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

1.1. Product identifier
Product name: Alere Afinion™ HbA1c Control

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

Relevant identified uses
Main use category: Professional use
Use of the substance/mixture: In Vitro Diagnostic Medical Device

Uses advised against
No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier
Alere Technologies AS
Kjelsåsveien 161, P.O. Box 6863 Rodeløkka
NO-0504 Oslo - Norway
T +47-24056000 - F +47-24056010
aleretech.no@alere.com - www.alere.com

Manufacturer
Alere Technologies AS
Kjelsåsveien 161, P.O. Box 6863 Rodeløkka
NO-0504 Oslo - Norway
T +47-24056000 - F +47-24056010
aleretech.no@alere.com - www.alere.com

1.4. Emergency telephone number

Country: United Kingdom
Organisation/Company: National Poisons Information Service (Newcastle Unit)
Address: Claremont Place, Newcastle-upon-Tyne, Newcastle
Emergency number: +44 191 2606182/+44 191 2606180 24H

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

2.2. Label elements
Labelling according to Regulation (EC) No. 1272/2008 [CLP]
EUH-statements: EUH210 - Safety data sheet available on request
Extra phrases: In vitro diagnostic medical devices, EU-regulation 1272/2008/EC, article 1, paragraph 5d

2.3. Other hazards
Other hazards not contributing to the classification: Afinion™ HbA1c Control kit contains liquid preparations of stabilized porcine whole blood (Control C I) and human whole blood (Control C II), respectively. No test method can offer complete assurance that products containing human source material will be absent infectious agents.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance
Not applicable

3.2. Mixture
Comment: None of the other components are subject to classification, or are present in quantities above regulatory disclosure limits
according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

### Table 1: Name, Product Identifier, and Classification

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>zinc chloride</td>
<td>(CAS No) 7646-85-7 (EC no) 231-592-0 (REACH-no) O1-2119472431-44</td>
<td>&lt; 0.06</td>
<td>Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</td>
</tr>
<tr>
<td>poly(oxy-1,2-ethanediyl), alpha-[(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxy-</td>
<td>(CAS No) 9036-19-5 (REACH-no) N/A</td>
<td>&lt; 0.05</td>
<td>Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Chronic 2, H411</td>
</tr>
<tr>
<td>sodium azide</td>
<td>(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) O11-004-00-7 (REACH-no) O1-2119457019-37</td>
<td>&lt; 0.05</td>
<td>Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</td>
</tr>
</tbody>
</table>

### Specific Concentration Limits:

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>Specific Concentration Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>zinc chloride</td>
<td>(CAS No) 7646-85-7 (EC no) 231-592-0 (REACH-no) O1-2119472431-44</td>
<td>(C &gt;= 5) STOT SE 3, H335</td>
</tr>
</tbody>
</table>

Full text of H-statements: see section 16

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of first aid measures

- **First-aid measures general**: Get medical advice/attention if you feel unwell.
- **First-aid measures after inhalation**: No specific first aid measures noted.
- **First-aid measures after skin contact**: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- **First-aid measures after eye contact**: Immediately flush with plenty of water or eyewash solution for up to 10 minutes. Obtain medical attention if pain, blinking or redness persist.
- **First-aid measures after ingestion**: (If swallowed, rinse mouth with water (only if the person is conscious)). Drink a few glasses of water or milk. Call a poison center or a doctor if you feel unwell.

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

- **Symptoms/injuries**: Not expected to present a significant hazard under anticipated conditions of normal use.

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

In all cases of doubt, or when symptoms persist, seek medical attention.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1. Extinguishing media

- **Suitable extinguishing media**: Use extinguishing media appropriate for surrounding fire.
- **Unsuitable extinguishing media**: None to our knowledge.

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

- **Fire hazard**: Non flammable.

#### 5.3. Advice for firefighters

- **Firefighting instructions**: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- **Protection during firefighting**: Do not enter fire area without proper personal protective equipment, including respiratory protection.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

- **General measures**: Wear appropriate personal protective equipment - see Section 8.

- **For non-emergency personnel**: Evacuate unnecessary personnel.

- **For emergency responders**: Equip cleanup crew with proper protection.

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

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

- **Methods for cleaning up**: Take up liquid spill into absorbent material. The contaminated area should be cleaned up immediately with a suitable decontaminant.
6.4. Reference to other sections
See section 13 for waste handling. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling
Precautions for safe handling: Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Wear appropriate personal protective equipment - see Section 8.

7.2. Conditions for safe storage, including any incompatibilities
Incompatible materials: Sources of ignition. Direct sunlight.
Storage temperature: 2 - 8 °C (36 - 46°F)

7.3. Specific end use(s)
For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

<table>
<thead>
<tr>
<th>local name</th>
<th>sodium azide (26628-22-8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>Local name</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>WEL TWA (mg/m³)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>WEL STEL (mg/m³)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Remark (WEL)</td>
</tr>
<tr>
<td>local name</td>
<td>zinc chloride (7646-85-7)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Local name</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>WEL TWA (mg/m³)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>WEL STEL (mg/m³)</td>
</tr>
</tbody>
</table>

8.2. Exposure controls
Appropriate engineering controls: Provide eyewash station.
Hand protection: Wear suitable gloves resistant to chemical penetration. Neoprene or nitrile rubber gloves. Layer thickness : 0,10mm. Breakthrough time : >480 min. STANDARD EN 374
Eye protection: Not necessary under the recommended storage and handling conditions. Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166
Skin and body protection: Lab coat
Respiratory protection: Respiratory protection not applicable
Other information: Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment. Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties
Physical state: Liquid
Colour: red.
Odour: No data available
Odour threshold: No data available
pH: 7.8 - 8.2
Relative evaporation rate (butylacetate=1): No data available
Melting point: No data available
Freezing point: No data available
Boiling point: No data available
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Flammability (solid, gas): Non flammable
Vapour pressure: No data available
Relative vapour density at 20 °C: No data available
Relative density: No data available
Solubility: Soluble in water.
Log Pow: No data available
Viscosity, kinematic: No data available
Viscosity, dynamic: No data available
Explosive properties: Not explosive.
Oxidising properties: Non flammable.
Explosive limits: No data available

9.2. Other information
Additional information: None to our knowledge

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity
Stable under normal conditions.

10.2. Chemical stability
Stable under normal conditions of use.

10.3. Possibility of hazardous reactions
Not established.

10.4. Conditions to avoid
Avoid strong heating.

10.5. Incompatible materials
None to our knowledge.

10.6. Hazardous decomposition products
No decomposition if stored normally.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
Acute toxicity: Ingestion may cause nausea and vomiting

**sodium azide (26628-22-8)**
- LD50 oral rat: 27 mg/kg
- LD50 dermal rat: 50 mg/kg
- LD50 dermal rabbit: 20 mg/kg

**zinc chloride (7646-85-7)**
- LD50 oral rat: 350 mg/kg

**poly(oxy-1,2-ethanediyl), alpha-[(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxy- (9036-19-5)**
- LD50 oral rat: 1900 mg/kg

Skin corrosion/irritation: Slight skin irritant
- pH: 7.8 - 8.2

Serious eye damage/irritation: Liquid splashes in the eye may cause irritation
- pH: 7.8 - 8.2

Respiratory or skin sensitisation: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

Specific target organ toxicity (single exposure): Not classified

Specific target organ toxicity (repeated exposure): Not classified

Aspiration hazard: Not classified

Potential adverse human health effects and symptoms: Low health hazard.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity
Ecology - general: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

**sodium azide (26628-22-8)**
- LC50 fish 1: 0.7 mg/l (96 hours - Lepomis macrochirus)
- EC50 Daphnia 1: 4.2 mg/l (48 hours - Daphnia pulex)

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 fish 1</th>
<th>EC50 Daphnia 1</th>
<th>IC50 algae</th>
</tr>
</thead>
<tbody>
<tr>
<td>zinc chloride (7646-85-7)</td>
<td>0.9 mg/l (96 hours - Salmo salar)</td>
<td>0.329 mg/l (48 hours - Daphnia magna)</td>
<td>0.002 mg/l</td>
</tr>
<tr>
<td>poly(oxy-1,2-ethanediyl), alpha-[(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxy- (9036-19-5)</td>
<td>7.2 mg/l (96 hours - Rainbow trout)</td>
<td>11.2 mg/l (48 hours - Daphnia magna)</td>
<td>0.21 mg/l (IC50, 72 hours - Selenastrum capricornutum)</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

Alere Afinion™ HbA1c Control

Persistence and degradability Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Alere Afinion™ HbA1c Control

Bioaccumulative potential Bioaccumulation unlikely.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Bioconcentration factor (BCF REACH)</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>zinc chloride (7646-85-7)</td>
<td>2000</td>
<td>&gt; 3</td>
</tr>
<tr>
<td>poly(oxy-1,2-ethanediyl), alpha-[(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxy- (9036-19-5)</td>
<td>37.15</td>
<td>5.09</td>
</tr>
</tbody>
</table>

12.4. Mobility in soil

Alere Afinion™ HbA1c Control

Ecology - soil No data available.

12.5. Results of PBT and vPvB assessment

Alere Afinion™ HbA1c Control

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Other adverse effects None to our knowledge.

Additional information Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) Dispose of contents/container in accordance with licensed collector’s sorting instructions. Used device to be handled as infectious.

Additional information The given EWC-code is a guiding, and the code depends on how the waste is formed. User must evaluate the choice of correct code.

Ecology - waste materials Avoid release to the environment.

European List of Waste (LoW) code 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

<table>
<thead>
<tr>
<th>ADR</th>
<th>IMDG</th>
<th>IATA</th>
<th>RID</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1. UN number</td>
<td>Not regulated for transport</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.2. UN proper shipping name</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.3. Transport hazard class(es)</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.4. Packing group</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.5. Environmental hazards</td>
<td>Dangerous for the environment : No</td>
<td>Dangerous for the environment : No</td>
<td>Dangerous for the environment : No</td>
</tr>
</tbody>
</table>
14.6. Special precautions for user

Special transport precautions: No particular precautions

- Overland transport
No data available

- Transport by sea
No data available

- Air transport
No data available

Rail transport
No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

SECTION 15: REGULATORY INFORMATION

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

EU-Regulations
Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

National regulations

15.2. Chemical safety assessment
No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Indication of changes:
Unknown.


Other information: None.

Date of issue: 15/02/2016
Revision date: 15/02/2016
Version: 1.0
Signature: K. Dyreskog

Full text of H- and EUH-statements:

<table>
<thead>
<tr>
<th>Acute Tox. 2 (Oral)</th>
<th>Acute toxicity (oral), Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4 (Oral)</td>
<td>Acute toxicity (oral), Category 4</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>Hazardous to the aquatic environment — Acute Hazard, Category 1</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 1</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 2</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>Serious eye damage/eye irritation, Category 2</td>
</tr>
<tr>
<td>Skin Corr. 1B</td>
<td>Skin corrosion/irritation, Category 1B</td>
</tr>
<tr>
<td>H300</td>
<td>Fatal if swallowed</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>EUH210</td>
<td>Safety data sheet available on request</td>
</tr>
</tbody>
</table>
The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.