

Safety Data Sheet Alere Afinion™ HbA1c

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

1.1. Product identifier

Product name : Alere Afinion™ HbA1c

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	Organisation/Company	Address	Emergency number
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+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 : None under normal conditions.

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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
zinc chloride	(CAS No) 7646-85-7 (EC no) 231-592-0 (EC index no) 030-003-00-2 (REACH-no) 01-2119472431-44	< 0.12	Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
zinc chloride	(CAS No) 7646-85-7 (EC no) 231-592-0 (EC index no) 030-003-00-2 (REACH-no) 01-2119472431-44	(C >= 5) STOT SE 3, H335

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general : The reagents are in a sealed test cartridge and designated first aid measures are actual only if the device is leaking.

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 plenty of water. 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

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : 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

Additional hazards when processed

: Exposure to content is unlikely by normal use.

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. Used device to be handled as infectious.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions

: Keep only in original container. Store at temperatures not exceeding 25°C. Protect from sunlight.

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

zinc chloride (7646-85-7)		
United Kingdom	Local name	Zinc chloride
United Kingdom	WEL TWA (mg/m³)	1 mg/m³ fume
United Kingdom	WEL STEL (mg/m³)	2 mg/m³ fume

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	: clear.
Odour	: No data available
Odour threshold	: No data available
pH	: 8 - 9.4
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	: No data available
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**

No data available.

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

zinc chloride (7646-85-7)

LD50 oral rat	350 mg/kg
Skin corrosion/irritation	: Slight skin irritant pH: 8 - 9.4
Serious eye damage/irritation	: Liquid splashes in the eye may cause irritation pH: 8 - 9.4
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.

zinc chloride (7646-85-7)

LC50 fish 1	0.9 mg/l (96 hours - <i>Salmo salar</i>)
EC50 Daphnia 1	0.329 mg/l (48 hours - <i>Daphnia magna</i>)
IC50 algae	0.002 mg/l

12.2. Persistence and degradability**Alera Afinion™ HbA1c**

Persistence and degradability : Biodegradability in water: no data available.

12.3. Bioaccumulative potential**Alera Afinion™ HbA1c**

Bioaccumulative potential : Bioaccumulation unlikely.

zinc chloride (7646-85-7)

Bioconcentration factor (BCF REACH)	2000
Log Pow	> 3

12.4. Mobility in soil**Alera Afinion™ HbA1c**

Ecology - soil	No data available.
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12.5. Results of PBT and vPvB assessment**Alera Afinion™ HbA1c**

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

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable			
14.3. Transport hazard class(es)			
Not applicable			
Not applicable			
14.4. Packing group			
Not applicable			
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

Special transport precautions	: No particular precautions
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- 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

EC-regulation 453/2010/EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Indication of changes:

Unknown.

Data sources	: EC-regulation 453/2010/EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.
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:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
EUH210	Safety data sheet available on request

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.