MATERIAL SAFETY DATA SHEET

Conforms to Regulation (EU) 2020/878

CoaFIB – Fibrinogen Kit (Clauss Method)

Imidazole Buffer (R2)

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

1.1 Product identifier

Product name:	**Imidazole Buffer – 4x25mL 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

SECTION 2: Hazards Identification

2.1 Classification of the substance/ mixture:

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

Pictograms: None
Hazard Class and Category Code(s): Non-hazardous
Hazard statement Code(s): Non-hazardous

2.2 Label elements:

Labelling according to Regulation (EC) No 1272/2008

Hazard pictogram:
None required since product non-hazardous

Signal word:
None required

Hazard statement(s):
Non-hazardous

Precautionary statements:
Nothing in particular

2.3 Other hazards:

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

No information on other hazards
This document is outside the scope of Article 31 of REACH

SECTION 3: Composition/ Information on Ingredients

3.1 Substances
Not Applicable

3.2 Mixtures
No substances to report.

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: Wash thoroughly with soap and running water.

After Eye Contact: Wash immediately and thoroughly with running water for at least 10 minutes. If irritation persists seek medical attention.

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
No data available.

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 with soil or sand.
If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify it to the authorities.

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
Avoid contact and inhalation of vapours. 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
No data available

8.2 Exposure controls

8.2.1 Appropriate engineering controls:
Public domain:
No specific monitoring foreseen

8.2.2 Individual protection measures:

8.2.2.1 Eye/ face Protection: Not needed for normal use.

8.2.2.2 Skin Protection: Not needed for normal use.

8.2.2.3 Hand Protection: Not needed for normal use.

8.2.2.4 Other: Wear normal work clothing.

8.2.2.4 Respiratory Protection: Not needed for normal use.

8.2.2.5 Thermal Hazards: No hazard to report.

8.2.3 Environmental Exposure Controls
Use according to good working practices to avoid pollution into the environment.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method
Appearance	liquid	
Colour	colourless	
Odour	odourless	
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	

9.2 Other safety information
No data available

SECTION 10: Stability and Reactivity

10.1 Reactivity: No reactivity hazards

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:
It can generate inflammable gases to contact with elementary metals, nitrides, inorganic sulfide, strong reducing agents. It can generate toxic gases to contact with inorganic sulfide, strong reducing agents.

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:	based on available data, the classification criteria are not met
D	Respiratory or skin sensitisation:	based on available data, the classification criteria are not met
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

11.2 Information on other hazards:

No data available.

SECTION 12: Ecological Information

12.1 Toxicity:

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.

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:

No data available

15.2 Chemical Safety Assessment:

No chemical safety assessment was carried out by the supplier.

SECTION 16: Other Information

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.