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

## 1.1 Product identifier

<table>
<thead>
<tr>
<th><strong>Product name</strong></th>
<th>Actim PROM Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product number</strong></td>
<td>30800ETAC, 30800ETUS, 30800ETAL</td>
</tr>
<tr>
<td><strong>Components</strong></td>
<td>Two vials of positive (low and high) IGFPB-1 controls, one vial of negative control and Reconstitution Solution (2 ml).</td>
</tr>
<tr>
<td><strong>REACH registration number</strong></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**
External quality controls for Actim PROM test, demonstration of negative and weak and clear positive test results.

## 1.3 Details of the supplier of the safety data sheet

<table>
<thead>
<tr>
<th><strong>Company</strong></th>
<th>Oy Medix Biochemica Ab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Street Address</strong></td>
<td>Klovinpellontie 3</td>
</tr>
<tr>
<td><strong>Postcode and post office</strong></td>
<td>FI-20180 ESPOO FINLAND</td>
</tr>
<tr>
<td><strong>Telephone</strong></td>
<td>+358-9-547680</td>
</tr>
<tr>
<td><strong>E-mail</strong></td>
<td><a href="mailto:medix@medixbiochemica.com">medix@medixbiochemica.com</a></td>
</tr>
</tbody>
</table>

## 1.4 Emergency telephone number

Your local emergency telephone number.

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# 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

<table>
<thead>
<tr>
<th>Component</th>
<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>Reconstituted Controls</td>
<td>Thimerosal</td>
<td>CAS 54-64-8</td>
<td>Not available for the substance.</td>
<td>&lt; 0,01 %</td>
<td>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</td>
</tr>
</tbody>
</table>

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 cloves 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Two vials of positive (low and high) IGFPB-1 controls, one vial of negative control and Reconstitution Solution.</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>Reconstituted Controls: 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>Property</td>
<td>Information not available for the product.</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td></td>
</tr>
<tr>
<td>Vapour density</td>
<td></td>
</tr>
<tr>
<td>Relative density</td>
<td></td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient; n-octanol/water</td>
<td></td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td></td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td></td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Explosive properties</td>
<td></td>
</tr>
<tr>
<td>Oxidising properties</td>
<td></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
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.