Safety Data Sheet
Afinion™ ACR Control

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

1.1. Product identifier

Product name : Afinion™ ACR 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
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 : Contains human blood derivatives. 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	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Hydrochloric acid, 10-20% Combi-Titrisol®	(CAS-No.) 7647-01-0 (EC-No.) 231-595-7	< 0.6	Met. Corr. 1, H290 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
citric acid	(CAS-No.) 5949-29-1 (EC-No.) 201-069-1 (REACH-no) 01-2119457026-42	< 0.3	Eye Irrit. 2, H319

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 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, vomiting and diarrhea.

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 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.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

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

Hydrochloric acid, 10-20% Combi-Titrisol® (7647-01-0)		
United Kingdom	Local name	Hydrogen chloride
United Kingdom	WEL TWA (mg/m³)	2 mg/m³ gas and aerosol mists
United Kingdom	WEL TWA (ppm)	1 ppm gas and aerosol mists
United Kingdom	WEL STEL (mg/m³)	8 mg/m³ gas and aerosol mists
United Kingdom	WEL STEL (ppm)	5 ppm gas and aerosol mists

8.2. Exposure controls

Appropriate engineering controls : Provide eyewash station.

Hand protection : Wear suitable gloves resistant to chemical penetration. Neoprene or nitrile rubber gloves. Latex. 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 : Colourless.

Odour : No data available

Odour threshold : No data available

pH : 2.7 - 2.9

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 and used normally.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity : Ingestion may cause nausea and vomiting.
Based on available data, the classification criteria are not met

citric acid (5949-29-1)	
LD50 oral rat	5400 mg/kg
LD50 dermal rat	> 2000 mg/kg

Hydrochloric acid, 10-20% Combi-Titrisol® (7647-01-0)	
LD50 oral rat	900 mg/kg

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met
pH: 2.7 - 2.9

Serious eye damage/irritation : Not classified
Based on available data, the classification criteria are not met
pH: 2.7 - 2.9

Respiratory or skin sensitisation : Not classified
Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified
Based on available data, the classification criteria are not met

STOT-single exposure : Not classified
Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified
Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
Based on available data, the classification criteria are not met

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.

citric acid (5949-29-1)	
LC50 fish 1	440 - 760 mg/l 96 h Leuciscus idus (golden orfe)
EC50 Daphnia 1	80 - 120 mg/l (48 hours - Daphnia magna)

Hydrochloric acid, 10-20% Combi-Titrisol® (7647-01-0)	
LC50 fish 1	232 mg/l (96 hours - Gambusia affinis - Mosquito fish)

Hydrochloric acid, 10-20% Combi-Titrisol® (7647-01-0)	
EC50 Daphnia 1	56 mg/l

12.2. Persistence and degradability

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

citric acid (5949-29-1)	
Biodegradation	70 % (28 days, method: OECD 301D)

12.3. Bioaccumulative potential

Afinion™ ACR Control	
Bioaccumulative potential	Bioaccumulation unlikely.

citric acid (5949-29-1)	
Log Pow	< 1

12.4. Mobility in soil

Afinion™ ACR Control	
Ecology - soil	No data available.

12.5. Results of PBT and vPvB assessment

Afinion™ ACR 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 LoW-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	ADN	RID
14.1. UN number				
Not regulated for transport				
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
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				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : 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.

- 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 2015/830 /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

Data sources	:	EC-regulation 2015/830 /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	:	05/03/2019
Supersedes	:	01/10/2018
Version	:	3.0

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Met. Corr. 1	Corrosive to metals, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
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.