Safety Data Sheet

Afinion™ ACR Control

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 15/02/2016 Revision date: 27/03/2023 Supersedes version of: 05/03/2019 Version: 5.0

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

1.1. Product identifier

Product form : Mixture
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
N-0504 Oslo - Norway
T +47 24 05 60 00 - F +47 24 05 60 10
ATN_customerservice@abbott.com - https://www.globalpointofcare.abbott

Manufacturer
Abbott Diagnostics Technologies AS
Kjelsåsveien 161, P.O. Box 6863 Rodeløkka
N-0504 Oslo - Norway
T +47 24 05 60 00 - F +47 24 05 60 10
ATN_customerservice@abbott.com - https://www.globalpointofcare.abbott

1.4. Emergency telephone number

Emergency number : 24 hour Emergency Contact Telephone Number
CHEMTREC: +1 703-527-3887 or +1 800-424-9300
CCN119 (Abbott Laboratories)

Country	Official advisory body	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182 +44 191 2606180	Hours of operation: 24hrs

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]

Extra phrases : In vitro diagnostic medical devices, REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Article 1, 5.(d).

2.3. Other hazards

Other hazards which do not result in classification : Contains human blood derivatives. Precautions should be taken as for any potentially biohazardous material. Contains liquid preparations of stabilized bovine haemoglobin. 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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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]
citric acid	(CAS-No.) 5949-29-1 (EC-No.) 201-069-1 (REACH-no) 01-2119457026-42	< 2	Eye Irrit. 2, H319
hydrochloric acid… % (Note B)	(CAS-No.) 7647-01-0 (EC-No.) 231-595-7 (EC Index-No.) 017-002-01-X (REACH-no) 01-2119484862-27	< 0.4	Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335

Specific concentration limits:		
Name	**Product identifier**	**Specific concentration limits**
hydrochloric acid… %	(CAS-No.) 7647-01-0 (EC-No.) 231-595-7 (EC Index-No.) 017-002-01-X (REACH-no) 01-2119484862-27	(10 ≤C < 100) STOT SE 3, H335 (10 ≤C < 25) Eye Irrit. 2, H319 (10 ≤C < 25) Skin Irrit. 2, H315 (25 ≤C < 100) Skin Corr. 1B, H314

Note B - Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid … %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.
Full text of H- and EUH-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 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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 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.

Explosion hazard : Product is not explosive.

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 (EN137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.1.1. For non-emergency personnel

Emergency procedures	:	Evacuate unnecessary personnel.

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

For containment	:	Collect all waste in suitable and labelled containers and dispose according to local legislation.
Methods for cleaning up	:	Take up liquid spill into absorbent material. The contaminated area should be cleaned up immediately with a suitable decontaminant. Place in an appropriate container and dispose of the contaminated material at a licensed site.

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. Used device to be handled as infectious.
Hygiene measures	:	Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	:	Keep in original container. Protect from sunlight.
Incompatible materials	:	Sources of ignition. Direct sunlight.
Storage temperature	:	2 – 8 °C

7.3. Specific end use(s)

For professional use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

hydrochloric acid… % (7647-01-0)	
United Kingdom - Occupational Exposure Limits	
Local name	Hydrogen chloride
WEL TWA (OEL TWA) [1]	2 mg/m³ gas and aerosol mists
WEL TWA (OEL TWA) [2]	1 ppm gas and aerosol mists
WEL STEL (OEL STEL)	8 mg/m³ gas and aerosol mists
WEL STEL (OEL STEL) [ppm]	5 ppm gas and aerosol mists
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

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.

8.2.2.2. Skin protection

Skin and body protection:
Lab coat.

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.

8.2.2.3. Respiratory protection

Respiratory protection:
Respiratory protection not applicable.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

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	:	Not available
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Non flammable.
Explosive properties	:	Not explosive.
Oxidising properties	:	Non flammable.
Explosive limits	:	Not available
Lower explosive limit (LEL)	:	Not available
Upper explosive limit (UEL)	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	2.8
Viscosity, kinematic	:	Not available
Solubility	:	Miscible with water.

Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle size	:	Not applicable
Particle size distribution	:	Not applicable
Particle shape	:	Not applicable
Particle aspect ratio	:	Not applicable
Particle aggregation state	:	Not applicable
Particle agglomeration state	:	Not applicable
Particle specific surface area	:	Not applicable
Particle dustiness	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified
Additional information	:	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… % (7647-01-0)	
LD50 dermal rabbit	5010 mg/kg
LC50 Inhalation - Rat (Vapours)	45.6 mg/l/4h

Skin corrosion/irritation	:	Not classified pH: 2.8
Additional information	:	Based on available data, the classification criteria are not met

Serious eye damage/irritation	:	Not classified pH: 2.8
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

hydrochloric acid… % (7647-01-0)	
STOT-single exposure	May cause respiratory irritation.

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute)	:	Not classified
Hazardous to the aquatic environment, long–term (chronic)	:	Not classified

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

hydrochloric acid… % (7647-01-0)	
LC50 - Fish [1]	20.5 mg/l Lepomis macrochirus (Bluegill)
EC50 - Crustacea [1]	0.45 mg/l Daphnia magna (OECD TG 202)
EC50 72h - Algae [1]	0.73 mg/l Chlorella vulgaris (OECD TG 201)

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)	
Partition coefficient n-octanol/water (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. Endocrine disrupting properties

No additional information available

12.7. 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. Waste disposal according to Directive 2008/98/EC, covering waste and dangerous waste. Used device to be handled as infectious.

Product/Packaging disposal recommendations : Do not discharge into drains or the environment. Used device to be handled as infectious. Can be disposed or incinerated according to local regulations.

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. Do not empty into drains.

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 / IMDG / IATA / ADN / RID /

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID 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. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Listed on REACH Annex XVII (Restriction Conditions). The following restrictions are applicable:		
Reference code	Applicable on	Entry title or description
3(b)	citric acid ; hydrochloric acid… %	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

Contains no substance(s) listed on the REACH Candidate List
Contains no substance(s) listed on REACH Annex XIV (Authorisation List)
Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)
Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

15.1.2. National regulations

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

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.