



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

SECTION 1: Identification of the Substance/ Mixture and of the Company/ Undertaking

1.1 Product identifier

Product name:	Thrombin Reagent – 5x2mL for CoaFIB Fibrinogen Kit
Product Number (REF#):	210-24-040-00 (content of CoaFIB Fibrinogen Kit)

1.2. Relevant identified uses of the substances or mixtures and uses advised against

In-Vitro Diagnostic Reagent

Sectors of use:

Professional use [SU22]

Uses advised against

Do not use for purposes other than those listed.

1.3. Details of the supplier of the Safety Data Sheet:

Contract:	LABiTec® LAbor BioMedical Technologies GmbH
Address:	An der Strusbek 6
Place:	D-22926 Ahrensburg, Germany
Telephone:	+49(0) 4102/4795-0
Fax:	+49(0) 4102/4795-35
E-mail:	info@labitec.de

1.4. Emergency contact

Telephone Number:	+49(0) 4102/4795-0
Opening hours (GMT +1):	Monday to Thursday 8:30am – 3:30pm
	Friday 8:30am – 1:00pm



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

SECTION 2: Hazards Identification

2.1 Classification of the substance/ mixture:

2.1.1 Classification according to Regulation (EC) No 1272/2008

Pictograms: GHS07, GHS08

Hazard Class and Category Code(s): Eye Irrit. 2, Resp. Sens 1

Hazard statement Code(s):

H319 – Causes serious eye irritation

H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.

The product, if inhaled, can cause sensitization.

2.2 Label elements:

Labelling according to Regulation (EC) No 1272/2008

Hazard pictogram:

GHS07, GHS08 - Danger

Hazard statement(s):

H319 – Causes serious eye irritation

H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements:

Prevention

P261 - Avoid breathing the product

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P284 - [In case of inadequate ventilation] wear respiratory protection.

Response:

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER/doctor

Contains:

BOVINE THROMBINE

UFI: TN10-K01W-S00J-7V5Q

Supplement Hazard Information (EU):

Not applicable



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

2.3 Other hazards:

The substance / mixture NOT contains substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/ Information on Ingredients

3.1 Substances

Not Applicable

3.2 Mixtures

Refer to paragraph 16 for full text of hazard statements.

Substance	Classification	Index	CAS	EINECS	REACH
BOVINE THROMBINE	Skin Corr. 2, H315; Eye Irrit. 2, H319; Resp. Sens. 1, H334; STOT SE 3, H335	ND	9002-04-4	232-648-7	NR
Sodium hydroxide 2N	Met. Corr. 1, H290; Skin Corr. 1A, H314; Skin Irrit. 2, H315; Eye Dam. 1, H318; Eye Irrit. 2, H319	ND	ND	ND	NR

SECTION 4: First Aid Measures

4.1 Description of first aid measures:

General advice: Consult a physician. Show this SDS to the doctor in attendance.

After Inhalation: Air the area. Immediately move the contaminated patient from the area and keep at rest in a well-ventilated area. If you feel unwell seek medical advice.

After Skin Contact: Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Claus Method) Thrombin Reagent (R1)

After Eye Contact: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately. Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

After Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

Self-protection for first aider: Personal protective equipment for first aid responder is recommended.

4.2 Most important symptoms and effects both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment

If eye irritation persists: Get medical advice/attention.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor

SECTION 5: Fire-fighting Measures

5.1 Extinguishing media:

Advised extinguishing agents:

Water spray, CO₂, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing means to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2 Special hazards arising from the substance or mixture:

No data available

5.3 Advice for firefighters

Use protection for the breathing apparatus safety helmet and full protective suit.

The spray water can be used to protect the people involved in the extinction.

You may also use self-respirator, especially when working in confined and poorly ventilated area and if you use halogenated extinguishers (Halon 1211 fluobrene, Solkan 123, NAF, etc...)

Keep containers cool with water spray.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Leave the area surrounding the spill or release. Do not smoke Wear gloves and protective clothing

6.1.2 For emergency responders

Wear gloves and protective clothing.

Eliminate all unguarded flames and possible sources of ignition. No smoking.

Provision of sufficient ventilation. Evacuate the danger area and, in case, consult an expert.

6.2 Environmental precautions:

Contain spill: Inform the competent authorities. Discharge the remains in compliance with the regulations.



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

6.3 Methods and material for containment and cleaning up:

6.3.1 For containment:

Recover the product for reuse, if possible, or for removal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleaning up:

After wiping up, wash with water the area and materials involved.

6.3.3 Other information:

Nothing in particular.

6.4 Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION 7: Handling and Storage

7.1 Precautions for safe handling

Wear protective gloves/protective clothing/eye protection/face protection. In residential areas do not use on large surfaces. At work do not eat or drink. See also paragraph 8 below.

7.2 Conditions for safe storage including any incompatibilities:

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and direct exposure of sunlight.

7.3 Specific end use:

Public domain:

Handle with care. Store in a ventilated area and away from heat, keep the container tightly closed. Use in accordance with product Instructions for use provided in kit. For In Vitro Diagnostic use only.

SECTION 8: Exposure Controls/ Personal Protection

8.1 Control Parameters

Sodium hydroxide 2N

OEL Maximum value 2 mg/m³

Derived No Effect Level (DNEL)

Worker DNEL, long-term: Local effects, inhalation, 1 mg/m³

User DNEL, long-term: Local effects, inhalation, 1 mg/m³

The methods for detecting the workplace atmosphere must comply with the requirements of the standards DIN EN 482 and DIN EN 689.

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Public domain:

No specific monitoring foreseen



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

8.2.2 Individual protection measures:

8.2.2.1 Eye/ face Protection: Wear mask

8.2.2.2 Skin Protection:

8.2.2.3 Hand Protection: When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

8.2.2.4 Other: When handling the pure product wear full protective skin clothing.

8.2.2.4 Respiratory Protection: Use adequate protective respiratory equipment (EN 14387:2008)

8.2.2.5 Thermal Hazards: No hazard to report.

8.2.3 Environmental Exposure Controls

Calcium Chloride Dihydrate: Do not let product enter drains.

Sodium hydroxide 2N: Do not let product enter drains.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method
Appearance	lyophilized, solid	
Colour	translucent white	
Odour	not determined	
Odour threshold	not determined	
pH	not determined	
Melting point/freezing point	not determined	
Initial boiling point and boiling range	not determined	
Flash point	not determined	ASTM D92
Evaporation rate	not determined	
Flammability (solid, gas)	not determined	
Upper/lower flammability or explosive limits	not determined	
Vapour pressure	not determined	
Vapour density	not determined	
Relative density	not determined	
Solubility(ies)	not determined	
Water solubility	not determined	
Partition coefficient: n-octanol/water	not determined	
Auto-ignition temperature	not determined	
Decomposition temperature	not determined	
Viscosity	not determined	
Explosive properties	not determined	
Oxidising properties	not determined	



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

9.2 Other safety information

No data available

SECTION 10: Stability and Reactivity

10.1 Reactivity: Calcium Chloride Dihydrate: Process of exothermic dissolution in water

10.2 Chemical stability: No hazardous reaction when handled and stored according to provisions.

10.3 Possibility of hazardous reactions: There are no hazardous reactions.

10.4 Conditions to avoid: Nothing to report

10.5 Incompatible materials:

Nothing in particular

10.6 Hazardous decomposition products:

Does not decompose when used for intended uses.

SECTION 11: Toxicological Information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

ATE(mix) oral = ∞

ATE(mix) dermal = ∞

ATE(mix) inhal = ∞

A	Acute toxicity:	based on available data, the classification criteria are not met
B	Skin corrosion/irritation:	based on available data, the classification criteria are not met
C	Serious eye damage/irritation:	If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
D	Respiratory or skin sensitisation:	The product, if inhaled, can cause sensitization.
E	Germ cell mutagenicity:	based on available data, the classification criteria are not met
F	Carcinogenicity:	based on available data, the classification criteria are not met
G	Reproductive toxicity:	based on available data, the classification criteria are not met
H	Specific target organ toxicity (STOT) single exposure:	based on available data, the classification criteria are not met
I	Specific target organ toxicity (STOT) repeated exposure	based on available data, the classification criteria are not met
J	Aspiration hazard:	based on available data, the classification criteria are not met



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

Calcium Chloride Dihydrate:

Symptoms: After uptake of large quantities: Stomach/intestinal disorders

Possible damages: mucosal irritations

Sodium hydroxide 2N

Symptoms: If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the esophagus and the stomach.

Symptoms: mucosal irritations, Cough, Shortness of breath

Possible damages: damage of respiratory tract.

11.2 Information on other hazards:

No data available.

SECTION 12: Ecological Information

12.1 Toxicity:

Calcium Chloride Dihydrate:

Toxicity to fish LC50 - Lepomis macrochirus (Bluegill sunfish) - 10.650 mg/l - 96 h

Toxicity to daphnia and other aquatic invertebrates EC50 - Daphnia magna (Water flea) - 144 mg/l - 48 h

Toxicity to algae IC50 - algae - 3.130 mg/l - 120 h

Use according to good working practices to avoid pollution into the environment.

12.2 Persistence and degradability:

No data available

12.3 Bio-accumulative potential:

No data available

12.4 Mobility in soil:

No data available

12.5 Results of PBT and vPvB assessment:

No PBT/vPvB ingredient is present

12.6 Endocrine disrupting properties:

No data available.

12.7 Other adverse effects:

No adverse effects

SECTION 13: Disposal Considerations

13.1 Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.

Recover if possible. Operate according to local or national regulations.



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

SECTION 14: Transport Information

14.1 UN number or ID number: Not included in the scope of application regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

14.2 UN Proper Shipping name: None

14.3 Transport Hazard Classes: None

14.4 Packaging Group: None

14.5 Environmental Hazards: None

14.6 Special precautions for user: No data available

14.7 Maritime transport in bulk according to IMO instruments:

It is not intended that this product is transported as bulk and therefore the shipping/ transport regulations for bulk hazardous material do not apply.

SECTION 15: Regulatory Information

15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture:

REGULATION (EU) No 1357/2014 - waste: HP4 - Irritant — skin irritation and eye damage

15.2 Chemical Safety Assessment:

No chemical safety assessment was carried out by the supplier.

SECTION 16: Other Information

Description of the hazard statements exposed to point 3

Hazard Statement	Description
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation.



MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method) Thrombin Reagent (R1)

Classification based on data of all mixture components

GENERAL BIBLIOGRAPHY:

- Council Regulation (EC) 1907/2006 of the European Parliament (REACH)
- Regulation (EC) 1272/2008 of the European Parliament (CLP) and subsequent updates
- Council Regulation (EC) no 758/2013 of the European Parliament
- Regulation (EC) no 2020/878 of the European Parliament
- Regulation (EC) No 528/2012 European Parliament and subsequent updates
- Commission Regulation (EC) No 790/2009 of 10 August 2009
- Commission Regulation (EU) No 286/2011 of 10 March 2011
- Commission Regulation (EU) No 618/2012 of 10 July 2012
- Commission Regulation (EU) No 487/2013 of 8 May 2013
- Council Regulation (EU) No 517/2013 of 13 May 2013
- Commission Regulation (EU) No 758/2013 of 7 August 2013
- Commission Regulation (EU) No 944/2013 of 2 October 2013
- Commission Regulation (EU) No 605/2014 of 5 June 2014
- Commission Regulation (EU) 2015/491 of 23 March 2015
- Commission Regulation (EU) No 1297/2014 of 5 December 2014- Council Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index
- Handling Chemical Safety
- Niosh Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty-Industrial Hygiene and Toxicology
- N.I. Sax-Dangerous properties of Industrial Materials-7 Ed., 1989

Note to the user:

The information in this sheet are based on knowledge available to us on the date of the latest version. The user must ensure the fitness and completeness of the information in relation to the specific use of the product. You should not interpret it as a guarantee of any specific property of the product. For the use of the product does not fall under our direct control, the obligation of the user to observe under their own liability laws and regulations on hygiene and safety. Do not assume liability for improper use.

This sheet replaces and cancels all previous.