

1. Identification

Product identifier	Dinoprost Tromethamine	
Other means of identification		
Catalog number	1213001	
Chemical name	Prosta-5,13-dien-1-ic acid, 9,11,15-trihydroxy-, (5Z, 9alpha, 11alpha, 13E, 15S)-, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)	
Synonym(s)	Prostaglandin F2-alpha tromethamine; Dinoprost Trometamol	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2A
	Reproductive toxicity	Category 1
	Specific target organ toxicity, single exposure	Category 1 (cardiovascular system)

OSHA hazard(s) Not classified.

Label elements



Signal word	Danger	
Hazard statement	Harmful if swallowed. Causes serious eye irritation. May damage fertility or the unborn child. Causes damage to organs (cardiovascular system).	
Precautionary statement		
Prevention	Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention. If exposed: Call a poison center/doctor.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Dinoprost Tromethamine	Prostaglandin F2-alpha tromethamine; Dinoprost Trometamol	38562-01-5	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Reproductive system effects. Cardiovascular effects. Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Dinoprost Tromethamine (CAS 38562-01-5)	STEL	10 micrograms/m3
	TWA	1 micrograms/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
Other	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White or off-white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	212 - 217.4 °F (100 - 103 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Freely soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Other information

Chemical family	Cyclopentane derivative.
Molecular formula	C ₂₀ H ₃₄ O ₅ . C ₄ H ₁₁ NO ₃
Molecular weight	475.62
Solubility (other)	Freely soluble in dimethylformamide; soluble in methanol; slightly soluble in chloroform.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	NO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Causes serious eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics Nausea. Vomiting. Stomach pain. Diarrhea. Chest tightness. Wheezing. Coughing. Difficulty breathing. Pale skin. Weak pulse. Fast heartbeat. Red eyes. Swelling. Decreased urination. Thirst. Breast fullness or tenderness. Vaginal bleeding. Uterine contractions.

Delayed and immediate effects of exposure Uterine and urinary infections. Prevention or termination of pregnancy. Increase in blood pressure. Kidney damage. Liver damage. Ovarian damage. Testicular damage.

Cross sensitivity Persons sensitive to other oxytocics may be sensitive to this material also.

Medical conditions aggravated by exposure Asthma. Epilepsy. Glaucoma. Pelvic inflammatory disease. Lung disease. Heart disease. Kidney disease. Liver disease.

Acute toxicity Harmful if swallowed.

Product	Species	Test Results
Dinoprost Tromethamine (CAS 38562-01-5)		
<i>Oral</i>		
LD50	Mouse	711 mg/kg
	Rat	665 mg/kg

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Causes serious eye irritation.

Local effects

Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Eye.
Severity: Severe.
Irritancy test
Result: Non-irritant.
Species: Rat
Organ: Skin.

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Based on available data, the classification criteria are not met.

Sensitization

Maximization test
Result: Non-sensitizing.
Species: Guinea pig
Organ: Skin.

Germ cell mutagenicity Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity

Bacterial Ames assay

Result: Negative.

DNA damage/alkaline elution assay

Result: Negative.

Carcinogenicity

Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Reproductive toxicity

May damage fertility or the unborn child. Prostaglandins cause smooth muscle contraction and may induce uterine contractions in pregnant women.

Specific target organ toxicity - single exposure

Causes damage to organs (cardiovascular system).

Specific target organ toxicity - repeated exposure

Due to lack of data the classification is not possible.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information**Ecotoxicity**

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Mobility in soil

Not available.

Other adverse effects

Not available.

13. Disposal considerations**Disposal instructions**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations

Not available.

Hazardous waste code

Not available.

Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information**DOT**

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

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

No information available.

15. Regulatory information**US federal regulations**

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories**

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

No

SARA 311/312 Hazardous chemical

No

Other federal regulations**Safe Drinking Water Act (SDWA)**

Not regulated.

Food and Drug Administration (FDA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

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Version # 02

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.