Safety Data Sheet
Afinion™ Lipid Panel

Product name

Afinion™ Lipid Panel

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

Afinion™ Lipid Panel	Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Part 1: Chol reagent	Warning. Causes serious eye irritation. 
Part 2: Dilution liquid, HDL-R1 reagent	Warning. May cause an allergic skin reaction. 
Part 3: Trig reagent, HDL-R2 reagent, Lysis reagent	Not classified.

Safety Data Sheet
Afinion™ Lipid Panel

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

1.1. Product identifier

Product name : Afinion™ Lipid Panel

Synonyms : Part 1: Chol reagent

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
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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]

Eye Irrit. 2 H319

Full text of H statements : see section 16

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazardous ingredients : Polidocanol

Hazard statements (CLP) : H319 - Causes serious eye irritation.

Precautionary statements (CLP) : P280 - Wear protective gloves/protective clothing/eye protection/face protection.

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. Substances

Not applicable

3.2. Mixtures

Comment : The Afinion Lipid Panel test cartridge contains 6 different solutions in separate wells of the cartridge; Trig reagent, Chol reagent, HDL-R2 reagent, Dilution Liquid, HDL-R1 reagent, Lysis reagent.

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Polidocanol	(CAS-No.) 9002-92-0 (EC-No.) 500-002-6 (REACH-no) 01-2119968561-30	1 - <3	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318
phenol; carbolic acid; monohydroxybenzene; phenylalcohol	(CAS-No.) 108-95-2 (EC-No.) 203-632-7 (EC Index-No.) 604-001-00-2 (REACH-no) -0000 01-2119471329	0.1 - 1	Muta. 2, H341 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 STOT RE 2, H373 Skin Corr. 1B, H314

Specific concentration limits:

Name	Product identifier	Specific concentration limits
phenol; carbolic acid; monohydroxybenzene; phenylalcohol	(CAS-No.) 108-95-2 (EC-No.) 203-632-7 (EC Index-No.) 604-001-00-2 (REACH-no) -0000 01-2119471329	(1 =<C < 3) Eye Irrit. 2, H319 (1 =<C < 3) Skin Irrit. 2, H315 (C >= 3) 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 : 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 : 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. Get medical attention if any discomfort continues.

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

Symptoms/effects after eye contact : Causes serious eye 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 : Carbon dioxide. Carbon monoxide.

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

phenol; carbolic acid; monohydroxybenzene; phenylalcohol (108-95-2)		
United Kingdom	Local name	Phenol
United Kingdom	WEL TWA (mg/m³)	7.8 mg/m³
United Kingdom	WEL TWA (ppm)	2 ppm
United Kingdom	WEL STEL (mg/m³)	16 mg/m³
United Kingdom	WEL STEL (ppm)	4 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)

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	:	Red.
Odour	:	Odourless.
Odour threshold	:	No data available
pH	:	6.8
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.

10.5. Incompatible materials

None to our knowledge.

10.6. Hazardous decomposition products

Stable when used at recommended storage and handling 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

Polidocanol (9002-92-0)	
LD50 oral rat	> 2000 mg/kg

phenol; carbolic acid; monohydroxybenzene; phenylalcohol (108-95-2)	
LD50 oral rat	317 mg/kg
LD50 dermal rat	660 mg/kg
LD50 dermal rabbit	630 mg/kg
LC50 inhalation rat (mg/l)	0.9 mg/kg

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met
pH: 6.8

Serious eye damage/irritation : Causes serious eye irritation.
pH: 6.8

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.

Polidocanol (9002-92-0)	
LC50 fish 1	1.5 mg/l (96 hours - Salmo salar)
EC50 Daphnia 1	6.46 mg/l (48 hours - Daphnia magna)

phenol; carbolic acid; monohydroxybenzene; phenylalcohol (108-95-2)	
LC50 fish 1	5.2 mg/l (96 hours - Rainbow trout)
EC50 Daphnia 1	4.2 (48 hours - Daphnia magna)
IC50 algae	> 61.1 mg/l (IC50, 72 hours -Selenastrum)

12.2. Persistence and degradability

Afinion™ Lipid Panel	
Persistence and degradability	Biodegradable.

Polidocanol (9002-92-0)	
Biodegradation	99 % (OECD 302A method)

12.3. Bioaccumulative potential

Afinion™ Lipid Panel	
Bioaccumulative potential	Unknown.

Polidocanol (9002-92-0)	
Bioconcentration factor (BCF REACH)	1.76

phenol; carbolic acid; monohydroxybenzene; phenylalcohol (108-95-2)	
BCF other aquatic organisms 1	1.7 - 39
Log Pow	1.48

12.4. Mobility in soil

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

12.5. Results of PBT and vPvB assessment

Afinion™ Lipid Panel
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.
Date of issue	:	30/11/2014
Revision date	:	05/03/2019
Supersedes	:	01/10/2018
Version	:	4.0

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
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Muta. 2	Germ cell mutagenicity, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.

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.

Safety Data Sheet
Afinion™ Lipid Panel

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

1.1. Product identifier

Product name : Afinion™ Lipid Panel

Synonyms : Part 2: Dilution liquid, HDL-R1 reagent

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
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Manufacturer
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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]

Skin Sens. 1 H317

Full text of H statements : see section 16

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazardous ingredients : Isothiazolin ketone

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) : P280 - Wear protective gloves/protective clothing/eye protection/face protection.

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. Substances

Not applicable

3.2. Mixtures

Comment : The Afinion Lipid Panel test cartridge contains 6 different solutions in separate wells of the cartridge; Trig reagent, Chol reagent, HDL-R2 reagent, Dilution Liquid, HDL-R1 reagent, Lysis reagent.

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Isothiazolin ketone	(CAS-No.) 55965-84-9 (EC-No.) 55965-84-9 (EC Index-No.) 613-167-00-5 (REACH-no) N/A	0,0015 - 0,03	Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Isothiazolin ketone	(CAS-No.) 55965-84-9 (EC-No.) 55965-84-9 (EC Index-No.) 613-167-00-5 (REACH-no) N/A	(C >= 0.0015) Skin Sens. 1, H317 (0.06 =<C < 0.6) Eye Irrit. 2, H319 (0.06 =<C < 0.6) Skin Irrit. 2, H315 (C >= 0.6) 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 : 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 : 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. Get medical attention if any discomfort continues.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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

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 : Carbon dioxide. Carbon monoxide.

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

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal protective equipment : Gloves.

Hand protection : Wear suitable gloves resistant to chemical penetration. Neoprene or nitrile rubber gloves. Latex. Layer thickness : >0,1mm. Breakthrough time : >480min. 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 : Dilution Liquid: Colourless. HDL-R1 reagent: Yellow.

Odour : Odourless.

Odour threshold : No data available

pH	:	7 (Dilution Liquid, HDL-R1 reagent)
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.

10.5. Incompatible materials

None to our knowledge.

10.6. Hazardous decomposition products

Stable when used at recommended storage and handling 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

Isothiazolin ketone (55965-84-9)	
LD50 oral rat	53 - 60 mg/kg
LD50 dermal rabbit	80 mg/kg
LC50 inhalation rat (ppm)	0.2 ppm/4h

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met

pH: 7 (Dilution Liquid, HDL-R1 reagent)

Serious eye damage/irritation : Not classified

Based on available data, the classification criteria are not met

pH: 7 (Dilution Liquid, HDL-R1 reagent)

Respiratory or skin sensitisation : May cause an allergic skin reaction.

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.

Isothiazolin ketone (55965-84-9)	
LC50 fish 1	6.1 mg/l (96 hours - Brachydanio rerio, zebra-fish)
EC50 Daphnia 1	0.18 (48 hours - Daphnia magna)

12.2. Persistence and degradability

Afinion™ Lipid Panel	
Persistence and degradability	The chemical is slowly, not readily biodegradable.

Isothiazolin ketone (55965-84-9)	
Biodegradation	39 - 62 % (28 days, method: OECD 301B)

12.3. Bioaccumulative potential

Afinion™ Lipid Panel	
Bioaccumulative potential	Unknown.

Isothiazolin ketone (55965-84-9)	
Bioconcentration factor (BCF REACH)	114

12.4. Mobility in soil

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

12.5. Results of PBT and vPvB assessment

Afinion™ Lipid Panel
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

ADR	IMDG	IATA	ADN	RID
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.
Date of issue	:	30/11/2014
Revision date	:	05/03/2019
Supersedes	:	01/10/2018
Version	:	4.0

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
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
Skin Sens. 1	Skin sensitisation, Category 1
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.

H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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.

Safety Data Sheet
Afinion™ Lipid Panel

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

1.1. Product identifier

Product name : Afinion™ Lipid Panel

Synonyms : Part 3: Trig reagent, HDL-R2 reagent, Lysis reagent

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/protective clothing/eye protection/face protection.

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. Substances

Not applicable

3.2. Mixtures

Comment : Afinion Lipid Panel test cartridge contains 6 different solutions in separate wells of the cartridge; Trig reagent, Chol reagent, HDL-R2 reagent, Dilution Liquid, HDL-R1 reagent, Lysis reagent.

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

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 : 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. Get medical attention if any discomfort continues.

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 : Carbon dioxide. Carbon monoxide.

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

No additional information available

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 : >0,10mm. Breakthrough time : >480min. 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 : Trig reagent, HDL-R2 reagent: Yellow. Lysis reagent: Colourless.

Odour : Odourless.

Odour threshold : No data available

pH : 6.8 - 9.6

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.

10.5. Incompatible materials

No data available.

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

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met
pH: 6.8 - 9.6

Serious eye damage/irritation : Not classified
Based on available data, the classification criteria are not met
pH: 6.8 - 9.6

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.

12.2. Persistence and degradability

Afinion™ Lipid Panel	
Persistence and degradability	No data.

12.3. Bioaccumulative potential

Afinion™ Lipid Panel	
Bioaccumulative potential	No data.

12.4. Mobility in soil

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

12.5. Results of PBT and vPvB assessment

Afinion™ Lipid Panel
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.

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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).

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15.2. Chemical safety assessment

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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.
Date of issue	:	30/11/2014
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Version	:	4.0

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