

**Trade name:** Quo-Lab A1C Control Kit / Quo-Test A1C Control Kit

**Product no.:** 0071 / 0061

**Current version :** 1.0.0, issued: 09.09.2016

**Replaced version:** -, issued: -

**Region:** GB

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

**Trade name**

**Quo-Lab A1C Control Kit / Quo-Test A1C Control Kit**

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

**Relevant identified uses of the substance or mixture**

Quality control material for checking the Quo-Lab/Quo-Test Analyzer and Quo-Lab/Quo-Test A1C Test Kit  
In-vitro diagnostic medical device

**Uses advised against**

No data available.

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

**Address**

EKF-diagnostic GmbH  
Ebendorfer Chaussee 3  
39179 Barleben  
Germany

Telephone no. +49 (0)3 92 03 / 511 - 0

Fax no. +49 (0)3 92 03 / 511 - 171

**Information provided by / telephone**

EKF-diagnostic GmbH  
Telephone: +49 (0)39203 / 511 - 0 (7 am - 4 pm on workdays)

**Advice on Safety Data Sheet**

support@ekf-diagnostic.de

### 1.4 Emergency telephone number

For medical advice (in German and English):  
+49 (0)551 192 40 (Giftinformationszentrum Nord)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification information**

This product does not meet the classification and labelling criteria given in the Regulation (EC) No 1272/2008 (CLP).

### 2.2 Label elements

Not relevant

### 2.3 Other hazards

This product contains materials of human origin and should be considered potentially infectious. Please observe the information given in this safety data sheet.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable. The product is not a substance.

### 3.2 Mixtures

**Chemical characterization**

Mixture (preparation)

**Hazardous ingredients**

This product does not contain substances to be mentioned according to EU Regulation No 1907/2006 (REACH), annex II.

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## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

In case of persisting adverse effects, consult a physician. In any case show the physician the Safety Data Sheet.

#### After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air. In case of breathing difficulties give oxygen.

#### After skin contact

When in contact with the skin, clean with soap and water.

#### After eye contact

Remove contact lenses. Rinse eye thoroughly under running water keeping eyelids wide open and protecting the unaffected eye (at least 10 to 15 minutes). Seek medical assistance.

#### After ingestion

Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

### 4.2 Most important symptoms and effects, both acute and delayed

No data available.

### 4.3 Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Dry chemical extinguisher; Water spray jet

#### Unsuitable extinguishing media

No data available.

### 5.2 Special hazards arising from the substance or mixture

Fire will produce dense black smoke.

### 5.3 Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Keep people away and stay on the upwind side.

#### For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

### 6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

### 6.3 Methods and material for containment and cleaning up

Contain and collect spillage with non-combustible absorbent materials, e.g. sand, earth, vermiculite, diatomaceous earth. When picked up, treat material as prescribed under heading "Disposal considerations".

### 6.4 Reference to other sections

No data available.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

**Advice on safe handling**

Avoid contact with skin and eyes. The product contains processed human blood. All blood donor units have been tested and found non-reactive for hepatitis B surface antigen, hepatitis C antibody, HIV-1 and HIV-2 antibodies and syphilis.

**General protective and hygiene measures**

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work.

**Advice on protection against fire and explosion**

No special measures necessary.

### 7.2 Conditions for safe storage, including any incompatibilities

**Technical measures and storage conditions**

Keep container tightly closed and dry in a cool, well-ventilated place. Protect from heat and direct sunlight.

**Recommended storage temperature**

Value 2 - 8 °C

**Requirements for storage rooms and vessels**

Keep the product in the original packing.

**Advice on storage assembly**

Do not store together with: Acids; heavy metal compounds; Oxidizing agents

### 7.3 Specific end use(s)

No data available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

No parameters available for monitoring.

### 8.2 Exposure controls

**Appropriate engineering controls**

No data available.

**Personal protective equipment**

**Respiratory protection**

No special measures required.

**Eye / face protection**

Safety glasses recommended

**Hand protection**

Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

**Other**

Check suitability of protective clothing for the specific workplace conditions. Chemical resistance of the protective equipment should be discussed with the manufacturer of the protective equipment.

**Environmental exposure controls**

No data available.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<b>Form/Colour</b>	
solid	
red	
<b>Odour</b>	
odourless	
<b>Odour threshold</b>	
No data available	
<b>pH value</b>	
Remarks	neutral

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<b>Boiling point / boiling range</b>
No data available
<b>Melting point / melting range</b>
No data available
<b>Decomposition point / decomposition range</b>
No data available
<b>Flash point</b>
No data available
<b>Auto-ignition temperature</b>
No data available
<b>Oxidising properties</b>
No data available
<b>Explosive properties</b>
No data available
<b>Flammability (solid, gas)</b>
No data available
<b>Lower flammability or explosive limits</b>
No data available
<b>Upper flammability or explosive limits</b>
No data available
<b>Vapour pressure</b>
No data available
<b>Vapour density</b>
No data available
<b>Evaporation rate</b>
No data available
<b>Relative density</b>
No data available
<b>Density</b>
No data available
<b>Solubility in water</b>
No data available
<b>Solubility(ies)</b>
No data available
<b>Partition coefficient: n-octanol/water</b>
No data available
<b>Viscosity</b>
No data available

## 9.2 Other information

<b>Other information</b>
No data available.

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**SECTION 10: Stability and reactivity**

**10.1 Reactivity**

No data available.

**10.2 Chemical stability**

Stable under recommended storage and handling conditions (See section 7).

**10.3 Possibility of hazardous reactions**

Dangerous reactions are not to be expected when handling product according to its intended use.

**10.4 Conditions to avoid**

None known

**10.5 Incompatible materials**

Acids; Heavy metals; Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products known.

**SECTION 11: Toxicological information**

**11.1 Information on toxicological effects**

**Acute oral toxicity**

No data available

**Acute dermal toxicity**

No data available

**Acute inhalational toxicity**

No data available

**Skin corrosion/irritation**

No data available

**Serious eye damage/irritation**

No data available

**Respiratory or skin sensitisation**

No data available

**Germ cell mutagenicity**

No data available

**Reproduction toxicity**

No data available

**Carcinogenicity**

No data available

**STOT-single exposure**

No data available

**STOT-repeated exposure**

No data available

**Aspiration hazard**

No data available

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

When handled appropriately adverse health effects are not to be expected.

**Other information**

The toxicological properties of the product are not yet fully determined.

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## SECTION 12: Ecological information

### 12.1 Toxicity

<b>Toxicity to fish (acute)</b>
No data available

<b>Toxicity to fish (chronic)</b>
No data available

<b>Toxicity to Daphnia (acute)</b>
No data available

<b>Toxicity to Daphnia (chronic)</b>
No data available

<b>Toxicity to algae (acute)</b>
No data available

<b>Toxicity to algae (chronic)</b>
No data available

<b>Bacteria toxicity</b>
No data available

### 12.2 Persistence and degradability

No data available.

### 12.3 Bioaccumulative potential

No data available.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of PBT and vPvB assessment

No data available.

### 12.6 Other adverse effects

No data available.

### 12.7 Other information

<b>Other information</b>
Do not let enter the product into drains or waterways and do not store on public depositories.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

**Product**

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.  
dispose of in accordance with local regulation.

**Packaging**

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

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## SECTION 14: Transport information

### 14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

### 14.2 Transport IMDG

The product is not subject to IMDG regulations.

### 14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

### 14.4 Other information

No data available.

### 14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

### 14.6 Special precautions for user

No data available.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulations

#### Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

#### REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

#### Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

#### Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

### 15.2 Chemical safety assessment

No data available.

## SECTION 16: Other information

#### Sources of key data used to compile the data sheet:

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EU

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

#### Department issuing safety data sheet

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This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

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