MATERIAL SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH), Annex II,
as amended by Regulation (EU) No. 453/2010

LABiTec -Control Plasma 2-

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

1.1 Product identifier

Product name: **LABiTec Control Plasma 2**
Product number: **210-13-000-00, CG0082**

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

LABiTec Control Plasma 2 may be used as an Abnormal Control when measuring PT, APTT and Fibrinogen. The LABiTec Control Plasma 2 is prepared from a normal plasma pool and then treated to achieve abnormal results. The Control Plasma should be used to gauge internal factors in each laboratory's system.
Source material for both plasma products has been tested and found negative for the presence of HIV and HCV antibodies as well as Hepatitis B Surface Antigen by approved test methods. However, no known test method can offer assurance that products derived from human blood are free of infectious agents. Therefore, handle this material observing the same safety precautions employed when handling any potentially infectious material.

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

Contract Manufacturer:	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):	8:30am – 3:30pm

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SECTION 2: Hazards Identification

2.1 Classification of the substance/ mixture:

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]
Non-hazardous

2.1.2 Additional information:
Routine PPE is recommended for handling of biological material. For the full text of R-phrases mentioned, see SECTION 16.

2.2 Label elements:

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictogram:
None required since product non-hazardous

Signal word: None required

Hazard statement(s): None required

Precautionary statements: None required

Supplement Hazard Information (EU): Not applicable

2.3 Other hazards:
None

SECTION 3: Composition/ Information on Ingredients

3.1 Mixtures:
Description of the mixture: LABiTec Control Plasma 2 is prepared from a frozen pool of citrated plasma and is treated to achieve the abnormality required. The control plasma comprises of buffer and lyo-protectant to ensure stability of all plasma constituents.

Hazardous Ingredients:
Chemical concentrations in LABiTec Control Plasma 2 are not classifiable as hazardous according to (EC) No 1272/2008 [CLP].

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: - If inhaled, remove person to fresh air. If breathing becomes difficult obtain immediate medical attention, give artificial respiration. Consult a physician.

After Skin Contact: - Immediately wash skin with soap and copious amounts of water. Consult a physician.

After Eye Contact: - Irrigate with copious amounts of clean fresh water for at least 15 minutes. If irritation persists seek medical attention.

After Ingestion: - Wash out mouth with water provided person is conscious. Urgently seek immediate medical attention. Consult a doctor/ physician or poison centre.

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

SECTION 5: Fire-fighting Measures

5.1 Extinguishing media:

Suitable extinguishing media: Water, alcohol resistant foam, CO_2, Dry Chemical Extinguisher.

5.2 Special hazards arising from the substance or mixture:

No hazardous decomposition materials known.

5.3 Advice for firefighters

Wear suitable protective clothing/ equipment. Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Protective Equipment: Exercise appropriate precautions to minimise direct contact with skin or eyes and prevent inhalation of vapours – Wear personal protective equipment (PPE) such as gloves, safety glasses.
Emergency Procedures: Wear respiratory protection, avoid dust formation and avoid breathing vapours, dust, mist or gas. Ensure adequate ventilation and evacuate personnel to safe areas.

6.1.2 For emergency responders

Personal protective equipment for first aid responder/s is/ are recommended.

6.2 Environmental precautions:

Prevent further leakage or spillage if safe to do so and do not let product enter drains.

6.3 Methods and material for containment and cleaning up:

6.3.1 **For containment:** Spillages should be contained using absorbent material to prevent contamination of drains and watercourses.

6.3.2 **For cleaning up:** Pick up and arrange disposal without additional leaking of material. Use adsorbent materials and wash spill site for decontamination after material pickup. Waste material from spillages should be disposed of in accordance with local regulations.

6.3.3 **Other information:** Spilled material may cause surfaces to become slippery, clear spills immediately.

6.4 Reference to other sections

Refer to section 8 for exposure controls and personal protection and sections 13 for disposal considerations.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling

7.1.1 **Recommendations:** Wear appropriate PPE. Avoid contact with eyes, skin and clothing. For IVD Use Only. Not for medicinal use. DO NOT INGEST. Reduce the release of substance to the environment by avoiding spillages. For precautions see section 2.2.

7.1.2 **General occupational hygiene:** Do not eat, drink or smoke in work areas. Wash hands after use. Remove protective equipment before entering eating areas.

7.2 Conditions for safe storage including any incompatibilities:

Store securely in the original labelled container. Storage conditions according to product label.

7.3 Specific end use:

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

8.1.1 **Components with workplace control parameters:** Contains no substances with occupational exposure limit values.

8.2 Exposure controls

8.2.1 Appropriate engineering controls:
Follow good clinical hygiene practices adopting suitable individual protective measures. Avoid contact with skin, eyes and clothing. Do not eat or smoke while handling the product. Wash hands before breaks and immediately after handling the product.

8.2.2 Personal Protection Equipment:

8.2.2.1 Eye/ face Protection:
Wear safety glasses or goggles. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).

8.2.2.2 Skin Protection:
Handle with gloves. Gloves must be inspected prior to use to ensure good condition.
Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with good laboratory practice and applicable laws. Wash hands and dry.

8.2.2.3 Body Protection:
Wear laboratory coat/ work coat or apron in line with protective equipment at the specific work place.

8.2.2.4 Respiratory Protection
Wear simple mask to prevent inhalation of dust / vapour.

8.2.3 Environmental Exposure Controls
Prevent further leakage or spillage if safe to do so as described in section 6.3. Do not let product enter drains.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

a)	**Appearance:** - Lyophilised: Buff compact cake at base of vial, sealed with stopper and screw cap. Once reconstituted the plasma is a pale straw colour.	
b)	**Odour:**	Odourless
c)	**Odour threshold:**	No data available
d)	**pH:**	Neutral
e)	**Melting point/ freezing point:**	Melting point/ range: No data available
f)	**Initial boiling point and boiling range:**	No data available
g)	**Flash Point:**	No data available
h)	**Evaporation Weight**	No data available
i)	**Flammability (solid, gas):**	No data available
j)	**Upper/ lower flammability or explosive limits:**	No data available

k)	**Vapour Pressure:**	No data available
l)	**Vapour Density:**	No data available
m)	**Relative Density**	No data available
n)	**Water Solubility**	No data available
o)	**Partition Coefficient: n-octanol/ water**	No data available
p)	**Auto-ignition temperature**	No data available
q)	**Decomposition temperature**	No data available
r)	**Viscosity**	No data available
s)	**Explosive properties**	No data available
t)	**Oxidising Properties**	No data available

9.2 Other safety information

Water soluble

SECTION 10: Stability and Reactivity

10.1 Reactivity: No data available

10.2 Chemical stability: This product is stable in normal conditions of use and storage.

10.3 Possibility of hazardous reactions: No data available

10.4 Conditions to avoid: No data available

10.5 Incompatible materials: Bases, oxidising agents, iron and irons salts, copper.

10.6 Hazardous decomposition products: No known hazardous decomposition products

SECTION 11: Toxicological Information

11.1 Information on toxicological effects:

Acute Toxicity: No data available
Skin corrosion/ irritation: No data available
Serious Eye damage/ irritation: No data available
Respiratory or skin sensitisation: No data available
Germ cell mutagenicity: No data available
Carcinogenicity: IARC: No data available
Reproductive Toxicity: No data available
Summary of evaluation of the CMR properties: No data available
STOT-single exposure: No data available
STOT-repeated exposure: No data available
Aspiration hazard: No data available
Additional Information: No data available

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SECTION 12: Ecological Information

12.1 Toxicity: No data available

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 data available

12.6 Other adverse effects: No data available
Use according to good clinical hygiene practices; avoid dispersion of the product in the environment.

SECTION 13: Disposal Considerations

13.1 Waste treatment methods

Product: Disposal of waste must always comply with existing EEC, national and local regulations. Registered waste carriers and licensed disposal sites must be used.
Contaminated packaging: Dispose of as unused product.

SECTION 14: Transport Information

14.1 UN number: No number available/ not required for mixture

14.2 UN Proper Shipping name: Not required

14.3 Transport Hazard Classes: Not required

14.4 Packaging Group: Not required

14.5 Environmental Hazards: Not required

14.6 Special precautions for user: Not required

14.7 Transport in bulk according to Annex II MARPOL73/78 and the IBC Code: 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: None required

15.2 Chemical Safety Assessment: No chemical safety assessment has been carried out for this substance/ mixture by the supplier.

SECTION 16: Other Information

Full text of H-Statements referred to under sections 2 and 3
Not applicable

Full text of R-phrases referred to under sections 2 and 3
Not applicable

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

- LABiTec Control Plasma 2 is a non-hazardous product

Note for the user: The data contained in this sheet is the result of the most up to date information available in our company. The user must ensure that the information is suitable and complete in relation to the specific use of the product.