

Material safety data sheet

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

Date: June 19th 2019

Former Date: December 21st 2017

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

1.1 Product identifier

Product name	Actim Pancreatitis
Product number	32731ETAC, 32732ETAC, 32735BU
Components	Dipsticks
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	For <i>in vitro</i> diagnostic use. Qualitative test for acute pancreatitis screening.
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1.3 Details of the supplier of the safety data sheet

Company	Actim Oy
Street Address	Klovinpellontie 3
Postcode and post office	FI-02180 ESPOO FINLAND
Telephone	+385-9-547680
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

None of the components of the product is classified as dangerous according to Regulation (EC) 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
None required.

2.3 Other hazards

None of the components of the product is classified as 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.

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

Instructions for waste disposal, 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

Instructions for waste disposal, 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...+25°C.

7.3 Specific end use(s)

See section 1.2.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Controls parametres

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

Information not available for the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information of basic physical and chemical properties**

Appearance	Test kits contains dipsticks
Odour	Not applicable
Odour threshold	Not applicable
pH	Not applicable
Melting point / freezing point	Not applicable
Initial boiling point and boiling range	Not applicable
Flash point	Not applicable
Evaporation rate	Not applicable
Flammability (solid, gas)	Not applicable
Upper/lower flammability or explosive limits	Not applicable
Vapour pressure	Not applicable
Vapour density	Not applicable
Relative density	Not applicable
Solubility(ies)	Not applicable
Partition coefficient; n-octanol/water	Not applicable
Auto-ignition temperature	Not applicable
Decomposition temperature	Not applicable
Viscosity	Not applicable
Explosive properties	Not applicable
Oxidising properties	Not applicable

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

Moisture damages the dipsticks.

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

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

None of the components of the product is dangerous to the 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

The product used in *in vitro* diagnostic, as all biological samples and materials, need to be discarded following the local waste disposal regulations.

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.

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14.6 Special precautions for user
Information not available for the product.

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
Directive (EC) 98/79.

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
Regulation (EC) 1272/2008 added to section 2.2.
Disclaimer added to the section 16.
Company name change

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
Actim Oy, see section 1.3.
Instructions for use are delivered within each kit.

Disclaimer
The information provided in this Safety Data Sheet is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions and is not to be considered a warranty or quality specification.