

# Material safety data sheet

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

Date: July 4<sup>th</sup> 2019

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

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

### 1.1 Product identifier

<b>Product name</b>	Actim Pancreatitis Controls
<b>Product number</b>	32700ETAC
<b>Components</b>	Two vials of positive (low and high) Actim Pancreatitis controls, one vial of negative control and Reconstitution solution (2 ml).
<b>REACH registration number</b>	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

<b>Intended uses</b>	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

<b>Company</b>	Actim Oy
<b>Street Address</b>	Klovinpellontie 3
<b>Postcode and post office</b>	FI-02180 ESPOO FINLAND
<b>Telephone</b>	+358-9-547680
<b>E-mail</b>	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.  
None required.

### 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 (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**

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**

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

Company name change

Clarification in section 2.2.

Disclaimer added to the section 16.

### **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 is 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.