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)392 03 / 511 - 0
   Fax no. +49 (0)392 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.
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.
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 workstation 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.
### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Form/Colour</th>
<th>solid</th>
<th>red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour</td>
<td>odourless</td>
<td></td>
</tr>
<tr>
<td>Odour threshold</td>
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<td></td>
</tr>
<tr>
<td>pH value</td>
<td>Remarks</td>
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</tbody>
</table>

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

### 9.2 Other information

<table>
<thead>
<tr>
<th>Other information</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other information</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Acute inhalational toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>No data available</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Reproduction toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>No data available</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>No data available</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>No data available</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>No data available</td>
</tr>
<tr>
<td>Delayed and immediate effects as well as chronic effects from short and long-term exposure</td>
<td>When handled appropriately adverse health effects are not to be expected.</td>
</tr>
<tr>
<td>Other information</td>
<td>The toxicological properties of the product are not yet fully determined.</td>
</tr>
</tbody>
</table>
SECTION 12: Ecological information

12.1 Toxicity

<table>
<thead>
<tr>
<th>Toxicity to fish (acute)</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish (chronic)</td>
<td>No data available</td>
</tr>
<tr>
<td>Toxicity to Daphnia (acute)</td>
<td>No data available</td>
</tr>
<tr>
<td>Toxicity to Daphnia (chronic)</td>
<td>No data available</td>
</tr>
<tr>
<td>Toxicity to algae (acute)</td>
<td>No data available</td>
</tr>
<tr>
<td>Toxicity to algae (chronic)</td>
<td>No data available</td>
</tr>
<tr>
<td>Bacteria toxicity</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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.
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

<table>
<thead>
<tr>
<th>EU regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>REACH candidate list of substances of very high concern (SVHC) for authorisation</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances</td>
</tr>
<tr>
<td>This product is not subject to Part 1 or 2 of Annex I.</td>
</tr>
</tbody>
</table>

15.2 Chemical safety assessment
No data available.

SECTION 16: Other information

Sources of key data used to compile the data sheet:
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
UMCO Umwelt Consult GmbH
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Tel.: +49 40 / 555 546 300  Fax: +49 40 / 555 546 357  e-mail: umco@umco.de
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