

# Material safety data sheet

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

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

Former Date: June 24<sup>th</sup> 2019

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

### 1.1 Product identifier

<b>Product name</b>	Actim PROM Controls
<b>Product number</b>	30800ETAC, 30800ETUS, 30800ETAL
<b>Components</b>	Two vials of positive (low and high) IGFPB-1 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>	External quality controls for Actim PROM test, demonstration of negative and weak and clear 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-20180 ESPOO FINLAND
<b>Telephone</b>	+358-9-547680
<b>E-mail</b>	medix@medixbiochemica.com

### 1.4 Emergency telephone number

Your local emergency telephone 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

The product is not considered dangerous according to Regulation (EC) 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**

Component	Name of the ingredient	CAS-, EC- or index number	REACH registration number	Concentration	Classification
Reconstituted Controls	Thimerosal	CAS 54-64-8	Not available for the substance.	< 0,01 %	<b>EC 1272/2008:</b> Acute toxicity, oral, cat. 1, H300 Acute toxicity, dermal, cat. 1, H310 Acute toxicity, inhalation, cat. 2, H330 Specific target organ toxicity - repeated exposure, cat. 2, H373 Acute aquatic toxicity, cat.1, H400 Chronic aquatic toxicity, cat. 1, H410

**SECTION 4: FIRST AID MEASURES****4.1 Description of first aid measures**

No specific advices. Contact a doctor if necessary.

**If inhaled:**

Remove to fresh air.

**In case of skin contact:**

Wash off with plenty of water. Remove contaminated clothing.

**In case of eye contact:**

Rinse out with plenty of water with eyelid held wide open. Contact an ophthalmologist if necessary.

**If swallowed:**

Rinse the mouth with water. 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**

Use personal protective equipment, e.g. protective clothes and safety glasses when cleaning up spills. Avoid breathing vapors/mist/gas. Ensure adequate ventilation.

**6.2 Environmental precautions**

Indications about waste treatment, see section 13.

**6.3 Methods and material for containment and cleaning up**  
Wipe up with appropriate absorbent, e.g. paper towel, and place clean up supplies in sealed container for disposal.

**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 label 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**  
Handle with general industrial hygiene and safety practice.

**Eye/face protection**  
Wear approved safety goggles.

**Skin protection**  
Wear appropriate clothing.

**Hand protection**  
Wear protective gloves.

**Respiratory protection**  
Respiratory protection is not required.

**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

<b>Appearance</b>	Two vials of positive (low and high) IGFPB-1 controls, one vial of negative control and Reconstitution Solution.
<b>Odour</b>	Odourless.
<b>Odour threshold</b>	Information not available for the product.
<b>pH</b>	Reconstituted Controls: 6,0 ± 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...+25°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**  
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 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.

**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

**Abbreviations and acronyms**

Not applicable.

**Literature references and sources for data**

Suppliers MSDS for Thimerosal.

**Methods used for classification**

Regulation (EC) 1272/2008

**Hazard and precautionary statements**

H300 Fatal if swallowed

H310 Fatal in contact with skin

H330 Fatal if inhaled

H373 May cause damage to organs through prolonged or repeated exposure

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

**Training advice**

Instructions for use is delivered within each kit.

Actim Oy, see section 1.3.

**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.