

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**Fibrinogen Calibrator**

Revision date: 14.01.2019

Product code: OR655503-2

Page 1 of 5

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Fibrinogen Calibrator

Product group: Endprodukt

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture**

In-vitro-Diagnostics

**1.3. Details of the supplier of the safety data sheet**

Company name: Analyticon® Biotechnologies AG  
Street: Am Mühlenberg 10  
Place: D-35104 Lichtenfels  
Telephone: +49 (0) 6454/7991-0  
e-mail: support@analyticon-diagnostics.com  
Contact person: Zentrale  
Internet: <http://www.analyticon-diagnostics.com>

Telefax: +49 (0) 6454/7991-30  
Telephone: +49 (0) 6454/7991-0

**1.4. Emergency telephone number:** Giftnotruf Mainz: +49 (0) 6131 / 19240**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture**

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

**2.2. Label elements****Hazard components for labelling**

No label required according to 1999/45/EC, annex V B, No. 9.

**2.3. Other hazards**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Hazardous components**

CAS No	Chemical name	Quantity		
	EC No	Index No	REACH No	
	GHS Classification			
-	lyophilised normal plasma			>90 %

Full text of H and EUH statements: see section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

Move victim out of danger zone.

**After inhalation**

Provide fresh air.

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### Fibrinogen Calibrator

Revision date: 14.01.2019

Product code: OR655503-2

Page 2 of 5

#### After contact with skin

Wash with plenty of soap and water.

#### After contact with eyes

In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.

#### After ingestion

Rinse mouth thoroughly with water.

#### **4.2. Most important symptoms and effects, both acute and delayed**

Causes mild skin irritation. Causes eye irritation. Causes tears.

#### **4.3. Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

### SECTION 5: Firefighting measures

#### **5.1. Extinguishing media**

##### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings. The product itself does not burn.

#### **5.2. Special hazards arising from the substance or mixture**

Thermal decomposition can lead to the escape of irritating gases and vapours.

#### **5.3. Advice for firefighters**

In case of fire: Wear self-contained breathing apparatus. Wear suitable protective clothing and gloves.

### SECTION 6: Accidental release measures

#### **6.1. Personal precautions, protective equipment and emergency procedures**

Wear personal protection equipment. Avoid dust formation.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

#### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

Prevent spread over a wide area (e.g. by containment or oil barriers).

Do not allow to enter into soil/subsoil.

#### **6.3. Methods and material for containment and cleaning up**

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

#### **6.4. Reference to other sections**

See section 8.

### SECTION 7: Handling and storage

#### **7.1. Precautions for safe handling**

##### **Advice on safe handling**

Avoid direct contact with the substance. The blood products have been tested and have no results for the following genes (unless otherwise stated on the packaging or ampoules): Hepatitis B antibodies (HbsAg) HIV antibodies 1 HIV antibodies 2 HCV antibodies However, they shall be treated with the same precautions as samples from human patients.

##### **Advice on protection against fire and explosion**

Usual measures for fire prevention.

When using do not smoke.

#### **7.2. Conditions for safe storage, including any incompatibilities**

**Fibrinogen Calibrator**

Revision date: 14.01.2019

Product code: OR655503-2

Page 3 of 5

**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep only in the original container in a cool, well-ventilated place.

**Hints on joint storage**

The product is not: Combustible. Exclude sources of ignition-no smoking

**Further information on storage conditions**

Recommended storage temperature: of °C: 2 up to °C: 8

Protect against: heat. UV-radiation/sunlight.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****8.2. Exposure controls****Protective and hygiene measures**

Change contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

**Eye/face protection**

Eye protection: Tightly sealed safety glasses.

**Hand protection**

Tested protective gloves are to be worn: German Industry Norms (DIN) / European Norms (EN): DIN EN 374  
Breakthrough times and swelling properties of the material must be taken into consideration.

**Skin protection**

Suitable protective clothing: Lab apron.

Footwear: Chemical resistant safety shoes.

**Respiratory protection**

Respiratory protection necessary at: insufficient ventilation. Handling larger quantities.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	solid
Colour:	light yellow
Odour:	odourless
pH-Value:	No data available

**Changes in the physical state**

Flash point: No flash point - measurement carried out until boiling temperature.

**Explosive properties**

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

**Oxidizing properties**

Not oxidizing.

Density: 1,01 g/cm<sup>3</sup>  
Water solubility: highly soluble.

**SECTION 10: Stability and reactivity****10.1. Reactivity**

The mixture is chemically stable under recommended conditions of storage, use and temperature.

**10.2. Chemical stability**

The mixture is chemically stable under recommended conditions of storage, use and temperature.

**Fibrinogen Calibrator**

Revision date: 14.01.2019

Product code: OR655503-2

Page 4 of 5

**10.3. Possibility of hazardous reactions**

No hazardous reaction when handled and stored according to provisions. Thermal decomposition can lead to the escape of irritating gases and vapours.

**10.4. Conditions to avoid**

heat.

**10.5. Incompatible materials**

strong acids Oxidizing agents, strong.

**10.6. Hazardous decomposition products**

This information is not available.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute toxicity**

No information available.

**Irritation and corrosivity**

Causes mild skin irritation. Causes eye irritation.

**Sensitising effects**

No information available.

**Carcinogenic/mutagenic/toxic effects for reproduction**

No information available.

**STOT-single exposure**

Coughing.

**STOT-repeated exposure**

No information available.

**Specific effects in experiment on an animal**

No information available.

**Additional information on tests**

The classification was carried out according to the calculation method of the Preparations Directive (1999/45/EC).

**SECTION 12: Ecological information****12.1. Toxicity**

The product has not been tested.

**12.2. Persistence and degradability**

The product has not been tested.

**12.3. Bioaccumulative potential**

The product has not been tested.

**12.4. Mobility in soil**

The product has not been tested.

**12.6. Other adverse effects**

The product has not been tested.

**Further information**

The classification was carried out according to the calculation method of the Preparations Directive (1999/45/EC).

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

**Fibrinogen Calibrator**

Revision date: 14.01.2019

Product code: OR655503-2

Page 5 of 5

**Advice on disposal**

Dispose of waste according to applicable legislation.

Dispose of waste according to "Kreislaufwirtschafts- und Abfallgesetz (KrW-/AbfG)".

**Contaminated packaging**

Water (with cleaning agent). Completely emptied packages can be recycled.

**SECTION 14: Transport information****Land transport (ADR/RID)****Other applicable information (land transport)**

Not restricted

**Inland waterways transport (ADN)****Other applicable information (inland waterways transport)**

Not restricted

**Marine transport (IMDG)****Other applicable information (marine transport)**

Not restricted

**Air transport (ICAO-TI/IATA-DGR)****Other applicable information (air transport)**

Not restricted

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulatory information**

Water contaminating class (D): 1 - slightly water contaminating

**SECTION 16: Other information****Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights.

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*