SAFETY DATA SHEET

Tafluprost Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tafluprost Formulation

Manufacturer or supplier’s details

Company : MSD

Address : Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A Parque Industrial Vice Presidente José Alencar Aparecida de Goias – GO, Brazil

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

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Not a hazardous substance or mixture.

GHS label elements in accordance with ABNT NBR 14725 Standard
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tafluprost</td>
<td>209860-87-7</td>
<td>Acute toxicity (Oral), Category 4, Eye irritation, Category 2B, Reproductive toxicity, Category 1B, Specific target organ toxicity - single exposure (Oral) (Lungs, Cardio-vascular system), Category 1, Specific target organ toxicity - repeated exposure (Oral) (Lungs, Cardio-vascular system)</td>
<td>&gt;= 0,0003 - &lt; 0,0025</td>
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</tbody>
</table>
SAFETY DATA SHEET

Tafluprost Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
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<tbody>
<tr>
<td>1.9</td>
<td>10.10.2020</td>
<td>558014-00010</td>
<td>23.03.2020</td>
<td>15.03.2016</td>
</tr>
</tbody>
</table>

|          |                          | vascular system), Category 1<br>Long-term (chronic) aquatic hazard, Category 4 |

SECTION 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.

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

SECTION 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 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.
- 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

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

**Ingredients with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tafluprost</td>
<td>209860-87-7</td>
<td>TWA</td>
<td>0.002 µg/m3</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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Further information: Skin, Eye
| Wipe limit | 0.02 µg/100 cm² | 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**

Organic vapor Type

**Hand protection**

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**

No data available
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Tafluprost Formulation

Range

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 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: No hazardous decomposition products are known.
SECTION 11. TOXICOLOGICAL INFORMATION

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 administration):
- (Dog): 3 mg/kg
  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.

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 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: 0.3 µg/kg

## Test Type: Embryo-fetal development
Species: Rat
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 0.01 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:

<table>
<thead>
<tr>
<th>Tafluprost:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Organs:</strong> Lungs, Cardio-vascular system</td>
</tr>
<tr>
<td><strong>Assessment:</strong> Causes damage to organs.</td>
</tr>
</tbody>
</table>

### STOT-repeated exposure
Not classified based on available information.

### Components:

<table>
<thead>
<tr>
<th>Tafluprost:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Organs:</strong> Lungs, Cardio-vascular system</td>
</tr>
<tr>
<td><strong>Assessment:</strong> Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

### Components:

<table>
<thead>
<tr>
<th>Tafluprost:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species:</strong> Rat</td>
</tr>
<tr>
<td><strong>LOAEL:</strong> 0.01 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route:</strong> Intravenous</td>
</tr>
<tr>
<td><strong>Exposure time:</strong> 6 Months</td>
</tr>
<tr>
<td><strong>Target Organs:</strong> Cardio-vascular system, Blood, Bone marrow, Kidney, Liver, spleen</td>
</tr>
</tbody>
</table>
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: 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

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

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
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