Cryopep
La cryogénie au service de l'hémostase

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83 rue Yves Montand - 34080 Montpellier, France
contact@cryopep.com
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1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product identifier

Part code	Trade name	Packaging
6-1800-05	Factor VIII Inhibitor Weak Control	25 x 0.5 mL
6-1850-05	Factor VIII Inhibitor Negative Control	25 x 0.5 mL
6-1900-ID	Factor IX Inhibitor Weak Control	25 x 0.5 mL
6-1900-ID-10	Factor IX Inhibitor Weak Control	10 x 0.5 mL
6-1950-05	Factor IX Inhibitor Negative Control	25 x 0.5 mL
6-1950-05-10	Factor IX Inhibitor Negative Control	10 x 0.5 mL

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

Recommended use : Laboratory reagents

Use advised against :

1.3. Company identification

Manufacturer : **Cryopep**

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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

Non-hazardous

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 : Biological risks 

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 : 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.

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3. COMPONENT / INFORMATION ON INGREDIENTS

3.1. Product description

Human plasma

3.2. Hazardous components

CAS nr	Name	Concentration	Symbol	Risk

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 immediately with plenty of water for at least 15 minutes. Seak 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 (*Exposure Control / Personal Protection*, page 3) and 13 (*Disposal Considerations*, page 6).

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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

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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 determinated
pH (entre 20 et 25°C) :	6.8 – 7.5
Melting point :	Not determinated
Boiling point :	Not determinated
Boiling ranges :	Not determinated
Flash point :	Not determinated
Evaporation rate :	Not determinated
Flammability (solid, gaz) :	Not determinated
Explosion limit :	None
Vapor pressure :	Not determinated
Vapor density :	Not determinated
Specific gravity :	Not determinated
Solubility :	Soluble in water
Partition coefficient :	n-octanol/water : Not déterminated
Self ignition :	No
Decomposition temperature :	Not déterminated
Viscosity :	Not déterminated
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

10.3. Possibility of hazardous reactions

Hazardous polymerization :	None
Hazardous reactions :	None

10.4. Conditions to avoid

None

10.5. Incompatible materials

None

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11. TOXICOLOGICAL INFORMATION

11.1. Information on toxilogical 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

Biodegradable

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

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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
Risks 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.

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17. REVISION

Version n°	Date	Motif
2014/03	03/2014	Creation
2014/07	29/07/2014	Revising the presentation Adding details in the whole text
2015/03	02/03/2015	Adding a product : 6-1900-ID
2015/08	25/08/2015	Adding a product : 6-1850-05 (update packaging)
2015/12	03/12/2015	Adding a product : 6-1900-ID-10 (new packaging) Add R and S risk phases
2017/01	05/01/2017	Adding products : 6-1950-05 et 6-1950-05-10