

# Safety Data Sheet

## Afinion™ ACR

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

#### 1.1. Product identifier

Product name : Afinion™ ACR

#### 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](mailto:aleretech.no@alere.com) - [www.abbott.com/poct](http://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](mailto:aleretech.no@alere.com) - [www.abbott.com/poct](http://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 : EUH208 - Contains Neomycin sulfate. May produce an allergic reaction.

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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Neomycin sulfate	(CAS-No.) 1405-10-3 (EC-No.) 215-773-1 (REACH-no) N/A	0.1	Resp. Sens. 1B, H334 Skin Sens. 1, H317

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 : 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 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

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**

No additional information available

**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 : Conjugate: Red. Enzyme Solution 1: light yellow. Enzyme Solution 2: Colourless.  
 Odour : No data available  
 Odour threshold : No data available  
 pH : 7.5 - 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) : 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
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: 7.5 - 8
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: 7.5 - 8
Respiratory or skin sensitisation	: The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals after repeated contact.
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
Potential adverse human health effects and symptoms	: Low health hazard.

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1. Toxicity**

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

**12.2. Persistence and degradability**

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

**12.3. Bioaccumulative potential**

Afinion™ ACR	
Bioaccumulative potential	Bioaccumulation unlikely.

**12.4. Mobility in soil**

Afinion™ ACR	
Ecology - soil	No data available.

**12.5. Results of PBT and vPvB assessment**

Afinion™ ACR	
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
<b>14.1. UN number</b>				
Not regulated for transport				
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
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**

Indication of changes:

Unknown.

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.

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Version : 3.0

Full text of H- and EUH-statements:

Resp. Sens. 1B	Respiratory sensitisation, Category 1B
Skin Sens. 1	Skin sensitisation, Category 1
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
EUH208	Contains Neomycin sulfate. May produce an allergic reaction.

*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.*