

# Material safety data sheet

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

Date: May 16<sup>th</sup> 2016

Former Date: January 15<sup>th</sup> 2016

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

### 1.1 Product identifier

**Product name** Actim Pancreatitis  
**Product number** 32731ETAC, 32732ETAC, 32734BU, 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 *in vitro* diagnostic use. Qualitative test for acute pancreatitis screening.

### 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** +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

Not applicable according to the Directive (EC) 98/79.

### 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 (CO<sub>2</sub>), 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**

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