Safety Data Sheet
Afinion™ Lipid Panel Control

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

1.1. Product identifier

Product name : Afinion™ Lipid Panel 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]

Precautionary statements (CLP) : P280 - Wear protective gloves, eye protection.

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]
methanol	(CAS-No.) 67-56-1 (EC-No.) 200-659-6 (EC Index-No.) 603-001-00-X (REACH-no) 01-2119433307-44	< 1	Flam. Liq. 2, H225 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 STOT SE 1, H370
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	< 0.1	Skin Corr. 1B, H314 STOT SE 3, H335

Specific concentration limits:

Name	Product identifier	Specific concentration limits
methanol	(CAS-No.) 67-56-1 (EC-No.) 200-659-6 (EC Index-No.) 603-001-00-X (REACH-no) 01-2119433307-44	(3 =<C < 10) STOT SE 2, H371 (C >= 10) STOT SE 1, H370
hydrochloric acid	(CAS-No.) 7647-01-0 (EC-No.) 231-595-7 (EC Index-No.) 017-002-01-X (REACH-no) 01-2119484862-27	(C >= 10) STOT SE 3, H335 (10 =<C < 25) Eye Irrit. 2, H319 (10 =<C < 25) Skin Irrit. 2, H315 (C >= 25) Skin Corr. 1B, H314

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 : Rinse nose and mouth with water. Get medical attention if any discomfort continues.

First-aid measures after skin contact : Wash skin with soap and water. Get medical attention if any discomfort continues.

First-aid measures after eye contact : Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyes wide apart. Get medical attention if any discomfort continues.

First-aid measures after ingestion : Rinse nose, mouth and throat with water. Call a physician immediately.

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

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

No specific first aid measures noted.

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.

Reactivity in case of fire : No incompatible groups noted.

Hazardous decomposition products in case of fire : No specific hazardous decomposition products noted.

5.3. Advice for firefighters

Firefighting instructions : No specific fire fighting procedure given.

Protection during firefighting : Wear self-contained breathing apparatus (SCBA) to prevent contact with thermal decomposition products.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special precautions required.

For non-emergency personnel

Protective equipment : Wear appropriate personal protective equipment - see Section 8.

Emergency procedures : No special precautions required.

For emergency responders

Protective equipment : No special precautions required.

Emergency procedures : No special precautions required.

6.2. Environmental precautions

Prevent discharge of larger quantity to drain.

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 : Wipe up with adsorbent material. Place in suitable container for prompt disposal. Label the container as to the potential infectious hazard. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g, a fresh 1:10 dilution of common household bleach.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Additional hazards when processed : Unspecified storage.

Precautions for safe handling : Avoid spilling, skin and eye contact.

Hygiene measures : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : No special storage requirements.

Storage temperature : 2 - 8 °C (36 - 46°F)

7.3. Specific end use(s)

No additional data.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

methanol (67-56-1)		
United Kingdom	Local name	Methanol
United Kingdom	WEL TWA (mg/m³)	266 mg/m³
United Kingdom	WEL TWA (ppm)	200 ppm
United Kingdom	WEL STEL (mg/m³)	333 mg/m³
United Kingdom	WEL STEL (ppm)	250 ppm
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)

hydrochloric acid (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 : Ensure good ventilation of the work station.

Hand protection : Wear suitable gloves resistant to chemical penetration. Neoprene or nitrile rubber gloves. Latex. Layer thickness : >0,1mm. 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.

Thermal hazard protection : No special precautions required.

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 : Yellow.

Odour : Mild (or faint).

Odour threshold : No data available

pH	:	No data available
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)	:	No data available
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Density	:	≈ 1 g/cm³ @ 20 °C
Solubility	:	Miscible with water.
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	Not explosive.
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

Additional information : None to our knowledge.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

Will not polymerise.

10.4. Conditions to avoid

Avoid strong heating. Protect against frost.

10.5. Incompatible materials

None to our knowledge.

10.6. Hazardous decomposition products

Stable under normal conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity : Not classified

Based on available data, the classification criteria are not met

methanol (67-56-1)	
LD50 oral rat	5300 mg/kg
LD50 dermal rabbit	15800 mg/kg
LC50 inhalation rat (Vapours - mg/l/4h)	85 mg/l/4h

hydrochloric acid (7647-01-0)	
LD50 oral rat	900 mg/kg
LC50 inhalation rat (mg/l)	4726 mg/l/4h

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified

Based on available data, the classification criteria are not met

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.

methanol (67-56-1)	
LC50 fish 1	15400 mg/l (96 hours - Lepomis macrochirus)
EC50 Daphnia 1	24500 mg/l (48 hours - Daphnia magna)
IC50 algae	441 mg/l 72 hours

hydrochloric acid (7647-01-0)	
LC50 fish 1	232 mg/l (96 hours - Gambusia affinis - Mosquito fish)
EC50 Daphnia 1	> 56 mg/l (48 hours - Daphnia magna)

12.2. Persistence and degradability

Afinion™ Lipid Panel Control	
Persistence and degradability	No data.

methanol (67-56-1)	
BOD (% of ThOD)	0.4 - 0.8 % ThOD BOD5/COD
Biodegradation	99 % (OECD 301D method)

12.3. Bioaccumulative potential

Afinion™ Lipid Panel Control	
Bioaccumulative potential	No data.

methanol (67-56-1)	
Bioconcentration factor (BCF REACH)	1
Log Pow	-0.64

12.4. Mobility in soil

Afinion™ Lipid Panel Control	
Ecology - soil	The product is miscible with water. May spread in water systems.

12.5. Results of PBT and vPvB assessment

Afinion™ Lipid Panel 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 : No other effects known

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) : Dispose as hazardous waste.

Waste treatment methods : Absorb in vermiculite or dry sand, dispose in licensed special waste.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

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

- 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

IBC code : No IBC-code for bulk transport offshore (MARPOL).

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 for the substance or the mixture by the supplier

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. In vitro diagnostic medical devices, EU-regulation 1272/2008/EC, article 1, paragraph 5d.

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Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Flam. Liq. 2	Flammable liquids, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
STOT SE 1	Specific target organ toxicity — single exposure, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H370	Causes damage to organs.
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.