Material safety data sheet

According to the Regulation (EC) 1907/2006

Date: May 13th 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 CRP
Product number	31031ETAC
Components	Dipsticks (20 pcs), Capillaries (20 pcs) and Specimen Dilution Buffer solution (20 pcs, 0.5 ml / tube).
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. Semiquantitative test for detection of C-Reactive Protein (CRP) in whole blood samples.

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 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 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. Consult 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 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

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, capillaries and Specimen Dilution Buffer (clear, colourless solution).
Odour	Odourless
Odour threshold	Information not available for the product.
pH	Specimen Dilution Buffer: 7,3 ± 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 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 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.

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 are delivered within each kit.

Signatures:

Dokumentti hyväksytty:	Olen hyväksynyt dokumentin.	
Name:	**Korvuo Armi** **MEDIXBIOCHEMICA\KORVUAR** Korvuo Armi	Title:
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