

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Dip Check Level 2

Revision date: 05.12.2018

Product code: 2R93010

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

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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

Regulation (EC) No. 1272/2008

Special labelling of certain mixtures

Restricted to professional users.

2.3. Other hazards

Contains human sourced material. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Consider all blood derivatives potentially infectious.

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

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
	Human Source Material	10-60 %

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

Further Information

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

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

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General information

Move victim out of danger zone.

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

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

After ingestion

Rinse mouth immediately and drink plenty of water.

Rinse mouth thoroughly with water.

Seek medical advice immediately.

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

No information available.

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

Non-flammable.

5.3. Advice for firefighters

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

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

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.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

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.

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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 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.

7.3. Specific end use(s)

In-vitro-Diagnostics

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

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

Wash hands before breaks and after work.

Eye/face protection

Wear eye protection/face protection. Eye protection: Tightly sealed safety glasses.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. 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

Wear suitable protective clothing. Suitable protective clothing: Lab apron.
Footwear: Chemical resistant safety shoes.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Respiratory protection necessary at: insufficient ventilation. Handling larger quantities.

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

Physical state:	liquid
Colour:	yellowish
Odour:	characteristic

Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	No flash point - measurement carried out until boiling temperature.

Flammability

Solid:	not determined
Gas:	not applicable

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

Auto-ignition temperature

Solid:	not determined
Gas:	not applicable

Decomposition temperature:	not determined
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Oxidizing properties

Not oxidizing.

Vapour pressure:	not determined
Density:	not determined
Water solubility:	highly soluble.
Partition coefficient:	not determined
Vapour density:	not determined
Evaporation rate:	not determined

9.2. Other information

Solid content:	not determined
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SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

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10.6. Hazardous decomposition productsCarbon dioxide. Carbon monoxide. Nitrogen oxides (NO_x).**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute toxicity**

No information available.

Sensitising effects

No information available.

STOT-repeated exposure

No information available.

Specific effects in experiment on an animal

No information available.

Additional information on tests

The mixture is classified as not hazardous according to Directive 1999/45/EC.

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

The product has not been tested.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Other adverse effects

No data available

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Advice on disposal**

Dispose of waste according to applicable legislation. Dispose of waste according to applicable legislation.

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

Waste disposal number of waste from residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

Waste disposal number of used product

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

Waste disposal number of contaminated packaging

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150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number: No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.
14.4. Packing group: No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number: No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.
14.4. Packing group: No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number: No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.
14.4. Packing group: No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.
14.4. Packing group: No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

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

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 3,6.

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Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%

Further Information

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 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.)