

Material safety data sheet

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

Date: February 9th 2016

Former Date: February 3rd 2016

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

1.1 Product identifier

Product name	Actim PROM Controls
Product number	30800ETAC, 30800ETUS, 30800ETAL
Components	Two vials of positive (low and high) IGFPB-1 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	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

Company	Oy Medix Biochemica Ab
Street Address	Klovinpellontie 3
Postcode and post office	FI-20180 ESPOO FINLAND
Telephone	+358-9-547680
E-mail	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.

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 %	EC 1272/2008: 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 (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**

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

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

Correction in section 4.

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.

Oy Medix Biochemica Ab, see section 1.3.