

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

Section 1: Identification

Product identifier : Tafluprost Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification**Classification of the substance or mixture**

Not a hazardous substance or mixture.

GHS Label elements, including precautionary statements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Glycerine	56-81-5	≥ 1 - < 10
Tafluprost	209860-87-7	< 0.1

Section 4: First-aid measures**Description of necessary first-aid measures**

If inhaled : If inhaled, remove to fresh air.

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

In case of skin contact	: Get medical attention if symptoms occur. Wash with water and soap as a precaution.
In case of eye contact	: Get medical attention if symptoms occur. Flush eyes with water as a precaution.
If swallowed	: Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks	: None known.
Protection of first-aiders	: No special precautions are necessary for first aid responders.

Indication of any immediate medical attention and special treatment needed

Treatment	: Treat symptomatically and supportively.
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Section 5: Fire-fighting measures**Extinguishing media**

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
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Unsuitable extinguishing media	: None known.
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Special hazards arising from the substance or mixture

Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
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Hazardous combustion products	: Carbon oxides
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Special protective actions for fire-fighters

Special protective equipment for firefighters	: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.
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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.
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Section 6: Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Personal precautions	: Follow safe handling advice (see section 7) and personal pro-
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Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

ective equipment recommendations (see section 8).

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.

Methods and materials 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 absorbent.
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.

Section 7: Handling and storage**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
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.
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.

Conditions for safe storage, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Tafluprost Formulation

Version 2.0	Revision Date: 03.12.2024	SDS Number: 558029-00018	Date of last issue: 28.09.2024 Date of first issue: 15.03.2016
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Strong oxidizing agents

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycerine	56-81-5	PEL (long term) (Mist)	10 mg/m ³	SG OEL
Tafluprost	209860-87-7	TWA	0.002 µg/m ³ (OEB 5)	Internal
Further information: Skin, Eye				
		Wipe limit	0.02 µg/100 cm ²	Internal

Appropriate engineering control measures

: The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

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.

Individual protection measures, such as personal protective equipment (PPE)

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

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

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

Section 9: 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
Flammability (liquids)	:	No data available
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

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

II	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		
II	Viscosity, kinematic	:	No data available
	Explosive properties	:	Not explosive
	Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
	Molecular weight	:	No data available
	Particle characteristics		
II	Particle size	:	No data available

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

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

Not classified based on available information.

Components:**Glycerine:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity	:	LD50 (Guinea pig): > 5,000 mg/kg

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

II

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 administration)	:	(Dog): 3 mg/kg
		Application Route: Intravenous
		Target Organs: Cardio-vascular system

Skin corrosion/irritation

Not classified based on available information.

Components:**Glycerine:**

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Glycerine:**

Species	:	Rabbit
Result	:	No eye irritation

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.

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

Germ cell mutagenicity

Not classified based on available information.

Components:**Glycerine:**

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
		Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosome aberration test in vitro Result: negative
		Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative

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.

Components:**Glycerine:**

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

Tafluprost:

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

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

Exposure time	: 18 Months
Result	: negative

Reproductive toxicity

Not classified based on available information.

Components:**Glycerine:**

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

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

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

Developmental Toxicity: LOAEL: 1 µg/kg

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intravenous injection

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:****Glycerine:**

Species : Rat
NOAEL : 0.167 mg/l
LOAEL : 0.622 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

Species : Rat
NOAEL : 8,000 - 10,000 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Species : Rabbit
NOAEL : 5,040 mg/kg
Application Route : Skin contact
Exposure time : 45 Weeks

Tafluprost:

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

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**Toxicity****Components:****Glycerine:**

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 1,955 mg/l Exposure time: 48 h
Toxicity to microorganisms	: NOEC (Pseudomonas putida): > 10,000 mg/l Exposure time: 16 h Method: DIN 38 412 Part 8

Persistence and degradability**Components:****Glycerine:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 92 % Exposure time: 30 d Method: OECD Test Guideline 301D
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Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

Bioaccumulative potential**Components:****Glycerine:**

Partition coefficient: n-octanol/water	: log Pow: -1.75
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Tafluprost:

Partition coefficient: n-octanol/water	: log Pow: 4.5
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Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

Waste from residues	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
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.

Section 14: Transport information**International Regulations****UNRTDG**

UN number	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Environmentally hazardous	: no

IATA-DGR

UN/ID No.	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Packing instruction (cargo aircraft)	: Not applicable
Packing instruction (passenger aircraft)	: Not applicable

IMDG-Code

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

UN number	: Not applicable
UN proper shipping name	: Not applicable
Transport hazard class(es)	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
EmS Code	: Not applicable
Marine pollutant	: Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information**Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations	: Not applicable
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Fire Safety (Petroleum and Flammable Materials) Regulations	: Not applicable
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The components of this product are reported in the following inventories:

AICS	: not determined
DSL	: not determined
IECSC	: not determined

Section 16: Other information

Revision Date	: 03.12.2024
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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/
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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format	: dd.mm.yyyy
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Full text of other abbreviations

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	03.12.2024	558029-00018	Date of first issue: 15.03.2016

SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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 substance; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - 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; WHMIS - Workplace Hazardous Materials Information System

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.

SG / EN