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

Date issued 22.06.2012

1.1. Product identifier
Product name Afinion™ Lipid Panel

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use of the substance/preparation The Afinion™ Lipid Panel is an in vitro diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig), in whole blood, serum and plasma. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion™ AS100 Analyzer.

Uses advised against For in vitro diagnostic use only.

1.3. Details of the supplier of the safety data sheet
Producer
Company name Axis-Shield PoC AS
Office address Kjelsåsveien 161
Postal address PO Box 6863 Rodeløkka
Postcode NO-0504
City Oslo
Country Norway
Tel +47 24 05 60 00
Fax +47 24 05 60 10
E-mail pocweb@axis-shield.com

1.4. Emergency telephone number
Emergency telephone National emergency number : For each country.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Classification according to 67/548/EEC or 1999/45/EC Xi; R43

Classification notes The cartridge of Afinion Lipid Panel contains 6 different solutions in closed compartments. The solution in the compartment containing HDL-R1 reagent is classified as dangerous preparation according to 1999/45/EC. The classification applies only to this solution. The other solutions are not classified according to 1999/45/EC or 67/548/EEC.

Substance / mixture hazardous properties May cause sensitization by skin contact.

2.2. Label elements
Hazard symbol

[Image of hazard symbol]
R phrases

R43 May cause sensitization by skin contact.

S phrases

S24 Avoid contact with skin.
S37 Wear suitable gloves.
S35 This material and its container must be disposed of in a safe way.

Other Label Information

The hazard label is not placed on the cartridge due to the very small volume and the closed compartment not to be opened by the user.

2.3. Other hazards

Description of hazard

This safety data sheet is valid for all reagents in Afinion™ Lipid Panel.

Presents little hazard if spilled or in fire.

No ecotoxicological data available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Component name: A mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-8] (3:1)

Identification:
CAS no.: 55965-84-9
Index no.: 613-167-00-5

Classification:
T; R23/24/25
C; R34
N; R50, R53
Acute tox. 3; H311
Acute tox. 3; H301
Skin Corr. 1B; H314
Skin Sens. 1; H317
Aquatic Acute 1; H400
Aquatic Chronic 1; H410

Contents:
0.0015 - 0.06 %

Description of the mixture

Test cartridge containing 6 different solutions in separated compartments, only one classified according to 1999/45/EC.

Component comments

The component in this section is the component that cause classification of the HDL- R1 Reagent.

SECTION 4: First aid measures

4.1. Description of first aid measures

General
Seek medical advice in case of persistent symptoms of health damage.
Miscible with water.

Inhalation
Supply fresh air and call for doctor for safety reasons. In case of unconsciousness bring patient into stable side position for transport.

Skin contact
Wash with soap and plenty of water. Seek medical attention if symptoms of skin irritation occurs.

Eye contact
Flush eyes with water for at least 10 minutes. Consult a doctor for safety reasons.

Ingestion
Wash mouth thoroughly with water and drink water. If substance has been swallowed, drink large quantities of water. Seek immediate medical advice.

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

Information for health personnel
Wear suitable gloves and eye/face protection.

4.3. Indication of any immediate medical attention and special treatment needed

Other Information
No recommendation given.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding fire.

Improper extinguishing media
None.

5.2. Special hazards arising from the substance or mixture
## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

<table>
<thead>
<tr>
<th>Personal precautions</th>
<th>See section 8.</th>
</tr>
</thead>
</table>

### 6.2. Environmental precautions

<table>
<thead>
<tr>
<th>Environmental precautions</th>
<th>Rejection forbidden to the sewer and in natural environment.</th>
</tr>
</thead>
</table>

### 6.3. Methods and material for containment and cleaning up

<table>
<thead>
<tr>
<th>Methods for cleaning</th>
<th>Wipe up with absorbent material. Place in suitable container for disposal. Label container as to potential infectious hazard. Spill areas can be decontaminated with 0.5% sodium hypochlorite e.g. a fresh 1:10 dilution of common household bleach.</th>
</tr>
</thead>
</table>

### 6.4. Reference to other sections

<table>
<thead>
<tr>
<th>Other instructions</th>
<th>See section 8 and 13 for use of personal protective equipment and waste disposal.</th>
</tr>
</thead>
</table>

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

<table>
<thead>
<tr>
<th>Handling</th>
<th>Avoid spilling, skin and eye contact. Wear gloves.</th>
</tr>
</thead>
</table>

### 7.2. Conditions for safe storage, including any incompatibilities

<table>
<thead>
<tr>
<th>Storage</th>
<th>Storage according to package Insert and outer - container.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special risks and properties</td>
<td>Used device should be handled and disposed as potentially infectious waste.</td>
</tr>
</tbody>
</table>

### 7.3. Specific end use(s)

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>None specific.</th>
</tr>
</thead>
</table>

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

<table>
<thead>
<tr>
<th>Other Information about threshold limit values</th>
<th>The solution in the test cartridge is stored in closed, small volume compartments and exposure by skin contact or inhalation is unlikely by normal use.</th>
</tr>
</thead>
</table>

### 8.2. Exposure controls

<table>
<thead>
<tr>
<th>Occupational exposure controls</th>
<th>The test cartridge is a closed container not to be opened at any time by the user. Normally there will be no contact with the solutions in the cartridge. Accidents and leakage may cause contact. Eye Washing Station should be available. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>Respiratory protection not required.</th>
</tr>
</thead>
</table>

### Hand protection

<table>
<thead>
<tr>
<th>Hand protection</th>
<th>Normal use:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hand protection is recommended. Wear disposable gloves. (Latex gloves). Clean up after accidental release or leakage: Use hand protection. (Nitrile gloves).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reference to relevant standard</th>
<th>EN-374: 2003, parts 1, 2 and 3: Protective gloves against chemicals and micro-organisms.</th>
</tr>
</thead>
</table>

### Eye / face protection

<table>
<thead>
<tr>
<th>Eye protection</th>
<th>Normal use:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Clean up after accidental release or leakage:
Wear safety glasses.

Reference to relevant standard
EN 166:2001 Personal eye-protection - Specifications.

Skin protection
Suitable protective clothing
Lab Coat is recommended.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state
Liquid reagent in a topas/polypropylene/polystyrene test cartridge.
Solubility in water
The chemical contents of the device is readily miscible with water.

9.2. Other information

Other physical and chemical properties
Comments
No data recorded.

SECTION 10: Stability and reactivity

10.1. Reactivity
Reactivity
No data recorded.

10.2. Chemical stability
Stability
Stable and not reactive under normal conditions.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions
No recommendation given.

10.4. Conditions to avoid
Conditions to avoid
None.

10.5. Incompatible materials
Materials to avoid
None.

10.6. Hazardous decomposition products
Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Potential acute effects
Skin contact
Avoid skin contact. May cause sensitization by skin contact.
Eye contact
Splash in eye may cause irritation.

SECTION 12: Ecological information

12.1. Toxicity
Ecotoxicity
No ecotoxicological data available.
Contains small amounts of sodium azide (< 0.05 %). Sodium azide in higher concentrations is toxic to aquatic organisms.

Aquatic, comments
No potential for bioaccumulation.

12.2. Persistence and degradability
Persistence and degradability
description
No data available.
12.3. Bioaccumulative potential
Bioaccumulative potential: No data available on bioaccumulation.

12.4. Mobility in soil
Mobility: The chemical contents of the device is readily miscible with water.

12.5. Results of PBT and vPvB assessment
PBT assessment results: Not determined.

12.6. Other adverse effects
Other adverse effects / Remarks: No recommendation given.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Specify the appropriate methods of disposal:
- Rejection forbidden to the sewer and in natural environment.
- Used cartridges to be disposed according to national regulation for infectious waste.

Relevant waste regulation:

Product classified as hazardous waste: Yes
Packaging classified as hazardous waste: Yes
EWC waste code:
- EWC: 180103* wastes whose collection and disposal is subject to special requirements in order to prevent infection

Other Information:
The given EWC-code(s) are guidelines only. The end user has to choose the correct code(s) based on the actual use of the product.

SECTION 14: Transport information

14.1. UN number
Comment: Not relevant.

14.2. UN proper shipping name
Comment: Not relevant.

14.3. Transport hazard class(es)
Comment: Not relevant.

14.4. Packing group
Comment: Not relevant.

14.5. Environmental hazards
Comment: Not relevant.

14.6. Special precautions for user
Special precautions for user: Not relevant.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Pollution category: Not relevant.

Other applicable information.:
The product is not subject to transport regulation. Used product should be considered infectious waste, and transported in accordance with applicable transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
References (laws/regulations):

### 15.2. Chemical safety assessment

Chemical safety assessment has been carried out

### SECTION 16: Other information

**Supplier's notes**

The safety data sheet has been compiled, controlled and approved in accordance with the regulations in force. BIS Production Partner is not responsible for any errors or deficiencies in the information received from the manufacturer/importer/supplier. The manufacturer/importer/supplier mentioned in section 1 is legally responsible for the contents of the safety data sheet.

**List of relevant R phrases (under headings 2 and 3).**

- R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
- R34 Causes burns.
- R43 May cause sensitization by skin contact.
- R50 Very toxic to aquatic organisms.
- R53 May cause long-term adverse effects in the aquatic environment.

**List of relevant H-phrases (Section 2 and 3).**

- 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.

**Recommended restrictions on use**

For in vitro diagnostic use only.

**Sources of key data used to compile the safety data sheet**

Exact composition from the Manufacturer.

**Checking quality of information**

This Safety Data Sheet has been quality checked by BIS Production Partner, who has a NS-EN ISO 9001 certificate.

**Responsible for safety data sheet**

Axis-Shield PoC AS