



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	
	<u>www.solameds.us</u>	
	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).

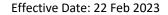
Precautionary Statement

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

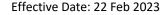
Section 3, Composition/Information on Ingredients

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.

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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 of 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 CO². 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.

And Precautions for Firefighters

Special Protective Equipment 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

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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,

Store in a tight container. This material should be handled and stored per label **Including any Incompatibilities** instructions to ensure product integrity.





Section 8: Exposure Controls / Personal Protection

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Exposure Limit Values

Industrial Use Material	Туре	Value
Carboprost Tromethamine (CAS 58551-69-2)	TWA	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

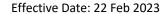
Section 9, Physical and Chemical Properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical stateSolid.FormPowder.

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

Flash point

Evaporation rate

Flammability (solid, gas)

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 pressureNot available.Vapor densityNot available.Relative densityNot 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 C21H36O5 . C4H11NO3

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.

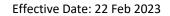
Hazardous Decomposition Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

Products

Section 11: Toxicological Information

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Information On Likely Routes of Exposure





InhalationKnowledge about health hazard is incomplete.Skin ContactKnowledge about health hazard is incomplete.Eye ContactKnowledge about health hazard is incomplete.IngestionKnowledge 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	1-69-2)		
OTHER: LD50	Rat	25.1 mg/kg (intravenous	

Skin Corrosion/Irriration Knowledge about health hazard is incomplete.

Serious Eye Damage/Eye

Irritation

Knowledge about health hazard is incomplete.

Respiratory or Skin Sensitization

Respiratory SensitizationKnowledge 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 Micronuleus 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

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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

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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 CodeThe waste code should be assigned in discussion between the user, the producer and

the waste disposal company.

Waste From Residues/

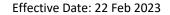
Unused Products

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

Section 14, Transport Information

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

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 (PICC	CS) No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States &	Toxic Substances Control Act (TSCA) Inventory	No
Puerto Rico		

^{*}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

Section 16, Other Information

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.