

Safety Data Sheet

Afinion™ HbA1c Control

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Revision date: 01/06/2019 Supersedes: 16/04/2019 Version: 4.0

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

1.1. Product identifier

Product name : 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

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

Manufacturer

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

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
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

Adverse physicochemical, human health and environmental effects

No additional information available

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, regulation 1272/2008/EC, article 1, paragraph 5d.

2.3. Other hazards

Other hazards not contributing to the classification : Contains liquid preparations of stabilized porcine whole blood (Control C I) and human whole blood (Control C II), respectively. Precautions should be taken as for any potentially bio hazardous material.

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. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	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	0.11	Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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Triton X (poly(oxy-1,2-ethanediyl), alpha-[(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxy-) substance listed as REACH Candidate (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]) substance listed in REACH Annex XIV (4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues))	(CAS-No.) 9036-19-5 (REACH-no) N/A	<= 0.1	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Chronic 2, H411
sodium azide	(CAS-No.) 26628-22-8 (EC-No.) 247-852-1 (EC Index-No.) 011-004-00-7 (REACH-no) 01-2119457019-37	<= 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
zinc chloride	(CAS-No.) 7664-85-7 (EC-No.) 231-592-0 (EC Index-No.) 030-003-00-2 (REACH-no) 01-2119472431-44	(5 =<C < 100) 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	: 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 persists.
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/effects	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact	: May cause skin irritation.
Symptoms/effects after eye contact	: Liquid splashes in the eye may cause irritation.
Symptoms/effects after ingestion	: Ingestion may cause nausea and vomiting.

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.
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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 the 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.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency 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

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
United Kingdom	Regulatory reference	EH40/2005 (Third edition, 2018). HSE

sodium azide (26628-22-8)		
United Kingdom	Local name	Sodium azide
United Kingdom	WEL TWA (mg/m³)	0.1 mg/m³ (as NaN ₃)
United Kingdom	WEL STEL (mg/m³)	0.3 mg/m³ (as NaN ₃)
United Kingdom	Remark (WEL)	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)
United Kingdom	Regulatory reference	EH40/2005 (Third edition, 2018). HSE

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.

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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. Protect against frost.

10.5. Incompatible materials

None to our knowledge.

10.6. Hazardous decomposition products

No decomposition if stored and used normally.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)

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Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

zinc chloride (7646-85-7)	
LD50 oral rat	1100 mg/kg OECD401

sodium nitrite (7632-00-0)	
LD50 oral rat	180 mg/kg
LC50 inhalation rat (Dust/Mist - mg/l/4h)	5.5 mg/l/4h

magnesium chloride (7786-30-3)	
LD50 oral rat	2800 mg/kg

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rabbit	20 mg/kg (ECHA)
LC50 inhalation rat (Vapours - mg/l/4h)	37 mg/l/4h

Skin corrosion/irritation : Not classified
pH: 7.8 - 8.2

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
pH: 7.8 - 8.2

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

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 nor to cause long-term adverse effects in the environment.

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Not classified

zinc chloride (7646-85-7)	
LC50 fish 1	0.169 mg/l (96 hours - Rainbow trout)
EC50 Daphnia 1	0.33 mg/l (48 hours - Daphnia magna)
ErC50 (algae)	0.0049 mg/l (96 hours - Pseudokirchneriella subcapitata)

sodium nitrite (7632-00-0)	
LC50 fish 1	0.54 - 26.3 mg/l (96 hours - Rainbow trout)
EC50 Daphnia 1	15.4 mg/l (48 hours -Daphnia magna Straus)
ErC50 (algae)	> 100 mg/l (72 hours -Desmodesmus subspicatus)

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magnesium chloride (7786-30-3)	
LC50 fish 1	4210 mg/l Gambusia affinis (Mosquito fish)
EC50 Daphnia 1	32 mg/l (48 hours -Daphnia hyalina)
ErC50 (algae)	2200 mg/l

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)
ErC50 (algae)	272 mg/l

Triton X (poly(oxy-1,2-ethanediyl), alpha-[(1,1,3,3- tetramethylbutyl)phenyl]-omega-hydroxy-) (9036-19-5)	
Additional information	Triton X is on the REACH Annex XIV List

12.2. Persistence and degradability

Afinion™ HbA1c Control	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Afinion™ HbA1c Control	
Bioaccumulative potential	Bioaccumulation unlikely.

zinc chloride (7646-85-7)	
Bioconcentration factor (BCF REACH)	2000
Log Pow	> 3

sodium azide (26628-22-8)	
Log Pow	0.3 OECD TG117

Triton X (poly(oxy-1,2-ethanediyl), alpha-[(1,1,3,3- tetramethylbutyl)phenyl]-omega-hydroxy-) (9036-19-5)	
Bioconcentration factor (BCF REACH)	2.39
Log Pow	4.86

12.4. Mobility in soil

Afinion™ HbA1c Control	
Ecology - soil	No data available.

12.5. Results of PBT and vPvB assessment

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	
Component	
Triton X (poly(oxy-1,2-ethanediyl), alpha-[(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxy-) (9036-19-5)	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 LoW-code is a guiding, and the code depends on how the waste is formed. User must evaluate the choice of correct code.

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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	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Special transport precautions

: No particular precautions.

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

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 a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (CAS 9036-19-5)

Contains REACH Annex XIV substances: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (CAS 9036-19-5)

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Substance(s) are not subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC.

National regulations

EU-regulation 2015/830, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

The product is seen as a medical device and therefore not subject to labelling (regulation 1272/2008/EC, article 1, paragraph 5d).

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15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:			
Section	Changed item	Change	Comments
3	Composition/information on ingredients	Modified	

SDS ID : 301087

Data sources : EU-regulation 2015/830, 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.

Full text of H- and EUH-statements:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
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
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH210	Safety data sheet available on request.