

# **Tafluprost Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.15
 28.09.2024
 558014-00016
 Date of first issue: 15.03.2016

#### **SECTION 1. IDENTIFICATION**

Product identifier : Tafluprost Formulation

Manufacturer or supplier's details

Company : MSD

Address : Avenue Comendador Antônio Loureiro Ramos,

nº 1500 – Distrito Industrial

Montes Claros - MG, Brazil 39404-620

Telephone : +55 (38) 3229 7000

Emergency telephone : +55 (38) 3201 5670

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

### GHS Classification in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

#### GHS label elements in accordance with ABNT NBR 14725 Standard

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.	Classification	Concentration (% w/w)
Tafluprost	209860-87-7	Acute Tox. (Oral), 4 Eye Irrit., 2B Repr., 1B STOT SE, (Oral)(Lungs, Cardio- vascular system), 1 STOT RE, (Oral)(Lungs, Cardio- vascular system), 1 Aquatic Chronic, 4	>= 0,0003 -< 0,0025



# **Tafluprost Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 30.09.2023 558014-00016 Date of first issue: 15.03.2016 1.15 28.09.2024

#### **SECTION 4. FIRST AID MEASURES**

If inhaled If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

Wash with water and soap as a precaution. In case of skin contact

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, DO NOT induce vomiting. If swallowed

> Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

None known.

delayed

Protection of first-aiders Notes to physician

No special precautions are necessary for first aid responders.

Treat symptomatically and supportively.

### **SECTION 5. FIRE-FIGHTING 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 prod-

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment:

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- : tive equipment and emer-

gency procedures

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

Avoid release to the environment. **Environmental precautions** 

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or



# **Tafluprost Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023
1.15 28.09.2024 558014-00016 Date of first issue: 15.03.2016

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 diking or other appropriate

containment to keep material from spreading. If diked 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**

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

Wash contaminated clothing before re-use. The effective operation of a facility should in

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

Keep in properly labeled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Gases

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

_	•			
Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	



# **Tafluprost Formulation**

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 1.15
 28.09.2024
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Tafluprost	209860-87-7	TWA	0.002 μg/m3 (OEB 5)	Internal	
	Further information: Skin, Eye				
		Wipe limit	0.02 μg/100 cm <sup>2</sup>	Internal	

**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

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Hand protection

Organic vapor Type

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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES** 

Physical state : Aqueous solution

Color : clear

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available



# **Tafluprost Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.15 28.09.2024 558014-00016 Date of first issue: 15.03.2016

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

Vapor pressure : No data available

Relative vapor 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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

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

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 reac- : Can react with strong oxidizing agents.

tions

: None known.

Conditions to avoid



# **Tafluprost Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 30.09.2023 28.09.2024 558014-00016 Date of first issue: 15.03.2016 1.15

Incompatible materials Oxidizing agents

No hazardous decomposition products are known. Hazardous decomposition

products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of: Inhalation

exposure 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

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

**Components:** 

Tafluprost:

Test Type **Maximization Test** 

Routes of exposure Dermal Species Guinea pig

Result : Not a skin sensitizer.



# **Tafluprost Formulation**

 Version
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 Date of last issue: 30.09.2023

 1.15
 28.09.2024
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## 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.

#### 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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Intravenous injection Developmental Toxicity: LOAEL: 10 µg/kg

Result: Malformations were observed., Reduced fetal weight.

Test Type: Embryo-fetal development

Species: Rat

Application Route: Intravenous injection



# **Tafluprost Formulation**

 Version
 Revision Date:
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 Date of last issue: 30.09.2023

 1.15
 28.09.2024
 558014-00016
 Date of first issue: 15.03.2016

Developmental Toxicity: NOAEL: 3 µg/kg

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Intravenous injection Developmental Toxicity: LOAEL: 0,03 µg/kg Result: Malformations were observed.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Intravenous injection Developmental Toxicity: NOAEL: 0,01 µg/kg

Test Type: Embryo-fetal development

Species: Rat

Application Route: Intravenous injection Developmental Toxicity: LOAEL: 1 µg/kg

Test Type: Embryo-fetal development

Species: Rat

Application Route: Intravenous injection Developmental Toxicity: NOAEL: 0,3 µg/kg

Reproductive toxicity - As-

sessment

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



# **Tafluprost Formulation**

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 1.15
 28.09.2024
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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

#### **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

No data available

Persistence and degradability

No data available

**Bioaccumulative potential** 

**Components:** 

Tafluprost:

Partition coefficient: n-

octanol/water

log Pow: 4,5

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



# **Tafluprost Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 30.09.2023 28.09.2024 558014-00016 Date of first issue: 15.03.2016 1.15

UNRTDG

Not regulated as a dangerous good

**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

**Domestic regulation** 

**ANTT** 

Not regulated as a dangerous good

Special precautions for user

Not applicable

**SECTION 15. REGULATORY INFORMATION** 

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

mixture

National List of Carcinogenic Agents for Humans -Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal Not applicable

Police

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

**AICS** not determined

**DSL** not determined

**IECSC** not determined

**SECTION 16. OTHER INFORMATION** 

**Revision Date** 28.09.2024 Date format dd.mm.yyyy

**Further information** 

**Data Sheet** 

Sources of key data used to

compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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



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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.

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