

Material safety data sheet

According to the Regulation (EC) No: 1907/2006

Date: May 16th 2016

Former Date: June 1st 2015

SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Product name	Actim Pancreatitis Controls
Product number	32700ETAC
Components	Two vials of positive (low and high) Actim Pancreatitis controls, one vial of negative control and Reconstitution solution (2 ml).
REACH registration number	Not applicable according to the Regulation (EC) 1907/2006 article 2.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Intended uses	Extrenal quality control for Actim Pancreatitis test, demonstration of negative and high and low positive test results.
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1.3 Details of the supplier of the safety data sheet

Company	Oy Medix Biochemica Ab
Street Address	Klovinpellontie 3
Postcode and post office	FI-02180 ESPOO FINLAND
Telephone	+358-9-547680
E-mail	medix@medixbiochemica.com

1.4 Emergency telephone number

Use your local emergency number.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

The product is not considered dangerous according to Regulation (EC) 1272/2008.

2.2 Label elements

The product is not considered dangerous according to Regulation (EC) 1272/2008.

2.3 Other hazards

The product is not considered dangerous according to Regulation (EC) 1272/2008.

SECTION 3 : COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

Name of the ingredient	CAS-, EC- or index number	REACH registration number	Concentration	Classification
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

No specific advices. Contact a doctor if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Information not available for the product.

4.3 Indication of any immediate medical attention and special treatment needed

Information not available for the product.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Water, carbon dioxide (CO₂), foam, dry powder.

5.2 Special hazards arising from the substance or mixture

No special hazards.

5.3 Advice for firefighters

Information not available for the product.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Information not available for the product.

6.2 Environmental precautions

Indications about waste treatment, see section 13.

6.3 Methods and material for containment and cleaning up

Information not available for the product

6.4 Reference to other sections

Indications about waste treatment, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Observe labels and instructions for use for precautions.

7.2 Conditions for safe storage, including any incompatibilities

Store at +2...+8°C.

7.3 Specific end use(s)

See section 1.2.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Controls parameters

Information not available for the product.

8.2 Exposure controls

Engineering controls

Information not available for the product.

Eye/face protection

Information not available for the product.

Skin protection

Information not available for the product.

Hand protection

Information not available for the product.

Respiratory protection

Information not available for the product.

Thermal hazards

Information not available for the product

Environmental exposure controls

Product contains biological material, and it should be disposed of in accordance with local authority guidelines.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information of basic physical and chemical properties

Trade name: Actim Pancreatitis Controls

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Appearance	Two vials of positive (low and high) Actim Pancreatitis controls, one vial of negative control and Reconstitution solution (clear, colourless).
Odour	Odourless.
Odour threshold	Information not available for the product.
pH	7,4 ± 0,1
Melting point / freezing point	Information not available for the product.
Initial boiling point and boiling range	Information not available for the product.
Flash point	Information not available for the product.
Evaporation rate	Information not available for the product.
Flammability (solid, gas)	Information not available for the product.
Upper/lower flammability or explosive limits	Information not available for the product.
Vapour pressure	Information not available for the product.
Vapour density	Information not available for the product.
Relative density	Information not available for the product.
Solubility(ies)	Information not available for the product.
Partition coefficient; n-octanol/water	Information not available for the product.
Auto-ignition temperature	Information not available for the product.
Decomposition temperature	Information not available for the product.
Viscosity	Information not available for the product.
Explosive properties	Information not available for the product.
Oxidising properties	Information not available for the product.

9.2 Other information
Information not available for the product.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity
Information not available for the product.

10.2 Chemical stability
The product is stable if stored according to the section 7.

10.3 Possibility of hazardous reactions
Information not available for the product.

10.4 Conditions to avoid
Do not use the controls if the vials are damaged. Do not store the product outside of the temperature range +2...+8°C.

10.5 Incompatible materials
Information not available for the product.

10.6 Hazardous decomposition products
Information not available for the product.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects
Acute toxicity

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Information not available for the product.

Irritation

Information not available for the product.

Corrosivity

Information not available for the product.

Sensitisation

Information not available for the product.

Repeated dose toxicity

Information not available for the product.

Carcinogenicity

Information not available for the product.

Mutagenicity

Information not available for the product.

Toxicity for reproduction

Information not available for the product.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The product is not considered dangerous to environment according to Regulation (EC) 1272/2008.

12.2 Persistence and degradability

Information not available for the product.

12.3 Bioaccumulative potential

Information not available for the product.

12.4 Mobility in soil

Information not available for the product.

12.5 Results of PBT and vPvB assessment

Information not available for the product.

12.6 Other adverse effects

Information not available for the product.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Local authority guidelines for disposing biological materials should be followed.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

Information not available for the product.

14.2 UN proper shipping name

Information not available for the product.

14.3 Transport hazard classes

Information not available for the product.

14.4 Packing group

Information not available for the product.

14.5 Environmental hazards

Information not available for the product.

14.6 Special precautions for user

Information not available for the product.

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14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Information not available for the product.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Not applicable.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this product.

SECTION 16: OTHER INFORMATION

Changes to previous version

Changes in sections 1, 3, 5 and 15.

Abbreviations and acronyms

Not applicable.

Literature references and sources for data

Not applicable.

Methods used for classification

Regulation (EC) 1272/2008.

Hazard and precautionary statements

Not applicable.

Training advice

Oy Medix Biochemica Ab, see section 1.3.
Instructions for use is delivered within each kit.