Material safety data sheet
According to the Regulation (EC) 1907/2006

Date: June 25th, 2019
Former Date: May 20th, 2019

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

1.1 Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>Actim PROM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product number</td>
<td>30830ETAC, 30831ETAC, 30832ETAC, 30834BU, 30831ETUS, 30830ETAL, 30831ETAL, 30832ETAL, 30831RETAC, 30832RETAL</td>
</tr>
<tr>
<td>Components</td>
<td>Dipstick, Specimen Extraction Solution (0.5 ml / tube) and swab.</td>
</tr>
<tr>
<td>REACH registration number</td>
<td>Not applicable according to the Regulation (EC) 1907/2006 article 2.</td>
</tr>
</tbody>
</table>

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. |

1.3 Details of the supplier of the safety data sheet

<table>
<thead>
<tr>
<th>Company</th>
<th>Actim Oy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address</td>
<td>Klovinpellontie 3</td>
</tr>
<tr>
<td>Postcode and post office</td>
<td>FI-02180 ESPOO FINLAND</td>
</tr>
<tr>
<td>Telephone</td>
<td>+358-9-547680</td>
</tr>
<tr>
<td>E-mail</td>
<td><a href="mailto:medix@medixbiochemica.com">medix@medixbiochemica.com</a></td>
</tr>
</tbody>
</table>

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

Labelling (REGULATION (EC) No 1272/2008)

None required.

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

<table>
<thead>
<tr>
<th>Name of the ingredient</th>
<th>CAS-, EC- or index number</th>
<th>REACH registration number</th>
<th>Concentration</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Test kit contains dipsticks, Specimen Extraction Solution (clear, colourless solution) and swabs.</td>
</tr>
<tr>
<td>Odour</td>
<td>Odourless</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>pH</td>
<td>Specimen Extraction Solution: 6.0 ± 0.1</td>
</tr>
<tr>
<td>Melting point / freezing point</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Flash point</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Relative density</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Partition coefficient; n-octanol/water</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Information not available for the product</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>Information not available for the product</td>
</tr>
</tbody>
</table>

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.
### 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 |

| 15.2 Chemical safety assessment |
| Information not available for the product. |

#### SECTION 16: OTHER INFORMATION

| Changes to previous version |
| Company name change. |

**Abbreviations and acronyms**
Not applicable.

**Literature references and sources for data**
Not applicable.

**Methods used for classification**

**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.