

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

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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

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

Safety data sheet in accordance with 1907/2006/EC



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

9.2 Other information

Other information
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

Toxicity to fish (acute)
No data available

Toxicity to fish (chronic)
No data available

Toxicity to Daphnia (acute)
No data available

Toxicity to Daphnia (chronic)
No data available

Toxicity to algae (acute)
No data available

Toxicity to algae (chronic)
No data available

Bacteria toxicity
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

Other information
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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