

SAFETY DATA SHEET

Product name	Product reference
BIOPHEN TM Factor XIII	227005

R1	Thrombin Reagent
R2	Detection Reagent



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Safety Data Sheet acc. to OSHA HCS

Printing date 02/23/2024

Version Number 2

Reviewed on 02/23/2024

1 Identification

- · Product identifier
- · Trade name: Thrombin Reagent
- · Article number: R1
- · 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:

25322-68-3 Polyethylene glycol

4 First-aid measures

- · Description of first aid measures
- · General information: 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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<50%



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Trade name: Thrombin Reagent

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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: Dilute with plenty of water. Do not allow to enter sewers/ surface or ground water. Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, saw 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 	dust).
• PAC-1:	
25322-68-3 Polyethylene glycol	30 mg/m³
10035-04-8 calcium chloride, dihydrate	16 mg/m³
· PAC-2:	
25322-68-3 Polyethylene glycol 1,	300 mg/m³
10035-04-8calcium chloride, dihydrate17	70 mg/m³
· PAC-3:	
25322-68-3 Polyethylene glycol 7,	700 mg/m³
10035-04-8calcium chloride, dihydrate1,	100 mg/m³

7 Handling and storage

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

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· Further information about storage conditions:

None.

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:

25322-68-3 Polyethylene glycol

WEEL Long-term value: 10 mg/m³

(H); MW>200

· 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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Physical and chemical prope	
Information on basic physical and General Information	chemical properties
Appearance:	
Form:	Fluid
Color:	According to product specification
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 determined.
Solubility in / Miscibility with	
Water:	Not determined.
Partition coefficient (n-octanol/wa	ter): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Solvent content:	
VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal
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.

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- · Possibility of hazardous reactions No dangerous reactions known.
- 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.
- · Additional toxicological information:

· 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.

13 Disposal considerations

- Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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· 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.

4 Transport information	
· UN-Number · DOT, IMDG, IATA	not regulated
 UN proper shipping name DOT, IMDG, IATA 	not regulated
· Transport hazard class(es)	
[·] DOT, ADN, IMDG, IATA [·] Class	not regulated
 Packing group DOT, IMDG, IATA 	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
 Transport in bulk according to Anne» MARPOL73/78 and the IBC Code 	x II of Not applicable.
· UN "Model Regulation":	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	i (extremely hazardous substances):	
None of the	ingredients is listed.	
· Section 313	(Specific toxic chemical listings):	
None of the	ingredients is listed.	
· TSCA (Toxi	c Substances Control Act):	
7732-18-5	water, distilled, conductivity or of similar purity	ACTIVE
25322-68-3	Polyethylene glycol	ACTIVE
150-25-4	N,N-bis(2-hydroxyethyl)glycine	ACTIVE
· Hazardous	Air Pollutants	
None of the	ingredients is listed.	
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· 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 02/23/2024 · 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 PEL: Permissible Exposure Limit **REL: Recommended Exposure Limit** * * Data compared to the previous version altered.



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1 Identification

- · Product identifier
- · Trade name: Detection Reagent
- · Article number: R2
- · 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



Eye Damage 1 H318 Causes serious eye damage.

- · Label elements
- · GHS label elements
- The product is classified and labeled according to the Globally Harmonized System (GHS).
- Hazard pictograms



- · Signal word Danger
- Hazard-determining components of labeling: ethyl glycinate hydrochloride
- · Hazard statements
- Causes serious eye damage.
- · Precautionary statements
- Wear protective gloves/protective clothing/eye protection/face protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- Immediately call a poison center/doctor.
- · Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.

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· vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Mixtures

• **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**
- 623-33-6 ethyl glycinate hydrochloride

<8%

4 First-aid measures

- Description of first aid measures
- · General information: 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.
- · After eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.

- 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 equipment. Keep unprotected persons away. Wear protective clothing.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Use neutralizing agent.
- Dispose contaminated material as waste according to section 13.
- **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.

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 Protective A 	Action	Criteria	for	Chemicals

· PAC-1:

 7365-45-9
 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
 30 mg/m³

 • PAC-2:
 7365-45-9
 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
 330 mg/m³

 • PAC-3:
 7365-45-9
 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
 2,000 mg/m³

7 Handling and storage

- · Handling:
- · Precautions for safe handling Open and handle receptacle with care.
- · Information about protection against explosions and fires: No special measures required.
- · 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: Keep receptacle tightly sealed.
- 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
- \cdot Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- Personal protective equipment:
- General protective and hygienic measures: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the eyes. Avoid contact with the eyes and skin. 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

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Trade name: Detection Reagent

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:



Tightly sealed goggles

Face protection

Information on basic physical and	chemical properties
General Information	
Appearance:	
Form:	Fluid
Color:	According to product specification
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.



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 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:	0.0 g/l / 0.00 lb/gal	
• 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.
- · **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 eye: Strong irritant with the danger of severe eye injury.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· 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.

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- · 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.

Must not reach bodies of water or drainage ditch undiluted or unneutralized.

- 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.

13 Disposal considerations

· Waste treatment methods

· Recommendation:

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.

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

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15 Regulatory information

Sara		
	5 (extremely hazardous substances):	
None of the	e ingredients is listed.	
	3 (Specific toxic chemical listings):	
None of the	e ingredients is listed.	
•	ic Substances Control Act):	
	water, distilled, conductivity or of similar purity	ACTIV
	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	ACTIV
	ethyl glycinate hydrochloride	ACTIV
16178-48-6	Adenosine 5'-(trihydrogen diphosphate),disodium salt	ACTIV
Hazardous	Air Pollutants	
None of the	e ingredients is listed.	
Propositio		
Chemicals	known to cause cancer:	
None of the	e ingredients is listed.	
Chemicals	known to cause reproductive toxicity for females:	
None of the	e ingredients is listed.	
Chemicals	known to cause reproductive toxicity for males:	
None of the	e ingredients is listed.	
Chemicals	known to cause developmental toxicity:	
None of the	e ingredients is listed.	
Carcinoge	nic categories	
EPA (Envir	ronmental Protection Agency)	
None of the	e ingredients is listed.	
TLV (Thres	shold Limit Value)	
None of the	ingredients is listed.	
NIOSH-Ca	(National Institute for Occupational Safety and Health)	
None of the	e ingredients is listed.	
GHS label of The product	elements It is classified and labeled according to the Globally Harmon I tograms	ized System (GHS).



· Signal word Danger

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- · Hazard-determining components of labeling: ethyl glycinate hydrochloride
- · Hazard statements

Causes serious eye damage.

• Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a poison center/doctor.

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 02/22/2024
- 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 PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Eye Damage 1: Serious eye damage/eye irritation - Category 1 * * Data compared to the previous version altered.

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