SAFETY DATA SHEET

Date of Original Issue: 19DEC2023 **Revision Number**: 2 **Revision:** 15MAR2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: Carboprost Tromethamine Injection

1.2. Relevant identified uses of the substance or mixture

Product Use: Pharmaceutical product indicated for aborting pregnancy between the 13th and 20th weeks of gestation

1.3. Details of the responsible party of the safety data sheet

Manufacturer
Stelis Biopharma Limited
Bengaluru
Karnataka, 561203
India
+91 80678 40444

Distributor
Xellia Pharmaceuticals
2150 East Lake Cook Road
Buffalo Grove, IL 60089
USA
+1 833 657 3519

Email address for the competent person responsible for the safety data sheet: sales@xellia.com

1.4. Emergency telephone number

Poison Control Center (USA):	+1 877 800 5553
CHEMTREC (USA Transportation):	+1 800 424 9300
CANUTREC (Canadian Transportation):	+1 613 996 6666
EU:	http://apps.who.int/poisoncentres/

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Respiratory Category - 1A

2.2. Label elements

DANGER

H360D May damage fertility.
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P281 Use personal protective equipment as required.
P308+313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.

2.3. Other hazards

The substance is not considered PBT/vPvB, or endocrine disruptive according to the criteria in the CLP regulation.

SECTION 3: Composition/information on ingredients

3.1. Substances

Active component	CAS #	EC/List #
Carboprost tromethamine 250 mcg/mL	58551-69-2	638-608-5

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: Remove the injured person from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health practitioner or other licensed health care provider familiar with chemical exposure in the workplace. If the person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons with severe hypersensitivity (anaphylactic) reactions should receive immediate medical attention.

Eye contact: Flush eyes for 15 minutes with plenty of water. Remove contact lenses, if any, and this is easy to do. Continue rinsing. Consult a specialist if irritation develops and persists.

Skin contact: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops. In case of eczema or other skin diseases, consult a doctor.

Ingestion: After ingestion of large amounts, call a poison center or doctor. Do not induce vomiting. Wash your mouth. Do not give anything orally to an unconscious person. Consult a doctor if symptoms occur. When vomiting, keep your head low so that stomach contents do not get into the lungs.

Inhalation: The person concerned should be taken out to the fresh air and placed in a resting position such that he or she can breathe easily. If the injured person is unconscious and not breathing: Ensure that there are no obstructions in the airways and have artificial respiration performed by appropriately trained persons. If necessary, apply external heart massage and consult a doctor. If breathing remains difficult, consult a doctor.

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

Symptoms and Effects of Exposure: A single dose of 3,2 mg/kg in rats was not well tolerated: Rapid weight loss, diarrhea and depression were the signs of intolerance. The recommended clinical dose of 250 µg with a 2 mg of maximum represents at least a thousand-fold margin of safety.

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

General support measures, symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Water, carbon dioxide, dry chemical, foam, or other alternatives.
Fire extinguishing agents not suitable for safety reasons: none.

5.2. Special hazards arising from the substance or mixture.

General hazards: No unusual fire or explosion hazards were detected.

Unsuitable extinguishing media: None
Specific methods: Not available.

5.3. Advice for firefighters
Wear appropriate protective equipment. Use water spray to cool unopened containers. As with any fire, evacuate personnel to a safe area.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures
Keep away unnecessary personnel. Wear appropriate protective equipment. Avoid inhaling dust from spills. Do not touch damaged containers or spills unless you wear appropriate protective clothing. Ensure adequate ventilation. Dust deposits should not accumulate on surfaces, as they can form explosive mixtures if released into the atmosphere in appropriate concentrations. For personal protection, see Section 8 of the Safety Data Sheet.

6.2. Environmental precautions
Water spill: In case of intrusion into inland waters or sewers, notify the competent authorities. Do not allow to enter sewer/surface water/groundwater.

6.3. Methods and materials for containment and cleaning up.
Avoid dust build-up during cleaning. Spilled material must be swept or vacuumed and collected in a suitable container for disposal. To remove residual dirt, thoroughly clean the surface. For waste disposal, see section 13 of the safety data sheet.

6.4. Reference to other sections
See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
For large quantities: To ensure adequate ventilation, it is recommended that exposure does not exceed the exposure limit values. With adequate ventilation, respiratory protection is not required. The need for additional personal protective equipment, including respirators and eye and skin protection, should be decided based on a job-specific risk assessment. Additional PPE may include chemically resistant gloves and suits, goggles, and face shields. Proper eye protection is always required. Keep dry and away from sources of ignition. Keep the storage device tightly closed when not in use. Facilities storing or using such material shall be equipped with emergency eye wash and safety showers. Good personal hygiene standards should always be followed.
For small quantities: Keep dry and away from sources of ignition. Keep the container tightly closed when not in use.

7.2. Conditions for safe storage, including any incompatibilities.
Storage conditions: Store in a closed container specified in USP-NF. This material must be handled and stored in accordance with the instructions on the label to ensure the integrity of the product. Store securely, not accessible to unauthorized persons. Product must be refrigerated at 2°C to 8°C (36°F to 46°F).

7.3. Specific end use(s)
See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
OEL for the Carboprost tromethamine: 0.06 µg/m3

8.2. Exposure controls
Appropriate engineering controls: For laboratory operations, use a local exhaust ventilation or ventilated chamber for high-energy operations such as shredding. Choose and use enclosed equipment and personal protective equipment based on the risk assessment. During transportation, cover all containers for storing solutions and suspensions. In the case of dust generation, exhaust ventilation or ensuring general ventilation of the room.

Personal protective equipment:
Eyes protection: If contact is likely, safety glasses with lateral protection must be used.
Hand protection: Wear chemically resistant gloves (tested according to EN 374) while completing training specific to the specific activity. The gloves should be regularly inspected and replaced for wear, tearing or contamination.
Skin: Laboratory clothes.
Respiratory protection: As a rule, a respirator is not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters to clean spills. Respiratory protection adapted to the task and the level of existing technical controls.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
(a) Physical state: Liquid
(b) Color: Clear/Transparent
(**c) Odor:** Not available
(**d) Melting point/freezing point:** Not available
(**e) Boiling point or initial boiling point and boiling range:** Not available
(f) Flammability: Not classified
(g) Lower and upper explosion limit: Not available
(h) Flash point: Not available
(i) Auto-ignition temperature: Not available
(j) Decomposition temperature: Not available
(k) pH: Not available
(l) Kinematic viscosity: Not available
(m) Solubility: Soluble in water.
(n) Partition coefficient n-octanol/water (log value): Not available
(o) Vapour pressure: Not available
(p) Density and/or relative density: Not available
(q) Relative vapour density: Not available
(r) Particle characteristics: Not available

9.2. Other information
Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity
The product is stable and does not react under normal conditions of use, storage, and transportation.

10.2. Chemical stability
Stable when used as intended.

10.3. Possibility of hazardous reactions
Under normal conditions, they are not known.

10.4. Conditions to avoid.
Incompatible materials, dust generation, excess heat, alkaline materials, strong oxidants, exposure to moist air or water.

10.5. Incompatible materials
Strong oxidants agents

10.6. Hazardous decomposition products
Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008
a) Acute toxicity: Acute oral LD50: 25.1 mg/kg (Rat - Intravenous).
b) Skin corrosion/skin irritation: Based on the available information the classification criteria are not met.
c) Severe eye damage/irritation: Based on the available information the classification criteria are not met.
d) Respiratory or skin sensitization: Based on the available information the classification criteria are not met.
e) Germ cell mutagenicity: Ames and micronucleus tests are negative. Based on the available information the classification criteria are not met.
f) Carcinogenicity: Not available

Listed by IARC: No Listed by NTP: No Listed by OSHA: No

g) Reproductive toxicity: May damage fertility or the unborn child. Prostaglandins cause smooth muscle contraction and may induce uterine contractions in pregnant women.

0.087mg/kg Reproduction Test (subcutaneous) Result: Positive: Embryotoxic Species: Rat
0.3mg/kg Reproduction Test (subcutaneous) Result: Positive: Embryotoxic Species: Rat

h) Single post-exposure specific target organ toxicity (STOT): Based on the available information the classification criteria are not met.
i) Specific target organ toxicity (STOT) after repeated exposure: Cardiovascular system. Based on the available information the classification criteria are not met.
j) Aspiration hazard: Based on its chemical structure, the product is not classified.

11.2. Information on other hazards
Pharmacologically active substances. Occupational exposure may cause physiological effects.

SECTION 12: Ecological information

12.1. Toxicity
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.

12.2. Persistence and degradability
No applicable information found.

12.3. Bio accumulative potential
No applicable information found.

12.4. Mobility in soil
No applicable information found.

12.5. Results of PBT and vPvB assessment
The substance shall not be considered PBT/vPvB according to the criteria in Annex XIII.

12.6. Endocrine disrupting properties
No such properties are known to the substance.

12.7. Other adverse effects
No other adverse environmental effects (e.g., ozone depletion, photochemical ozone creation potential, global warming potential) are expected from this component.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Both material and packaging waste must be handed over to a licensed undertaking for destruction.

SECTION 14: Transport information

14.1. UN Number or ID number
Not Regulated.

14.2. UN proper shipping name
Not Regulated.

14.3. Transport hazard class(es)
Not Regulated.

14.4. Packing group
Not Regulated.

14.5. Environmental hazards
Not Regulated.

14.6. Special precautions for user

Not Regulated.

14.7. Maritime transport in bulk according to IMO instruments

Not relevant.

USA DOT (DEPARTMENT OF TRANSPORTATION)

Proper Shipping Name: Not regulated.

CANADA TRANSPORT OF DANGEROUS GOODS

Proper Shipping Name: Not regulated.

AIR (ICAO/IATA)

Proper Shipping Name: Not regulated.

VESSEL (IMO/IMDG)

Proper Shipping Name: Not regulated.

EUROPEAN TRANSPORTATION:

ADR/RID HAZARD CLASSIFICATION: Not Regulated.

U.S. CUSTOMS HARMONIZATION NUMBER: Not Available.

SECTION 15: Regulatory information

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

EUROPEAN UNION

Regulation of 1907/2006/EU: the product as Repr. 1A substance cannot be sold to consumers.

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:
Must not be used by people under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding: The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7 December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).

For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:

Fire: No **Pressure generating**: No **Reactivity**: No **Acute**: No **Chronic**: No

313 Reportable Ingredients: Not Listed

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed.

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Exempt

National Response Center: US Coast Guard National Center Response Telephone +1 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification
WHMIS Controlled: Not regulated.
Canadian Environmental Protection Act: Not listed.

15.2. Chemical safety assessment

No CSR is compiled because the substance is exempted.

SECTION 16: Other information

Reason for issue: First version because Respiratory - Category 1A classification is added with appropriate labelling.
Contact Information: See Section 1.
Revision summary: Second issue which should be considered as new.
Disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents.