

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

D-Dimer Calibrator

Revision date: 17.01.2019

Product code: O255507-4

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

D-Dimer 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.

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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

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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 ³
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.

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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**

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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): - - not water contaminating

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 3,15.

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.)