

Material safety data sheet

According to the Regulation (EC) 1907/2006

Date: February 3rd, 2016

Former Date: June 1st, 2015

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

1.1 Product identifier

Product name	Actim PROM
Product number	30830ETAC, 30831ETAC, 30832ETAC, 30834BU, 30831ETUS, 30830ETAL, 30831ETAL, 30832ETAL, 30831RETAC, 30832RETAL
Components	Dipstick, Specimen Extraction Solution (0.5 ml / tube) and swab.
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 immunochromatographic dipstick test for detecting the presence of amniotic fluid in vaginal secretions during pregnancy.
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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-02180 ESPOO FINLAND
Telephone	+358-9-547680
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 the 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 the 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

Information not available for the product.

5.2 Special hazards arising from the substance or mixture

Information not available for the product.

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 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

Information not available for the product.

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

Appearance	Test kit contains dipsticks, Specimen Extraction Solution (clear, colourless solution) and swabs.
Odour	Odourless
Odour threshold	Information not available for the product
pH	Specimen Extraction Solution: 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

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 the 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

Because the product is intended to in vitro diagnostic use, local waste disposal regulations of biological material 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.

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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
Directive (EC) 98/79.

15.2 Chemical safety assessment
Information not available for the product.

SECTION 16: OTHER INFORMATION

Changes to previous version
Components added to section 1.

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 is delivered within each kit.