

# Material safety data sheet

According to the Regulation EC 1907/2006

Date: July 7<sup>th</sup>, 2022

Former Date: May 20<sup>th</sup>, 2022

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

### 1.1 Product identifier

<b>Product name</b>	Actim Partus
<b>Product number</b>	31930ETAC, 31931ETAC, 31934BU, 31930ETAL, 31931ETAL, 31931RETAC, 31931RETAL
<b>Components</b>	Dipstick, Specimen Extraction Solution (0.5 ml / tube) and swab.
<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>	For in vitro diagnostic use. Qualitative immunochromatographic dipstick test for detecting the presence of phosphorylated IGFBP-1 (insulin-like growth factor binding protein-1) in cervical secretions during pregnancy.
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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-02180 ESPOO FINLAND
<b>Telephone</b>	+358-9-547680
<b>E-mail</b>	actim@actimtest.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

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

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.

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## **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 parametres**

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.

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## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information of basic physical and chemical properties

<b>Appearance</b>	Test kit contains dipsticks, Specimen Extraction Solution (clear, colourless solution) and swabs. Versions 31931RETAC, 31931RETAL contain also one cartridge for reading the result with the Actim 1ngeni instrument.
<b>Odour</b>	Odourless
<b>Odour threshold</b>	Information not available for the product
<b>pH</b>	Specimen Extraction Solution: 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

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.

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## **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 be used for 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**

Section 1.2 updated  
Disclaimer modified

### **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**

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. Actim Oy does not guarantee this to be all-inclusive and shall not be held liable for any damages resulting from handling of or contact with the above product.