

SAFETY DATA SHEET

Product name	Product reference
GFC-Test	CK093K

R1	tPA with silica
R2	Thrombin reagent

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

Safety Data Sheet acc. to OSHA HCS

Printing date 07/12/2024

Version Number 2

Reviewed on 07/12/2024

1 Identification

- **Product identifier**
- **Trade name:** Thrombin 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**
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	<30%
------------	---------------------	------

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.

(Contd. on page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 07/12/2024

Version Number 2

Reviewed on 07/12/2024

Trade name: Thrombin reagent

(Contd. of page 1)

- **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 ³
10035-04-8	calcium chloride, dihydrate	16 mg/m ³

· **PAC-2:**

25322-68-3	Polyethylene glycol	1,300 mg/m ³
10035-04-8	calcium chloride, dihydrate	170 mg/m ³

· **PAC-3:**

25322-68-3	Polyethylene glycol	7,700 mg/m ³
10035-04-8	calcium chloride, dihydrate	1,100 mg/m ³

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:**
None.
2 - 8°C

(Contd. on page 3)

Safety Data Sheet acc. to OSHA HCS

Printing date 07/12/2024

Version Number 2

Reviewed on 07/12/2024

Trade name: Thrombin reagent

(Contd. of page 2)

- **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/m ³ (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

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Solid
Color:	Colorless
Odor:	Odorless

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/12/2024

Version Number 2

Reviewed on 07/12/2024

Trade name: Thrombin reagent

(Contd. of page 3)

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

US

(Contd. on page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 07/12/2024

Version Number 2

Reviewed on 07/12/2024

Trade name: Thrombin reagent

(Contd. of page 4)

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.

- **Uncleaned packagings:**

- **Recommendation:**

Disposal must be made according to official regulations.

Dispose of packaging according to regulations on the disposal of packagings.

US

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 07/12/2024

Version Number 2

Reviewed on 07/12/2024

Trade name: Thrombin reagent

(Contd. of page 5)

14 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 II of MARPOL73/78 and the IBC Code	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 (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
7647-14-5	sodium chloride	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.

(Contd. on page 7)

Safety Data Sheet acc. to OSHA HCS

Printing date 07/12/2024

Version Number 2

Reviewed on 07/12/2024

Trade name: Thrombin reagent

(Contd. of page 6)

· **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** 07/12/2024

· **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