

Carboprost Tromethamine Injection, USP

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Carboprost Tromethamine Injection, USP
Other means of identification : 1 ml single-dose vials, NDC 55150-459-01
1 ml single-dose vials, packaged in a carton of 10, NDC 55150-459-10

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Eugia US LLC
279 Princeton Hightstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. Label elements

GHS US labeling

No labeling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Sodium hydroxide	(CAS-No.) 1310-73-2	≤ 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Hydrochloric acid	(CAS-No.) 7647-01-0	≤ 1	Skin Corr. 1, H314 Eye Dam. 1, H318
Benzyl alcohol	(CAS-No.) 100-51-6	0.945	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332
Sodium chloride	(CAS-No.) 7647-14-5	0.9	Not classified
Carboprost tromethamine	(CAS-No.) 58551-69-2	0.025	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	(CAS-No.) 77-86-1	0.0083	Not classified

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.
First-aid measures after ingestion : Go into open air and ventilate suspected area.

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4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: None anticipated under normal use conditions.
Symptoms/effects after skin contact	: May cause skin irritation.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
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5.3. Advice for firefighters

Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special measures required.
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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Recycle product or dispose safely.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Do not eat, drink or smoke when using this product.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: The product must be refrigerated at 2° to 8°C (36° to 46°F).
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m ³
OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
IDLH	IDLH	10 mg/m ³
NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
OSHA	OSHA PEL (Ceiling)	7 mg/m ³
OSHA	OSHA PEL C [ppm]	5 ppm

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Hydrochloric acid (7647-01-0)		
IDLH	IDLH [ppm]	50 ppm
NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
NIOSH	NIOSH REL C [ppm]	5 ppm
Sodium chloride (7647-14-5)		
Not applicable		
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)		
Not applicable		
Benzyl alcohol (100-51-6)		
AIHA	WEEL TWA [ppm]	10 ppm
Carboprost tromethamine (58551-69-2)		
Not applicable		

8.2. Exposure controls

Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection	: Use neoprene or rubber gloves.
Eye protection	: In case of dust production: protective goggles.
Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: Wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Colorless
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability	: No data available
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

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10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Sodium hydroxide (1310-73-2)	
LD50 oral rat	140 – 340 mg/kg
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 – 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 Inhalation - Rat	1.68 mg/l (Exposure time: 1 h)
ATE US (oral)	238 mg/kg body weight
ATE US (vapors)	1.68 mg/l/4h
ATE US (dust, mist)	1.68 mg/l/4h
Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LD50 dermal rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation - Rat	> 42 g/m ³ (Exposure time: 1 h)
ATE US (oral)	3000000 mg/kg
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
LD50 oral rat	5900 mg/kg
Benzyl alcohol (100-51-6)	
LD50 oral rat	1230 mg/kg
LD50 dermal rabbit	2 g/kg
LC50 Inhalation - Rat	8.8 mg/l/4h
ATE US (oral)	1230 mg/kg body weight
ATE US (dermal)	2000 mg/kg body weight
ATE US (gases)	4500 ppmV/4h
ATE US (vapors)	8.8 mg/l/4h
ATE US (dust, mist)	1.5 mg/l/4h
Carboprost tromethamine (58551-69-2)	
ATE US (oral)	100 mg/kg body weight
ATE US (dermal)	300 mg/kg body weight
ATE US (gases)	700 ppmV/4h
ATE US (vapors)	3 mg/l/4h
ATE US (dust, mist)	0.5 mg/l/4h

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

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Hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

Reproductive toxicity : Not classified
STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

Sodium chloride (7647-14-5)	
LC50 - Fish [1]	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Benzyl alcohol (100-51-6)	
LC50 - Fish [1]	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 - Fish [2]	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Sodium chloride (7647-14-5)	
BCF - Fish [1]	(no bioaccumulation)

Benzyl alcohol (100-51-6)	
Partition coefficient n-octanol/water (Log Pow)	1.1

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

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International Air Transport Association (IATA)

In accordance with IATA

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ	1000 lb
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Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the United States SARA Section 302

Subject to reporting requirements of United States SARA Section 313

CERCLA RQ	5000 lb
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SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
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SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
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Sodium chloride (7647-14-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Benzyl alcohol (100-51-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

Hydrochloric acid (7647-01-0)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

Benzyl alcohol (100-51-6)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

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SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1	Skin corrosion/irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H331	Toxic if inhaled
H332	Harmful if inhaled

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.