

Revision date: 02-Jan-2007

Version: 1.2

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc Pfizer Pharmaceuticals Group 235 East 42nd Street New York, New York 10017 1-212-573-2222 Pfizer Ltd Ramsgate Road Sandwich, Kent CT13 9NJ United Kingdom +00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300 Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322

# Material Name: Carboprost Tromethamine Sterile Solution

Trade Name:	Hemabate (R) Sterile Solution
Chemical Family:	Mixture
Intended Use:	Not determined

# 2. COMPOSITION/INFORMATION ON INGREDIENTS

## Hazardous

Ingredient	CAS Number	EU EINECS List	%
Benzyl Alcohol	100-51-6	202-859-9	*
Carboprost Tromethamine	58551-69-2	Not listed	0.03

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Water	7732-18-5	231-791-2	98

**Additional Information:** 

#### \* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

Appearance: Signal Word:	clear solution WARNING
Statement of Hazard: Additional Hazard Information:	May cause reproductive system effects
Short Term:	May cause skin irritation. May cause irritation of respiratory tract.
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).
EU Indication of danger:	Not classified

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Note: 4. FIRST AID MEASURES	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.
Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Wash skin with soap and water. Remove contaminated clothing. If irritation occurs or persists, get medical attention.
Ingestion:	Drink 1 or 2 glasses of water. Do not induce vomiting without medical advice. Call a physician immediately.
Inhalation:	Move to fresh air If not breathing, give artificial respiration. Get medical attention.
5. FIRE FIGHTING MEASURES	
Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Carbon dioxide, carbon monoxide, and oxides of nitrogen
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self- contained breathing apparatus.
Fire / Explosion Hazards:	Not applicable
6. ACCIDENTAL RELEASE ME	EASURES
Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
7. HANDLING AND STORAGE	
General Handling:	Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

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Storage Conditions:

Store as directed by product packaging.

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

## No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Carboprost Tromethamine Pfizer OEL TWA-8 Hr: 0.1ug/m <sup>3</sup> The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.						
Analytical Method:	Analytical method available for Carboprost. Contact Pfizer Inc for further information.					
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels.					
Personal Protective Equipment:						
Hands: Eyes: Skin: Respiratory protection:	Rubber gloves Safety glasses or goggles Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. Not required for the normal use of this product. 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.					

# 9. PHYSICAL AND CHEMICAL PROPERTIES: Physical State: Solution Molecular Formula: Mixture Solubility: Soluble: Water

## **10. STABILITY AND REACTIVITY**

Stability:	Stable under normal conditions of use.
Conditions to Avoid:	None
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.

**11. TOXICOLOGICAL INFORMATION** 

General Information:

The remaining information describes the potential hazards of the individual ingredients.

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

#### **Carboprost Tromethamine**

Rat Intravenous LD 50 = 25100 ug/kg Mouse Intravenous LD 50 = 131 mg/kg

#### Sodium chloride

Rat Oral LD50 3000 mg/kg Mouse Oral LD 50 4000 mg/kg

## **Benzyl Alcohol**

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Rat Oral LD50 1.23 g/kg Rat Intravenous LD50 53 mg/kg

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

## Sodium chloride

Eye Irritation Rabbit Moderate Skin Irritation Rabbit Mild

## **Benzyl Alcohol**

Eye Irritation Rabbit Severe Skin Irritation Rabbit Moderate Skin Irritation Guinea Pig Moderate

## Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium chloride 10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

## Reproduction & Developmental Toxicity: (Study Type, 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/k	g LOAEI	L Teratogenic

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

## 12. ECOLOGICAL INFORMATION

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

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

# 14. TRANSPORT INFORMATION

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

## **15. REGULATORY INFORMATION**

EU Indication of danger:

Not classified

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OSHA Label: WARNING May cause reproductive system effects

## Canada - WHMIS: Classifications

## WHMIS hazard class:

Sodium chloride

Class D, Division 2, Subdivision B



Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	Present Present 231-598-3
Benzyl Alcohol Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	Present Present 202-859-9
Water Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	Present Present 231-791-2

## **16. OTHER INFORMATION**

 

 Reasons for Revision:
 Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

 Prepared by:
 Toxicology and Hazard Communication Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet