

## SAFETY DATA SHEET

Product name	Product reference
HEMOCLOT™ Thrombin Inhibitors	CK002K
HEMOCLOT™ Thrombin Inhibitors	CK002L

R1	Normal pool plasma
R2	Human calcium thrombin

In accordance with OSHA Regulations 1910.1200 (g), a Safety Data Sheet is required only for reagents R2 (see SDS below).

## Safety Data Sheet acc. to OSHA HCS

Printing date 10/25/2023

Version Number 6

Reviewed on 10/25/2023

### 1 Identification

- **Product identifier**
- **Trade name:** Human calcium thrombin
- **Application of the substance / the mixture** In vitro medical device for professional use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
HYPHEN BioMed  
155 rue d'Eragny  
F-95000 NEUVILLE-SUR-OISE  
FRANCE
- **Information department:**  
info@hyphen-biomed.com  
+33/1/34 40 65 10
- **Emergency telephone number:**  
INFOTRAC emergency phone number (for USA, Puerto Rico and Canada only): 1-800-535-5053  
(24-hours)

### 2 Hazard(s) identification

- **Classification of the substance or mixture**  
The product is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

10035-04-8	calcium chloride, dihydrate	<5%
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### 4 First-aid measures

- **Description of first aid measures**
- **General information:**  
No special measures required.  
Seek immediate medical advice.
- **After inhalation:**  
In case of unconsciousness place patient stably in side position for transportation.  
Supply fresh air and to be sure call for a doctor.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

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- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

· **PAC-1:**

25322-68-3	Polyethylene glycol	30 mg/m <sup>3</sup>
7365-45-9	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	30 mg/m <sup>3</sup>
10035-04-8	calcium chloride, dihydrate	16 mg/m <sup>3</sup>

· **PAC-2:**

25322-68-3	Polyethylene glycol	1,300 mg/m <sup>3</sup>
7365-45-9	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	330 mg/m <sup>3</sup>
10035-04-8	calcium chloride, dihydrate	170 mg/m <sup>3</sup>

· **PAC-3:**

25322-68-3	Polyethylene glycol	7,700 mg/m <sup>3</sup>
7365-45-9	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	2,000 mg/m <sup>3</sup>
10035-04-8	calcium chloride, dihydrate	1,100 mg/m <sup>3</sup>

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
No special measures required.  
Open and handle receptacle with care.
- **Information about protection against explosions and fires:** No special measures required.

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- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** 2 - 8°C
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.  
At this time, the remaining constituent has no known exposure limits.

#### 25322-68-3 Polyethylene glycol

WEEL	Long-term value: 10 mg/m <sup>3</sup> (H); MW>200
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- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.  
Do not eat or drink while working.
- **Breathing equipment:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Face protection

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### 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Like powder

**Color:** White

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

**Melting point/Melting range:** Undetermined.

**Boiling point/Boiling range:** Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

**Lower:** Not determined.

**Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapor density** Not determined.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

**Water:** Not determined.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

**Dynamic:** Not determined.

**Kinematic:** Not determined.

· **Solvent content:**

**VOC content:** 0.00 %

· **Other information** No further relevant information available.

### 10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

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- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to internally approved calculation methods for preparations:  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.  
Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Smaller quantities can be disposed of with household waste.  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:**  
Disposal must be made according to official regulations.  
Dispose of packaging according to regulations on the disposal of packagings.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · <b>DOT, IMDG, IATA</b>   | not regulated   |
| · <b>UN proper shipping name</b>   |                 |
| · <b>DOT, IMDG, IATA</b>   | not regulated   |
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>DOT, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | not regulated   |
| · <b>Packing group</b>   |                 |
| · <b>DOT, IMDG, IATA</b>   | not regulated   |
| · <b>Environmental hazards:</b>  | Not applicable. |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | not regulated   |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

56-40-6	Glycine	ACTIVE
25322-68-3	Polyethylene glycol	ACTIVE

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299-28-5	Calcium	ACTIVE
9048-46-8	Albumins, blood serum	ACTIVE
7365-45-9	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	ACTIVE
7647-14-5	sodium chloride	ACTIVE
555-06-6	sodium 4-aminobenzoate	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Contact:**

· **Date of preparation / last revision** 10/25/2023

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

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PEL: Permissible Exposure Limit  
REL: Recommended Exposure Limit

· \* **Data compared to the previous version altered.**

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