



analyticon

Analyticon® Biotechnologies AG

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### Serum Control CK, CK-MB

Revision date: 17.10.2018

Product code: 2R15149

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#### SECTION 1: Identification of the substance/mixture and of the company/undertaking

##### 1.1. Product identifier

Serum Control CK, CK-MB

Product group: Endprodukt / Endproduct

##### 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 Mühlberg 10	
Place:	D-35104 Lichtenfels	
Telephone:	+49 (0) 6454/7991-0	Telefax: +49 (0) 6454/7991-30
e-mail:	support@analyticon-diagnostics.com	
Contact person:	Zentrale	Telephone: +49 (0) 6454/7991-0
Internet:	http://www.analyticon-diagnostics.com	

##### 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

##### 2.3. Other hazards

Hazards identification : Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV.

#### SECTION 3: Composition/information on ingredients

##### 3.2. Mixtures

###### **Chemical characterization**

lyophilisate

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**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
	Enzymes			variabel %
	Anorganic ions			variabel %
	Buffering and Conserving components			<1 %
	Microbiozide			<1 %

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.

**After contact with skin**

After contact with skin, wash immediately with: Water.

**After contact with eyes**

Rinse immediately carefully and thoroughly with eye-bath or water.

**After ingestion**

If swallowed, immediately drink: Water. Rinse mouth thoroughly with water.

Seek medical advice immediately.

**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.

**5.3. Advice for firefighters**

In case of fire: Wear self-contained breathing apparatus.

**Additional information**

Suppress gases/vapours/mists with water spray jet.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation.

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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**

Take up mechanically.  
Treat the recovered material as prescribed in the section on waste disposal.  
Take up dust-free and set down dust-free.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Use only in well-ventilated areas.  
The floor should be leak tight, jointless and not absorbent.  
All work processes must always be designed so that the following is excluded:  
inhalation. skin contact. Eye contact.

**Advice on protection against fire and explosion**

Usual measures for fire prevention.  
When using do not smoke.

**Further information on handling**

When using do not eat, drink, smoke, sniff.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

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

**Advice on storage compatibility**

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.

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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:	yellowish
Odour:	characteristic
pH-Value:	7,2

**Changes in the physical state**

Initial boiling point and boiling range: not determined

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.

Lower explosion limits: not determined

Upper explosion limits: not determined

**Oxidizing properties**

Not oxidizing.

Vapour pressure: not determined

Density: not determined

Water solubility: highly soluble.

**Solubility in other solvents**

buffer

**SECTION 10: Stability and reactivity****10.4. Conditions to avoid**

May cause decomposition by long-term light influence.

**10.6. Hazardous decomposition products**

Carbon dioxide. Carbon monoxide. Nitrogen oxides (NOx).

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Toxicokinetics, metabolism and distribution**

No information available.

**Acute toxicity**

No information available.

**Irritation and corrosivity**

No information available.

**Sensitising effects**

No information available.

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

No information available.

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**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****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**



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#### 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

##### Changes

This data sheet contains changes from the previous version in section(s): 1,2.

##### 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.

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