



SAFETY DATA SHEET

Revision date 26-Feb-2023

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Carboprost Tromethamine Sterile Solution
Product Code(s) CARBOPROST TROMETHAMINE STERILE SOLUTION
Trade Name: HEMABATE; PROSTIN 15M
Item Code H000402239, H000478290, H000478295
Chemical Family: Mixture

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

Recommended Use No information available

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified as hazardous

2.2. Label elements

Signal word Not Classified

Hazard statements Non-hazardous in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
BENZYL ALCOHOL (CAS #: 100-51-6)	*		202-859-9	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	Not Listed	No data available	No data available
Carboprost Tromethamine (CAS #: 58551-69-2)	0.03		Not Listed	Repr. 1A (H360D)	Not Listed	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	98	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
BENZYL ALCOHOL 100-51-6	1230	2000	4.178	No data available	No data available

Additional information

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Non-hazardous ingredients provided for completeness.

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Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products	Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
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Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Restrict access to work area. Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

Carboprost Tromethamine

Pfizer OEL TWA-8 Hr: 0.1 µg/m³

SODIUM CHLORIDE

Latvia 5 mg/m³
Russia MAC: 5 mg/m³

BENZYL ALCOHOL

Bulgaria 5.0 mg/m³
Czech Republic 40 mg/m³
Ceiling: 80 mg/m³
Finland 10 ppm
45 mg/m³
Germany 22 mg/m³ can occur as vapor and aerosol at the same time
5 ppm can occur as vapor and aerosol at the same time
Ceiling / Peak: 44 mg/m³
Ceiling / Peak: 10 ppm
Skin
Germany 5 ppm
22 mg/m³
H*
Ceiling Limit Value 25 mg/m³
Latvia 5 mg/m³
Poland 240 mg/m³
Russia MAC: 5 mg/m³

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Switzerland

Skin
5 ppm
22 mg/m³
H*

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solution

Color

Clear

Odor

No information available.

Odor threshold

No information available

Molecular formula

Mixture

Molecular weight

Mixture

Property

Values

pH

No data available

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Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	Soluble Water
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

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11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	The information included in this section describes the potential hazards of the individual ingredients
Short term	May cause skin irritation. May cause irritation of respiratory tract (based on components).
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system
Known Clinical Effects:	Ingestion of this material may cause effects similar to those seen in clinical use including effects on gastrointestinal disturbances and abdominal pain. Clinical use may cause an increase in blood pressure (hypertension).
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

BENZYL ALCOHOL

Rat Oral LD 50 1230 mg/kg

Mouse Oral LD 50 1360 mg/kg

Rabbit Dermal LD 50 2 gm/kg

Carboprost Tromethamine

Rat Intravenous LD 50 = 25100 ug/kg

Mouse Para-periosteal LD 50 = 131 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
BENZYL ALCOHOL	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	> 4178 mg/m ³ (Rat) 4 h

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

BENZYL ALCOHOL

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Minimal

Skin Irritation Guinea Pig Moderate

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Carboprost Tromethamine

Reproductive & Fertility-Females Rat Subcutaneous = 87 ug/kg LOAEL Teratogenic

Reproductive & Fertility-Males Rat Subcutaneous = 6 mg/kg LOAEL Teratogenic

Reproductive & Fertility-Females Rat Subcutaneous = 300 ug/kg LOAEL Teratogenic

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Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Carboprost Tromethamine

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Bone Marrow Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

BENZYL ALCOHOL

Pimephales promelas (Fathead Minnow) EPA LC50 96 hours 460 - 770 mg/L
Daphnia magna (Water Flea) NPDES OECD EC50 48 Hours 230 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 hours 500 mg/L

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

BENZYL ALCOHOL

OECD Activated sludge Ready 92 % After 28 Day(s) Ready

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
BENZYL ALCOHOL	The substance is not PBT / vPvB

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12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present

BENZYL ALCOHOL

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-859-9
AICS	Present

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Carboprost Tromethamine

CERCLA/SARA Section 313 de minimus %
California Proposition 65
EINECS

Not Listed
Not Listed
Not Listed

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-
BENZYL ALCOHOL 100-51-6	RG 84	-

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Data Sources:

Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reason for revision

Updated Section 3 - Composition / Information on Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

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Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.