

Material safety data sheet

According to the Regulation (EC) No: 1907/2006

Date: June 25th, 2019

Former Date: September 26, 2017

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

1.1 Product identifier

Product name	Actim Calprotectin
Product number	35032ETAC
Components	Dipsticks and Specimen Dilution Buffer (2x10 Dipsticks, 20x3 ml Specimen Dilution Buffer)
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 <i>in vitro</i> diagnostic use. Semiquantitative test for detection of calprotectin in feces.
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1.3 Details of the supplier of the safety data sheet

Company	Actim Oy
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

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 Regulation (EC) 1272/2008.

SECTION 3 : COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

Component	Name of the ingredient	CAS-, EC- or index number	REACH registration number	Concentration	Classification
Specimen Dilution buffer 3 ml/tube	Sodium azide	CAS 26628-22-8	Information not available according to the Regulation (EC) 1907/2006	< 0,1 %	EC 1272/2008: Acute toxicity, cat. 2, H300 Acute aquatic toxicity, cat. 1, H400 Chronic aquatic toxicity, cat. 1, H410

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

No specific advices for the product. 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 gloves and safety glasses when cleaning up spills. Avoid breathing vapors/mist/gas. Ensure adequate ventilation.

6.2 Environmental precautions

Instructions for waste disposal, 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

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...+30°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.

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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

Appearance	Dipsticks and Specimen Dilution buffer (clear, colourless solution)
Odour	Odourless
Odour threshold	Information not available for the product
pH	Specimen Dilution Buffer: 8,0 ± 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 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

The product used in *in vitro* diagnostic, as all biological samples and materials, need to be discarded following the local waste disposal regulations.

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

A chemical safety assessment has not been carried out for this product.

SECTION 16: OTHER INFORMATION

Changes to previous version

Company name change.

Regulation (EC) 1272/2008 added to the section 2.2.

Disclaimer added to the section 16.

Abbreviations and acronyms

Not applicable.

Literature references and sources for data

Suppliers MSDS for Sodium azide.

Methods used for classification

Regulation (EC) 1272/2008.

Hazard and precautionary statements

H300: Fatal if swallowed

H400: Very toxic to aquatic life

H410: Toxic to aquatic life with long-lasting effects

Training advice

Instructions for use are delivered within each kit.

Actim Oy, see section 1.3.

Disclaimer

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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.