

Material safety data sheet

According to the Regulation (EC) 1907/2006

Date: September 1st, 2021

Former Date: -

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

1.1 Product identifier

| | |
|----------------------------------|---|
| Product name | Actim® SARS-CoV-2 + Actim® Influenza A&B |
| Product number | 36031ETAC |
| Components | Dipsticks (10 pcs SARS-CoV-2 and 10 pcs Influenza A&B), Swab Extraction Buffer (10x 0,3ml), Swabs (10 pcs). |
| REACH registration number | Not applicable according to Regulation (EC) 1907/2006 article 2. |

1.2 Relevant identified uses of the substance or mixture and uses advised against

| | |
|----------------------|--|
| Intended uses | <p>The Actim® SARS-CoV-2 is a visually interpreted, in vitro diagnostic immunochromatographic rapid test for the qualitative detection of SARS-CoV-2 virus antigens in nasopharyngeal swab samples. The test is intended for professional use to help diagnose acute COVID-19 infection.</p> <p>The Actim® Influenza A&B test is a visually interpreted, qualitative immunochromatographic rapid test for detection of influenza type A and type B virus antigens in respiratory samples. The test is intended for professional use to help diagnose acute influenza infections.</p> |
|----------------------|--|

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 | 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 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

| Name of the ingredient | CAS-, EC- or index number | REACH registration number | Concentration | Classification |
|------------------------|---------------------------|---------------------------|----------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

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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

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

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...+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

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.

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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, Swab Extraction Buffer (clear, colourless solution) and swabs. |
| Odour | Odourless |
| Odour threshold | Information not available for the product |
| pH | Swab Extraction Buffer: 9,3 ± 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

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Moisture damages the dipsticks and controls.

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

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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

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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.