

**Bio Cal®**

Revision date: 17.10.2018

Product code: 1R14209

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

Bio Cal®

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 Contains: Plasma/serum (P/S)

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 ingestionIf 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.

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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.

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

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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: | yellowish |
| Odour: | characteristic |
| pH-Value: | 7-7,4 |

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 (NO_x).

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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.

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)".

Waste disposal number of contaminated packaging

150101 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); paper and cardboard packaging

Contaminated packaging

Water (with cleaning agent).

Completely emptied packages can be recycled.

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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**Changes**

This data sheet contains changes from the previous version in section(s): 1,2,3,7,9,13.

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.)