


SAFETY DATA SHEET

Section 1: Identification	
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Product	Carboprost Tromethamine
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive, Ste B Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-859-01 (1mL) 70512-859-05 (1mL package of 5's)
Other Means of Identification	CAS Number 58551-69-2
Chemical Name	(Z)-7-[(1R,2R,3R,5S)-3,5-Dihydroxy-2-[(E)-(3S)-3-hydroxy-3-methyloct-1-enyl]cyclopentyl]-5-heptenoic acid compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)
Section 2: Hazard(s) Identification	
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Physical Hazards	Not classified
Health Hazards	Reproductive toxicity Category 1 Specific target organ toxicity, single exposure Category 1 (cardiovascular system)
Environmental Hazards	Not classified
OSHA Defined Hazards	Not classified
Label Elements	
Signal Word	Danger
	
Hazard Statement	May damage fertility or the unborn child. Causes damage to organs (cardiovascular system).
Precautionary Statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling.

Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazards Not Otherwise Classified (HNOC)	None known.
Supplemental Information	Potent pharmacologically active material.

Section 3: Composition/Information on Ingredients

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Substance

Chemical Name	Common Name and Synonyms	CAS Number	%
Carboprost		58551-69-2	
Tromethamine		74103-06-3	
Sodium Chloride		7440-23-5	
Benzyl Alcohol		100-51-6	0.945
Sodium Hydroxide		1310-73-2	
Hydrochloric Acid		7647-01-0	

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

Section 4: First-Aid Measures

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Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin Contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
Most Important Symptoms/ Effects, Acute and Delayed	Reproductive system effects. Cardiovascular effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
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.

Section 5: Fire-Fighting Measures	
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Suitable Extinguishing Media	Water. Foam. Dry chemical or CO ² . Use fire-extinguishing media appropriate for surrounding materials.
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	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.
General Fire Hazards	No unusual fire or explosion hazards noted.
Section 6: Accidental Release Measures	
Section 6, Accidental Release Measures	
Personal Precautions, Protective Equipment, And Emergency Procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective Clothing. Ensure adequate ventilation. For personal protection, see Section 8 of this SDS.
Methods and Materials for Containment and Cleaning Up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove Residual contamination. For waste disposal, see Section 13 of this SDS.
Environmental Precautions	Avoid discharge into drains, water courses or onto the ground.
Section 7: Handling and Storage	
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Precautions for Safe Handling	As a general rule, when handling USP materials, 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 a tight container. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls / Personal Protection	
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Exposure Limit Values	
Industrial Use Material	Type
Carboprost Tromethamine (CAS 58551-69-2)	TWA
	Value
	0.001 mg/m3
Biological Limit Values	No biological exposure limits noted for the ingredient(s).
Appropriate Engineering Controls	No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
Individual Protection Measures, Such As Personal Protective Equipment	
Eye/Face Protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin Protection	
Hand Protection	Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear Gloves that provide protection against the solvent.
Other	Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory Protection	Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal Hazards	Wear appropriate thermal protective clothing, when necessary
General Hygiene Considerations	Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.
Section 9: Physical and Chemical Properties	
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Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Powder.
Color	White. Off-white.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/	

Freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble.
Solubility (other)	Ethanol: Soluble. Acetone: Soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Prostaglandin.
Molecular formula	C ₂₁ H ₃₆ O ₅ . C ₄ H ₁₁ NO ₃
Molecular weight	489.64

Section 10: Stability and Reactivity

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Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	Contact with incompatible materials.
Incompatible Materials	Strong bases. Oxidizing agent.
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

Section 11: Toxicological Information

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Information On Likely Routes of Exposure

Inhalation Knowledge about health hazard is incomplete.
Skin Contact Knowledge about health hazard is incomplete.
Eye Contact Knowledge about health hazard is incomplete.
Ingestion Knowledge about health hazard is incomplete.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics Gastrointestinal disturbances. Chills. Dizziness. Fever. Headache. Flushing. Fast heartbeat. Increased body temperature. Swelling.

Information on Toxicological Effects

Acute Toxicity

Product	Species	Test Results
Carboprost Tromethamine (CAS 58551-69-2)		
OTHER: LD50	Rat	25.1 mg/kg (intravenous

Skin Corrosion/Irritation Knowledge about health hazard is incomplete.

Serious Eye Damage/Eye Irritation Knowledge about health hazard is incomplete.

Respiratory or Skin Sensitization

Respiratory Sensitization Knowledge about health hazard is incomplete.

Skin Sensitization Knowledge about health hazard is incomplete.

Germ Cell Mutagenicity

Mutagenicity Knowledge about health hazard is incomplete.

Ames Assay Result: Negative

Micronucleus Test Result: Negative

Carcinogenicity Knowledge about health hazard is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed

U.S. National Toxicology Program (NTP) Report of Carcinogens

Not listed

Reproductive Toxicity

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

Reproductivity

0.087mg/kg Reproduction Test (subcutaneous)

Result: Positive: Embryotoxic

Species: Rat

0.3mg/kg Reproduction Test (subcutaneous)
 Result: Positive: Embryotoxic
 Species: Rat

Specific Target Organ Toxicity - Single Exposure	Causes damage to organs (cardiovascular system).
Specific Target Organ Toxicity - Repeated Exposure	Knowledge about health hazard is incomplete.
Aspiration Hazard	Based on available data, the classification criteria are not met.
Further Information	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Section 12: Ecological Information

Section 12, Ecological Information	
Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and Degradability	No data is available on the degradability of this substance.
Bioaccumulative Potential	No data available.
Mobility in Soil	No data available.
Other Adverse Effects	No other adverse environmental effects (e.g., ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Section 13: Disposal Considerations

Section 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	Dispose in accordance with all applicable regulations.
Hazardous Waste Code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section 14: Transport Information

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DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

General Information
It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

Section 15: Regulatory Information

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US Federal Regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)
Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous Chemical	Yes
Classified Hazard Categories	Reproductive toxicity. Specified target organ toxicity (single or repeated exposure).
SARA 313 (TRI reporting)	Not regulated.

Other Federal Regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US State Regulations

California Proposition 65

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. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or Region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
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)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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)
 A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Section 16: Other Information

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The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.