SAFETY DATA SHEET

Tafluprost Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/12/03
8.1	2025/04/14	558024-00020	Date of first issue: 2016/03/15

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Tafluprost Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Ethylene diamine tetraacetic acid	60-00-4	< 0.1	2-1263, 2-1296
Tafluprost	209860-87-7	>= 0.0002 - < 0.0025	-

4. FIRST AID MEASURES

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.
Most important symptoms and effects, both acute and delayed	:	None known.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
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.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

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.
Avoidance of contact	:	Oxidizing agents
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.

Storage

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: Strong oxidizing agents
Packaging material	:	Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Tafluprost	209860-87-7	TWA	0.002 µg/m3 (OEB 5)	Internal
	Further information: Skin, Eye			
		Wipe limit	0.02 µg/100 cm²	Internal

Engineering 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.

Personal protective equipment

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.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	Aqueous solution
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit		
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available

Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Density and / or relative density		
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	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		
Particle size	:	No data available

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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Components:

Ethylene diamine tetraacetic acid:

Acute oral toxicity	:	LD50 (Rat): 4,500 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 1 mg/l

Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 412
Remarks: Based on data from similar materials

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:

Ethylene diamine tetraacetic acid:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ethylene diamine tetraacetic acid:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

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:

Ethylene diamine tetraacetic acid:

Test Type : Maximisation Test
Exposure routes : Skin contact

Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

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:

Ethylene diamine tetraacetic acid:

Genotoxicity in vitro	:	Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials

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:

Ethylene diamine tetraacetic acid:

Species	:	Rat
Application Route	:	Ingestion

Exposure time	:	103 weeks
Result	:	negative
Remarks	:	Based on data from similar materials

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:

Ethylene diamine tetraacetic acid:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
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
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:

Ethylene diamine tetraacetic acid:

Species : Mouse
NOAEL : >= 500 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Remarks	:	Based on data from similar materials

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ethylene diamine tetraacetic acid:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 159 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 625 mg/l Exposure time: 24 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 1,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials NOEC (Pseudokirchneriella subcapitata (algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): >= 25.7 mg/l Exposure time: 35 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 25 mg/l Exposure time: 21 d Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC50: 2.4 mg/l Exposure time: 24 h

Persistence and degradability

Components:

Ethylene diamine tetraacetic acid:

Biodegradability	:	Result: Inherently biodegradable. Biodegradation: 80 - 90 % Exposure time: 28 d

Bioaccumulative potential

Components:

Ethylene diamine tetraacetic acid:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 1.8 Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water	:	log Pow: 0.13

Tafluprost:

Partition coefficient: n-octanol/water	:	log Pow: 4.5

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations.

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	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

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Ethylenediaminetetraacetic acid	36

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation	:	Noxious liquid substance(Category Z)
Pack transportation	:	Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

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

16. OTHER INFORMATION

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/
Date format	:	yyyy/mm/dd

Full text of other abbreviations

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.

JP / EN