



## Tafluprost Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 558031-00016      Date of last issue: 04.04.2023  
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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Tafluprost	209860-87-7	Acute Tox. 4; H302 Eye Irrit. 2; H319 Repr. 1B; H360D STOT SE 1; H370 (Lungs, Cardio-vascular system) STOT RE 1; H372 (Lungs, Cardio-vascular system) Aquatic Chronic 4; H413	>= 0,0002 - < 0,0025

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- Protection of first-aiders : No special precautions are necessary for first aid responders.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

None known.

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

**5.3 Advice for firefighters**

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**6.2 Environmental precautions**

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absor-

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Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | : | Use only with adequate ventilation.  |
| Advice on safe handling | : | Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Take care to prevent spills, waste and minimize release to the environment.  |
| Hygiene measures        | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

### 7.2 Conditions for safe storage, including any incompatibilities

- |   |   |   |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Gases                  |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Tafluprost	209860-87-	TWA	0.002 µg/m <sup>3</sup> (OEB 5)	Internal

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	Further information: Skin, Eye			
		Wipe limit	0.02 µg/100 cm <sup>2</sup>	Internal

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

Substance name	End Use	Exposure routes	Potential health effects	Value
Glycerine	Workers	Inhalation	Long-term local effects	56 mg/m <sup>3</sup>
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m <sup>3</sup>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

Substance name	Environmental Compartment	Value
Glycerine	Fresh water	0,885 mg/l
	Marine water	0,0885 mg/l
	Intermittent use/release	8,85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3,3 mg/kg dry weight (d.w.)
	Marine sediment	0,33 mg/kg dry weight (d.w.)
	Soil	0,141 mg/kg dry weight (d.w.)

**8.2 Exposure controls****Engineering measures**

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Personal protective equipment**

Eye/face protection : Wear safety glasses with side shields or goggles.  
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.  
 Skin and body protection : Work uniform or laboratory coat.  
 Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

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suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Organic vapour type (A)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Appearance	: Aqueous solution
Colour	: clear
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive

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Oxidizing properties : The substance or mixture is not classified as oxidizing.

**9.2 Other information**

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

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**SECTION 10: Stability and reactivity****10.1 Reactivity**

Not classified as a reactivity hazard.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions : Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : None known.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Tafluprost:**

Acute oral toxicity : LD50 (Rat): 665 mg/kg

LD50 (Rat): > 100 mg/kg

Remarks: No mortality observed at this dose.

Acute toxicity (other routes of : (Dog): 3 mg/kg

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administration)

Application Route: Intravenous

Target Organs: Cardio-vascular system

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Tafluprost:**

Species : Monkey  
Result : No eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Tafluprost:**

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Result : Not a skin sensitizer.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Tafluprost:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

**Carcinogenicity**

Not classified based on available information.



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**Components:****Tafluprost:**

Species : Rat  
Application Route : Subcutaneous  
Exposure time : 24 Months  
Result : negative

Species : Mouse  
Application Route : Subcutaneous  
Exposure time : 18 Months  
Result : negative

**Reproductive toxicity**

Not classified based on available information.

**Components:****Tafluprost:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intravenous injection  
Fertility: NOAEL: 100 µg/kg  
Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: LOAEL: 10 µg/kg  
Result: Malformations were observed., Reduced foetal weight

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 3 µg/kg

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: LOAEL: 0,03 µg/kg  
Result: Malformations were observed.

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 0,01 µg/kg

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: LOAEL: 1 µg/kg

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection

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Developmental Toxicity: NOAEL: 0,3 µg/kg

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

**Components:****Tafluprost:**

Target Organs : Lungs, Cardio-vascular system  
Assessment : Causes damage to organs.

**STOT - repeated exposure**

Not classified based on available information.

**Components:****Tafluprost:**

Target Organs : Lungs, Cardio-vascular system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Tafluprost:**

Species : Rat  
LOAEL : 0,01 mg/kg  
Application Route : Intravenous  
Exposure time : 6 Months  
Target Organs : Cardio-vascular system, Blood, Bone marrow, Kidney, Liver, spleen

Species : Dog  
NOAEL : 0,0001 mg/kg  
LOAEL : 0,001 mg/kg  
Application Route : Intravenous  
Exposure time : 39 Weeks  
Target Organs : Cardio-vascular system, Eye  
Symptoms : Dilatation of the pupil

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Tafluprost:**

Eye contact : Symptoms: dryness of the eyes, Blurred vision

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**SECTION 12: Ecological information****12.1 Toxicity**

No data available

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential****Components:****Taf luprost:**

Partition coefficient: n- : log Pow: 4,5  
octanol/water

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment****Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects****Product:**

Endocrine disrupting poten- : The substance/mixture does not contain components consid-  
tial : ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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**SECTION 14: Transport information****14.1 UN number**

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ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

**14.2 UN proper shipping name**

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

**14.4 Packing group**

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA (Cargo) : Not regulated as a dangerous good  
IATA (Passenger) : Not regulated as a dangerous good

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

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

Remarks : Not applicable for product as supplied.

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

The components of this product are reported in the following inventories:

AICS : not determined

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DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

#### Full text of H-Statements

H302 : Harmful if swallowed.  
 H319 : Causes serious eye irritation.  
 H360D : May damage the unborn child.  
 H370 : Causes damage to organs if swallowed.  
 H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.  
 H413 : May cause long lasting harmful effects to aquatic life.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
 Aquatic Chronic : Long-term (chronic) aquatic hazard  
 Eye Irrit. : Eye irritation  
 Repr. : Reproductive toxicity  
 STOT RE : Specific target organ toxicity - repeated exposure  
 STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-

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stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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