliographic research
Explosive properties:	Not found after bibliographic research
Oxidising properties:	Not found after bibliographic research

9.2. Other information

Miscibility:	Not found after bibliographic research
Fat solubility:	Not found after bibliographic research
Conductivity:	Not found after bibliographic research
Henry's Law Constant:	$6.773x10^{-14}$ atm-m^3/mole (predicted using EPISuite). [1]
Optical rotatory power:	+32.7 °(Conc: 1.03 g/100mL; Solvent: acetonitrile; λ: 589.3 nm; Temp: 20 °C).[7]

SECTION 10
STABILITY AND REACTIVITY

10.1. Reactivity

This substance is considered not reactive under the normal conditions of usage.

10.2. Chemical stability

The substance is stable at the normal conditions of temperature and pressure and if stored in closed containers in well ventilated and cool place.

	NO	YES	Used stabiliser
- Stabilisers:	X	-	
- Change in physical appearance	X	-	

10.3. Possibility of hazardous reactions

	NO	YES
- Possibility of an exothermic reaction:	X	-
- Possibility of a reaction releasing excessive pressure	X	-
- Possible degradation with unstable products formation	X	-

10.4. Conditions to avoid

Avoid exposure to moisture and excessive heat.

10.5. Incompatible materials

Strong oxidising agents.

10.6. hazardous decomposition products

If heated at high temperatures, decomposes releasing fumes and toxic gases of COx.

SECTION 11
INFORMATION ON TOXICOLOGICAL EFFECTS

- Exposure routes:	YES	NO
- Inhalation:	X	
- Ingestion:	X	
- Skin contact:	X	
- Eye contact:	X	

- Effects (acute, delayed, chronic) following the exposure (short and/or prolonged):

- Ingestion:	Strong abdominal and stomach pain; fatal if swallowed.
-Inhalation:	Possible irritation of the mucous membranes and upper breathing intakes.
-Skin contact:	Possible redness.
-Eye contact:	Possible burning sensation, redness of conjunctiva.

- **Toxico-kinetics information (ADME = Adsorption, Distribution, Metabolism, Excretion):**

Absorption:
Latanoprost is absorbed through the cornea where the isopropyl ester prodrug is hydrolyzed to the acid form to become biologically active. Studies in man indicate that the peak concentration in the aqueous humor is reached about two hours after topical administration.
Distribution:
The distribution volume in humans is 0.16 ± 0.02 L/kg. The acid of latanoprost can be measured in aqueous humor during the first 4 hours, and in plasma only during the first hour after local administration.
Metabolism:
Latanoprost, an isopropyl ester prodrug, is hydrolyzed by esterases in the cornea to the biologically active acid. The active acid of Latanoprost reaching the systemic circulation is primarily metabolized by the liver to the 1,2-dinor and 1,2,3,4-tetranor metabolites via fatty acid ß-oxidation.
Excretion:
The elimination of the acid of Latanoprost from human plasma is rapid (t =17 min) after both intravenous and topical administration. Systemic clearance is approximately 7 mL/min/kg. Following hepatic ß-oxidation, the metabolites are mainly eliminated via the kidneys. Approximately 88% and 98% of the administered dose is recovered in the urine after topical and intravenous dosing, respectively.[4]

- Acute Toxicity:

- *Oral:*	LD_{50} rat/mouse > 50 mg/kg.[2]
- *Dermal:*	Not found after bibliographic research.
- *Inhalation:*	Not found after bibliographic research.
- *Other information:*	LD_{50} i.v. rat/mouse > 2 mg/kg.[6]

- Corrosion/Irritation effects: May be irritant.

- Severe ocular lesion: May be irritant.

- Sensitisation:

- *Dermal:*	Not found after bibliographic research.
- *Respiratory:*	Not found after bibliographic research.

- Repeated dose toxicity (experimental): not found after bibliographic research.

- CMR effects:

- Germinal cell mutagenicity	Latanoprost was not mutagenic in bacteria, in mouse lymphoma or in mouse micronucleus tests. Chromosome aberrations were observed *in vitro* with human lymphocytes. Additional *in vitro* and *in vivo* studies on unscheduled DNA synthesis in rats were negative.[4]
- Carcinogenicity:	Latanoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of up to 170 µg/kg/day (approximately 2,800 times the recommended maximum human dose) for up to 20 and 24 months, respectively.[4]
- Reproductive toxicity:	Latanoprost induced embryolethal effects in rabbits in doses above 5 micrograms/kg/day. This dose caused significant embryo-fetal toxicity characterized

by increased incidence of late resorption and miscarriage and by reduced fetal weight. No consistent indications of embryo fetal toxicity were observed with the low and intermediate doses of 0.2 and 1 micrograms/kg/day.[2]
Studies in rats showed increased pup mortality at doses of 10 micrograms/kg with very high pup mortality at 100 micrograms/kg/day. Latanoprost was toxic to embryos at intravenous doses of 0.001 mg/kg/day[2].
Further reproduction studies have been performed in rats and rabbits. In rabbits an incidence of 4 of 16 females had no viable fetuses at a dose that was approximately 80 times the maximum human dose, and the highest nonembryocidal dose in rabbits was approximately 15 times the maximum human dose. There are no adequate and well-controlled studies in pregnant women [4]

- Specific Target Organ Toxicity (STOT)-single exposure:
Not found after bibliographic research

- Specific Target Organ Toxicity (STOT)- repeated exposure :
Not found after bibliographic research

- Aspiration hazards: not found after bibliographic research

- Epidemiology:
It is not known whether this drug or its metabolites are excreted in human milk.
The following events have been identified during postmarketing use of latanoprost ophthalmic solution in clinical practice: asthma and exacerbation of asthma; corneal edema and erosions; dyspnea; eyelash and vellus hair changes (increased length, thickness, pigmentation, and number); eyelid skin darkening; herpes keratitis; intraocular inflammation (iritis/uveitis); keratitis; macular edema, including cystoid macular edema; dizziness, headache, and toxic epidermal necrolysis.[4]

- Reasons for the lack of classification:
Where the substance resulted non classified, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Directives mentioned in this data sheet.

SECTION 12
ECOLOGICAL INFORMATION

12.1. Toxicity
Not found after bibliographic research.

12.2. Persistence and degradability
Not found after bibliographic research.

12.3. Bioaccumulative potential
Partition coefficient Octanol/water (Log Kow): 4.276 ± 0.338 (Temp: 25 ° C, calculated).[5] Based on this value a real potential to bioconcentrate can be expected.

12.4. Mobility in soil
Not found after bibliographic research.

12.5. Results of PBT e vPvB assessment

On the base of the available information the substance does not satisfy the criteria in order to be considered a PBT or vPvB.

12.6. Other adverse effects

Not found after bibliographic research

- Reasons for the lack of classification:

Where the substance resulted non classified, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Directives mentioned in this data sheet.

SECTION 13
DISPOSAL CONSIDERATION

13.1. Waste treatment methods

	Incineration	Recycling	Landfilling
- Substance wastes:	X		
- Contaminated packaging:	X		

It is not recommended disposal through wastewater.
Refer to Community/National/Local requirements concerning the waste disposal.

SECTION 14
TRANSPORT INFORMATION

- ONU Number: 2810
- UN proper shipping name: TOXIC LIQUID, ORGANIC, N.O.S.

ADR

Class, Code, Group: 6.1 T1 III
Hazard identification number: 60
LQ: 5 L
Tunnel Restriction Code: (E)

RID

Class, Code, Group: 6.1 T1 III
Hazard identification number: 60
LQ: 5 L

IMDG

Class: 6.1
Packaging group: III
Limited quantities (QL): 5 L
EmS sheet: F-A, S-A
Marine Pollutant: NO

IATA

Class: 6.1
Hazard Label: Toxic
Packaging group: III
Erg code: 6L
Passenger and cargo: (LIMITED QUANTITY) P.I.: Y642; max net q.ty per pack: 2 L;
Passenger and cargo: P.I.: 655; max net q.ty per pack: 60 L;
Cargo only: P.I.: 663; max net q.ty per pack: 220 L.
Special provisions: A137.

SECTION 15
REGULATORY INFORMATION

All other information on regulations are reported if not provided in other sections/subsection of the Safety Data Sheet.

15.1 Safety, Health and Environmental regulation/legislation specific for the substance

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 - 0023

15.2. Chemical Safety Assessment

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 16
OTHER INFORMATION

Revisions:
- **Edition n. 03 dated 22/04/2013 (General Revision)**
- **Revision n. 02**

Bibliographic sources:

[1] Data bank Chemspider [http://chemspider.com]
[2] MSDS USP Latanoprost
[3] Investigative Ophthalmology and Visual Science. 2005;46:2444-2450. © 2005 by The Association for Research in Vision and Ophthalmology, Inc.

[4] Data bank DailyMed [http://dailymed.nlm.nih.gov/dailymed/drugInfo]
[5] Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (1994-2013 ACD/Labs)
[6] Data bank ChemIDplus [http://chem.sis.nlm.nih.gov]
[7] Ref: Zanoni, Giuseppe; Tetrahedron 2010, 66(38), 7472-7478

Acronyms
- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI : Biological Esposure Indices
- CAS: Chemical Abstract Service (division of the American Chemical Society
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for re production substances
- EINECS: European Inventory of existing Commercial Substances
- EPA: US Environmental Protection Agency
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- N.A.: Not Applicable
- N.A.: Not Available
- NOAEL: No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE : Personal protective Equipment
- PBT: Persistent, Bioaccumulative and Toxic substances
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative

Information related to the regulation EC/1272/2008

List of hazards statements

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

List of P statements

Prevention

P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.

Reaction

P301+P310	IF swallowed: immediately call a poison center or doctor/physician.
P330	Rinse mouth.

Storage

P405	Store locked up.

Disposal

P501	Dispose of contents/container in accordance to local/regional/national/international rules.

Information related to the Directive 67/ 548/ EEC, Directive 1999/45/EC and Regulation (EC) n. 1907/2006

R phrases

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

S phrases

S24/25	Avoid contact with skin and eyes.
S36/37	Wear suitable protective clothing and gloves.
S39	Wear eye/face protection.
S53	Avoid exposure - obtain special instructions before use.

Information on workers training
Follow criteria of Directive 98/24/EC, its amendments and National reinforcements

Restriction of use : None

Substance under authorisation : No

DISCLAIMER
This document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless adequate written information on how to handle the material are given
The provider of this document can not provide any warnings about the dangers of use or interaction with other chemicals or materials. It is responsibility of the user the safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information reported should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Annex I of Regulation No 453/2010/EU.