CAPLIN STERILES LIMITED
SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: **Carboprost tromethamine Injection**

Trade Name: **Carboprost tromethamine Injection**
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Not determined

Details of the Supplier of the Safety Data Sheet

Caplin Steriles Ltd
Ashvich Tower, No. 3,
Developed Plots
Industrial Estate,
Perungudi,
Chennai – 600 096

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards No data available
Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace..

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS no	EUEINECS/ELINCS List	GHS Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	*
Carboprost Tromethamine	58551-69-2	Not Listed	Repr. 1A (H360D)	0.03
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	98
Other 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.				

4. FIRST AID MEASURES

Eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately
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.

5. FIRE FIGHTING MEASURES

Flammable Properties: Not available

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Specific hazards:
Hazardous combustion: Formation of toxic gases is possible during heating or fire.
Fire/ Explosion hazards: Fine particles may fuels fires
Advice for fire-fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
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. Additional
Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel

7. HANDLING AND STORAGE

Precautions for Safe Handling
Minimize generating airborne mists and vapors. 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.
Storage conditions: Store as directed by product packing

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE)
Hands:	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.)
Eyes:	Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present.
Skin:	Wear a laboratory coat (EN 340) when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat (EN 340)or coverall of low permeability (EN 1149-1). For manufacturing operations, wear coverall of low permeability (EN 465/1149-1). For manufacturing operations, wear coverall of low permeability.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solution
Odor: No data available.
Molecular Formula: Mixture
Color: Clear, colorless
Odor Threshold: No data available.
Molecular Weight: Mixture
Solvent Solubility: No data available
Water Solubility: No data available
pH: 7.0 to 8.0
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available
Flammablity:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: No data available.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
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 anincrease in blood pressure (hypertension).

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

Carboprost Tromethamine

Rat Intravenous LD 50 = 25100 ug/kg

Mouse Para-periosteal LD 50 = 131mg/kg

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg

Rat Para-periosteal LD50 53mg/kg

Rat Inhalation LC50 >4.178mg/L

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

SODIUM CHLORIDE
Skin Irritation Rabbit Mild
Eye Irritation Rabbit
Moderate
Benzyl Alcohol
Skin Irritation Rabbit
Minimal
Eye Irritation Rabbit
Severe

Reproduction and development toxicity Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Carboprost Tromethamine
Rat Para-periosteal LD50 53mg/kg Reproductive & Fertility-Females Rat Subcutaneous =87 ug/kg LOAEL Teratogenic
Mouse Para-periosteal LD 50 = 131mg/kg Reproductive & Fertility-Males Rat Subcutaneous = 6 mg/kg LOAEL Teratogenic
Rat Inhalation LC50 >4.178mg/L Reproductive & Fertility-Females Rat Subcutaneous = 300 ug/kg LOAEL Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Carboprost Tromethamine
Bacterial Mutagenicity (Ames) Salmonella Negative
In Vivo Micronucleus Rat Bone Marrow Negative
Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSH

12. ECOLOGICAL INFORMATION

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

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

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

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzyl Alcohol
Daphnia magna (Water Flea) OECD 21 Day(s) EC50 66 mg/L Reproduction

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Benzyl Alcohol

OECD	Activated sludge	Ready	92% After	14 Day(s)	Ready

13. DISPOSAL CONSIDERATIONS

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 waste water 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

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

15. REGULATORY INFORMATION

EEC regulations	US federal regulations CERCLA/SARA Hazardous Substances - Not listed
Federal and State Regulations:	TSCA 8(b) inventory: No products were found.
Protective Equipment:	Gloves, Lab coat, Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles
	Not applicable
Hazard Class	Not applicable
U.S. OSHA Classification	TSCA inventory list: The product is exempted from TSCA, it is FDA regulated

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in 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

History:

Creation Date	:	22.10.24
Revision Date	:	Not Applicable
Version	:	00

End of Safety Data Sheet