

Tafluprost Formulation

Date of last issue: 30.09.2023 Version Revision Date: SDS Number: 1.15 28.09.2024 558026-00016 Date of first issue: 15.03.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name **Tafluprost Formulation**

Manufacturer or supplier's details

Company name of supplier **MSD**

Address 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone 908-740-4000 Emergency telephone 1-908-423-6000

E-mail address EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Pharmaceutical Recommended use Restrictions on use Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

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

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. Flush eyes with water as a precaution.

In case of eye contact 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 None known.

and effects, both acute and

delayed

Protection of first-aiders No special precautions are necessary for first aid responders.

Notes to physician Treat symptomatically and supportively.



Tafluprost Formulation

Date of last issue: 30.09.2023 Version Revision Date: SDS Number: 1.15 28.09.2024 558026-00016 Date of first issue: 15.03.2016

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- :

ucts

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

necessary.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive 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 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



Tafluprost Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.15 28.09.2024 558026-00016 Date of first issue: 15.03.2016

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.

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 (Form of exposure) | Control parameters / Permissible concentration | Basis | |
|------------|--------------------------------|-------------------------------------|--|-----------------------|--|
| Glycerine | 56-81-5 | VLE-PPT (Mist) | 10 mg/m³ | NOM-010- STPS-2014 | |
| Tafluprost | 209860-87-7 | TWA | 0.002 μg/m3 (OEB 5) | Internal | |
| | Further information: Skin, Eye | | | | |
| | | Wipe limit | 0.02 µg/100 cm ² | 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



Tafluprost Formulation

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

 1.15
 28.09.2024
 558026-00016
 Date of first issue: 15.03.2016

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

Appearance : Aqueous solution

Color : clear

Odor : No data available

Odor 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



Tafluprost Formulation

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

 1.15
 28.09.2024
 558026-00016
 Date of first issue: 15.03.2016

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-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.



Tafluprost Formulation

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

 1.15
 28.09.2024
 558026-00016
 Date of first issue: 15.03.2016

Components:

Glycerine:

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

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

Tafluprost:

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

LD50 (Rat): > 100 mg/kg

(Dog): 3 mg/kg

Remarks: No mortality observed at this dose.

Acute toxicity (other routes of :

administration)

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 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



Tafluprost Formulation

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

 1.15
 28.09.2024
 558026-00016
 Date of first issue: 15.03.2016

Result : Not a skin sensitizer.

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 syn-

thesis 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: 30.09.2023

 1.15
 28.09.2024
 558026-00016
 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 fetal development : Test Type: Embryo-fetal 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 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 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 $\mu g/kg$

Test Type: Embryo-fetal development



Tafluprost Formulation

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

 1.15
 28.09.2024
 558026-00016
 Date of first issue: 15.03.2016

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:

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 y

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

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,



Tafluprost Formulation

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

 1.15
 28.09.2024
 558026-00016
 Date of first issue: 15.03.2016

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

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

Bioaccumulative potential

Components:

Glycerine:

Partition coefficient: n-

octanol/water

log Pow: -1.75



Tafluprost Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 1.15 28.09.2024 558026-00016 Date of first issue: 15.03.2016

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

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

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

producing capsules, tablets and pills.

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

: Hydrochloric acid

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

AICS : not determined

DSL : not determined



Tafluprost Formulation

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

 1.15
 28.09.2024
 558026-00016
 Date of first issue: 15.03.2016

IECSC : not determined

SECTION 16. OTHER INFORMATION

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

Full text of other abbreviations

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

Time weighted average limit value

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

NOM-010-STPS-2014 / VLE- :

PPT

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 Recom-

Sources of key data used to compile the Material Safety

Data Sheet

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

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

mendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumu-

lative; WHMIS - Workplace Hazardous Materials Information System



Tafluprost Formulation

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

 1.15
 28.09.2024
 558026-00016
 Date of first issue: 15.03.2016

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