

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

Factor Xa Substrate

Revision date: 15.01.2019

Product code: O705506-1

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

Factor Xa Substrate

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**

For this product, a hazard label is not required according to section 1.3.4 of Annex I of the CLP regulation.

2.3. Other hazards

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

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

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
100-01-6	p-nitroaniline			<1 %
	202-810-1	612-012-00-9		
	Acute Tox. 3, Acute Tox. 3, Acute Tox. 3, STOT RE 2, Aquatic Chronic 3; H331 H311 H301 H373 ** H412			

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.

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After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Change contaminated clothing.

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

In rare cases the product can cause temporary erythema of the skin. Causes eye irritation.

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

The product itself does not burn.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus. Wear protective gloves/protective clothing/eye protection/face protection.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment. Make sure spills can be contained, e.g. in sump pallets or kerbed areas.

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

Do not breathe gas/fumes/vapour/spray. 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.

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.

7.3. Specific end use(s)

This information is not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Protect skin by using skin protective cream. After work, wash hands and face. 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.

Environmental exposure controls

No special environmental measures are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	whitish
Odour:	odourless
pH-Value:	No data available

Changes in the physical state

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

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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 g/cm³

Water solubility:

highly soluble.

Solubility in other solvents

buffer

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

The product is stable under storage at normal ambient temperatures.

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

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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
100-01-6	p-nitroaniline				
	oral	ATE 100 mg/kg			
	dermal	ATE 300 mg/kg			
	inhalation vapour	ATE 3 mg/l			
	inhalation aerosol	ATE 0,5 mg/l			

Irritation and corrosivity

In rare cases the product can cause temporary erythema of the skin.

Sensitising effects

No information available.

Carcinogenic/mutagenic/toxic effects for reproduction

No information available.

STOT-repeated exposure

No information available.

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Aspiration hazard

Coughing.

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**

No data available

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.

12.5. Results of PBT and vPvB assessment

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

12.6. Other adverse effects

The product has not been tested.

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)**

No dangerous good in sense of this transport regulation.

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

No dangerous good in sense of this transport regulation.

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

No dangerous good in sense of this transport regulation.

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

No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

SECTION 15: Regulatory information

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15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**EU regulatory information**

2004/42/EC (VOC): 0,5 % (5 g/l)

National regulatory information

Water contaminating class (D): 2 - clearly water contaminating

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 4,7,9,10,11.

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.

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.)