# 1. Product and Company Identification

## 1.1. Product identifier

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</table>

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

**Recommended use:** Medical disposal – In-vitro diagnostic

**Use advised against:**

Medical disposal – In-vitro diagnostic
1.3. **Company identification**

Manufacturer: Precision BioLogic Inc.
140 Eileen Stubbs Avenue
Dartmouth, Nova Scotia, Canada B3B 0A9
Tel: 00 (1) 902 468 6422

Distributor: Cryopep
83 rue Yves Montand, 34080 Montpellier, France
Tel: 0033 4 67 10 71 20
Fax: 0033 4 67 10 71 21
Email: contact@cryopep.com

1.4. **Emergency phone**

NVIC (NL) Tél.: 030 274 88 88
ANTIGIFCENTRUM (B): Tél.: 070 245 245

2. **HAZARDS IDENTIFICATION**

2.1. **Product classification**

2.1.1. CLP classification – Regulation (CE) n° 1272/2008
Not applicable (article 1, § 5.d – in-vitro diagnostic medical devices according to directive 98/79/CE)

2.1.2. Classification according to directive 67/548/CE
Non-hazardous

2.1.3. Classification according to directive 1999/45/CE
Phase R: None

2.2. **Labelling elements**

Hazard statements: None
Safety advice: None

2.3. **Other hazards**

Major hazards: All blood product should be treated as potentially infectious.

Source material from which this product was derived was found to be negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents. Accordingly, these human blood based products should be handled and discarded as recommended for any potentially infectious human specimen

Potential health effects:

- **Eyes:** Direct eye contact may cause irritation.
- **Skin:** Can enter the circulatory system through an open wound.
- **Ingestion:** May cause abdominal pain, nausea and vomiting.
- **Inhalation:** May irritate the respiratory system.

3. **COMPONENT / INFORMATION ON INGREDIENTS**

3.1. **Product description**

Human plasma

3.2. **Hazardous components**

<table>
<thead>
<tr>
<th>No/CAS</th>
<th>Name</th>
<th>Concentration</th>
<th>Symbol</th>
<th>Risk</th>
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</table>
4. **FIRST AID MEASURES**

4.1. **Description of first aid measures**

**Inhalation:** Remove individual to fresh air. Obtain medical attention if breathing becomes difficult.

**Skin contact:** Promptly wash exposed areas thoroughly with soap and water. Remove all contaminated clothing.

**Eye contact:** Flush eyes with plenty of water for at least 15 minutes. Seek medical attention if irritation develops.

**Ingestion:** Rinse mouth with plenty of water if the person is conscious. Seek medical attention and contact local poison control center.

5. **FIRE FIGHTING MEASURES**

5.1. **Suitable extinguishing media**

Suitable extinguishing media: Any extinguishing media suitable for the surrounding fire.

Unsuitable extinguishing media: No data available

5.2. **Special hazards arising from the product**

No specific risk

5.3. **Fire fighting instructions**

Wear self-contained breathing apparatus and protective clothing that is appropriate for fighting a fire involving chemicals.

6. **ACCIDENTAL RELEASE MEASURES**

6.1. **Personal precautions, protective equipment and emergency procedures**

Wear a lab-coat, disposable gloves and safety glasses.

6.2. **Environment precautions**

Do not discharge into the environment.

Do not allow to enter sewers / surface or ground water.

6.3. **Methods and material for containment and cleaning up**

Ensure adequate ventilation.

Collect the spilled product.

Sweep up or vacuum up material and place in an approved container for proper disposal.

Dispose of in accordance with local regulations.

6.4. **Reference to other sections**

See sections 8 protection measures and section 13 disposal considerations

7. **HANDLING AND STORAGE**

7.1. **Precautions for safe handling**

Treat as potentially infectious. Wear personal protective equipment (a lab-coat, disposable gloves and safety glasses).

Avoid contact with eyes and skin.

Wash hands after handling.

Remove lab coats before entering eating areas.

7.2. **Conditions for safe storage, including any incompatibilities**

Keep in closed vials.
7.3. **Specific End Uses**

For use in laboratories.

8. **EXPOSURE CONTROL / PERSONAL PROTECTION**

8.1. **Exposure parameters**

8.1.1. **Exposure limit**

Product as shipped do not contain hazardous materials of which occupational exposure limits have not been made by the local specific regulatory organization.

8.1.2. **Valeurs limites biologiques**

Product as shipped do not contain hazardous materials of which biological limit values have not been made by the local specific regulatory organization.

8.1.3. **Monitoring method**

No data available

8.1.4. **Derived no-effect level (DNEL)**

No data available

8.1.5. **Predicted no-effect concentration (PNEC)**

No data available

8.2. **Exposure controls**

8.2.1. **Technical measures**

Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

8.2.2. **Individual protection measures, such as personal protective equipment.**

**Eye / face protection**

Chemical safety glasses (European standard EN166)

**Hand protection**

Protective gloves (European standard EN 374)

- Inspect gloves before use.
- Respect permeability and penetration time instructions through gloves defined by the manufacturer
- Use gloves appropriate for work or task being performed (chemical compatibility, dexterity, experimental conditions, ...).
- Take account of regional and local conditions of use.
- Be careful when remove gloves to avoid self-contamination.

**Skin and body protection**

Wear suitable protective clothing and gloves to prevent skin exposure.

**Respiratory protection**

None

8.2.3. **Health safety**

Handle in accordance with good laboratory hygiene

8.2.4. **Environmental exposure controls**

No data available

9. **PHYSICAL AND CHEMICAL PROPERTIES**

9.1. **Information on basic physical and chemical properties**

**Appearance**:

Frozen human plasma light yellow colored after thawing

**Odor**:

Slight plasma smell

**Odor threshold**:

Not determined

**pH (entre 20 et 25°C)**:

6.5 – 7.5

**Melting point**:

Not determined

**Boiling point**:

Not determined

**Boiling ranges**:

Not determined

**Flash point**:

Not determined
Evaporation rate: Not determined
Flammability (solid, gaz): Not determined
Explosion limit: None
Vapor pressure: Not determined
Vapor density: Not determined
Specific gravity: Not determined
Solubility: Soluble in water
Partition coefficient: n-octanol/water: Not determined
Self ignition: No
Decomposition temperature: Not determined
Viscosity: Not determined
Explosive properties: None
Oxidising properties: None

9.2. Other information
None

10. Stability and Reactivity

10.1. Reactivity
None known

10.2. Chemical stability
Stable under recommended conditions of storage, use and temperature

10.3. Possibility of hazardous reactions
Hazardous polymerization: None
Hazardous reactions: None

10.4. Conditions to avoid
None

10.5. Incompatible materials
None

11. Toxicological Information

11.1. Information on toxicological effects
11.1.1. Acute toxicity
No data available
11.1.2. Skin corrosion / irritation
No data available
11.1.3. Serious eye damage
No data available
11.1.4. Respiratory sensibilisation
No data available
11.1.5. Skin sensibilisation
No data available
11.1.6. Germ cell mutagenicity
No data available
11.1.7. Carcinogenicity
No data available

11.1.8. Reproductive toxicity
No data available

11.1.9. Specific target organ toxicity (single exposure)
No data available

11.1.10. Specific target organ toxicity (repeated exposure)
No data available

11.1.11. Aspiration hazard
No data available

11.1.12. Other adverse effects
All blood product should be treated as potentially infectious.
Source material from which this product was derived was found to be negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents. Accordingly, these human blood based products should be handled and discarded as recommended for any potentially infectious human specimen.
The health effects mentioned above are based on the extrapolation of data regarding the substances of pure product. No health effects have been identified in normal conditions, ie, a mixture of these compounds. These effects, however, have not been fully investigated.

11.1.13. Symptoms and effects, both acute and delayed
No data available

12. ECOLOGICAL INFORMATION

12.1. Toxicity
No data available

12.2. Persistence and degradability
No data available

12.3. Bioaccumulative potential
No data available

12.4. Mobility in soil
No data available

12.5. Results of PBT and vPvB assessment
No data available

12.6. Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods
The product must be disposed of as laboratory chemical in suitable containers and in accordance with local regulations.

13.2. Waste from residues / unused products
The product must be disposed of as laboratory chemical in suitable containers and in accordance with local regulations.

13.3. Contaminated packaging
Packaging should be disposed in suitable containers in accordance with local regulations.
14. TRANSPORT INFORMATION (INTERNATIONAL REGULATIONS)

14.1. Sea transport (IMDG / IMO)
Not applicable

14.2. Land transport (ADR)
Not applicable

14.3. Air transport (IATA)
Not applicable

15. REGULATORY INFORMATION

Symbols: None

Risk phrases R:
- R 36/37: Irritating to eyes and respiratory system

Risk phrases S:
- S 20/21: When using do not eat, drink or smoke
- S 24/25: Avoid contact with skin and eyes
- S 29/56: Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point
- S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection
- S 64: If swallowed, rinse mouth with water (only if the person is conscious)

Other regulatory requirements: This document does not in any way excuse the user from knowing and applying all national and international regulations of its activity.

16. OTHER INFORMATION

This document complements the technical sheets but does not replace it. The information contained herein is based on the state of our knowledge of the product, at the date indicated. They are given in good faith.
In addition, we draw the attention of the user to the possible risks incurred when a product is used for purposes other than those for which it is designed. The user must accept the sole responsibility in the matter and take the necessary precautions when using this product.

17. REVISION

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<td>Adding details in the whole text</td>
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<td>Adding two products: CCNSF100-10 / CCNSM100-10</td>
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<td>Add R and S risk phases</td>
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