Declaration Concerning the Content of Dangerous Substances in Labsystems Diagnostics' products

Infectious diseases I


Components of these products are not classified as dangerous with respect to the above mentioned regulations.

A Material Safety Data Sheet (MSDS) according to EC regulation N:o 1907/2006/EC, Article 31, had been generated for the kit component Stopping solution as it contains more than 1% sulfuric acid.

The Material Safety Data Sheet is attached as additional enclosure.

When using the kit components the general safety precautions for laboratories are sufficient. The information written in the Instructions for use has to be followed.

The information in this data sheet is to our best knowledge correct and complete and is offered in good faith as accurate. It is the user’s obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. No warranty is made, either expresses or implied.

Infectious diseases I

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product name abbreviation</th>
<th>Article number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia pneumonia IgG EIA</td>
<td>CPG</td>
<td>6111300</td>
</tr>
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<td>Chlamydia pneumonia IgA EIA</td>
<td>CPA</td>
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</table>

For further health and safety information please contact:

Labsystems Diagnostics Oy  
Tiilitie 3  
FIN-01720 Vantaa, Finland  
Telephone +358-20-155 7530  
Telefax +358-20-155 7521
SAFETY DATA SHEET

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

1.1 Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product name abbreviation</th>
<th>Company product code</th>
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<tbody>
<tr>
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</tr>
</tbody>
</table>

Component of these kits: Stopping solution
Contains >1% - <5% sulfuric acid
This component is also sold separately with Cat.no. 6111060

REACH Registration number

- 

1.2 Relevant identified uses of the substance or mixture and uses advised against

The uses of the chemical For in vitro diagnostic use only.

1.3 Details of the supplier of the Safety Data Sheet

- 

1.4 Emergency telephone number

Emergency telephone in Finland: 112
Telephone number of the official advisory body in Finland: Poison information center direct 09-471997 / 09-4711.
SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Not a hazardous product.

Classification according to EU Directives 67/548/EEC or 1999/45/EC
Not a hazardous product.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008
- 

Labelling according to European Directive 67/548/EEC
- 

2.3 Other hazards
- 

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous ingredients according to Regulation (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS-, EC- or index number</th>
<th>REACH Registration No.</th>
<th>Classification</th>
<th>Additional information Concentration</th>
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</thead>
<tbody>
<tr>
<td>Sulfuric acid</td>
<td>EINECS: 231-639-5 CAS: 7664-93-9</td>
<td>Met. Corr. cat. 1; Skin corr. cat. 1A, H290, H314</td>
<td>&gt;1 % - &lt;5 %</td>
<td></td>
</tr>
</tbody>
</table>

Hazardous ingredients according to Directive 1999/45/EC

<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS-, EC- or index number</th>
<th>REACH Registration No.</th>
<th>Classification</th>
<th>Additional information Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid</td>
<td>CAS: 7664-93-9</td>
<td>C; R 35</td>
<td>&gt;1 % - &lt;5 %</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Remove to fresh air and consult a doctor in case of symptoms.
After skin contact: Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Cover irritated skin with an emollient. Get medical attention.
After eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, then consult a doctor.
After swallowing: Wash out mouth with water, drink plenty of water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

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

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

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### SECTION 5: FIREFIGHTING MEASURES

5.1 **Extinguishing media**

Product itself does not burn. Use firefighting measures that suit the environment.

5.2 **Special hazards arising from the substance or mixture**

its products of combustion or flue gases: Sulphur dioxide (SO2).

5.3 **Advice for firefighters**

In case of burning of a larger amount wear self-contained breathing apparatus and protective clothing that is appropriate for fighting a typical fire involving chemical materials. Collect contaminated firefighting water separately. It must not enter drains.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 **Personal precautions, protective equipment and emergency procedures**

Prevent contact with skin and eyes.

6.2 **Environmental precautions**

Do not allow product to reach sewage system or water bodies.

6.3 **Methods and material for containment and cleaning up**

Absorb with liquid binding material. Use neutralizing agent or dilute with water. Afterwards clean with water and cleansing agent. Dispose of the material collected according to regulations. Ensure adequate ventilation.

Additional information: Neutralization possible with diluted sodium hydroxide solution (heat development!) or sodium carbonate or hydrogen carbonate (bubbles!)

6.4 **Reference to other sections**

- 

### SECTION 7: HANDLING AND STORAGE

7.1 **Precautions for safe handling**

No special precautions necessary if used correctly.

7.2 **Conditions for safe storage, including any incompatibilities**

Refer to the package insert or product label for additional information on storage conditions. Keep containers tightly closed. Further information about storage conditions: Keep cool (2 - 8°C). Protect from heat and direct sunlight.

7.3 **Specific end use(s)**

- 

### SECTION 8: EXPOSURE CONTROLS/PARTNERS PROTECTION

8.1 **Control parameters**

**National occupational exposure limit values**

HTP (Sulfuric acid) 0.05 mg/m\(^3\) /8 h
0.1 mg/m\(^3\) /15 min

**Other limit values**

- DNEL
- PNEC
8.2 Exposure controls

Appropriate engineering controls
Provide exhaust ventilation or other engineering control to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash facilities and a safety showers are proximal to the work-station location.

Eye / face protection
Protective eyeglasses recommended.

Skin protection
Wear appropriate protective clothing to prevent skin exposure.

Hand protection
Protective gloves.

Respiratory protection
Not required, if room is well ventilated.

Thermal hazards
- Environmental exposure controls
- 

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>9.1 Information on physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
</tr>
<tr>
<td>Odour</td>
</tr>
<tr>
<td>Odour threshold</td>
</tr>
<tr>
<td>pH</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
</tr>
<tr>
<td>Flash point</td>
</tr>
<tr>
<td>Evaporation rate</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
</tr>
<tr>
<td>Vapour pressure</td>
</tr>
<tr>
<td>Vapour density</td>
</tr>
<tr>
<td>Relative density</td>
</tr>
<tr>
<td>Solubility(ies)</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
</tr>
<tr>
<td>Decomposition temperature</td>
</tr>
<tr>
<td>Viscosity</td>
</tr>
<tr>
<td>Explosive properties</td>
</tr>
<tr>
<td>Oxidising properties</td>
</tr>
</tbody>
</table>
### Section 10: Stability and Reactivity

#### 10.1 Reactivity
- The product is stable.

#### 10.2 Chemical stability
- The product is stable.

#### 10.3 Possibility of hazardous reactions
- Reactive with oxidizing agents, combustible materials, organic materials, metals, acids, alkalis.

#### 10.4 Conditions to avoid
-  

#### 10.5 Incompatible materials
-  

#### 10.6 Hazardous decomposition products
- Hydrochloric acid and chlorine may be formed during thermal decomposition.

### Section 11: Toxicological Information

#### 11.1 Information on toxicological effects

**Acute toxicity**
-  

**Skin corrosion/irritation**
- Slight irritations

**Serious eye damage/irritation**
- Slight irritations

**Respiratory or skin sensitisation**
-  

**Germ cell mutagenicity**
-  

**Carcinogenicity**
-  

**Reproductive toxicity**
-  

**STOT—single exposure**
-  

**STOT—repeated exposure**
-  

**Aspiration hazard**
-  

**Other information**
-  

### SECTION 12: ECOLOGICAL INFORMATION

12.1 **Toxicity**  
Not available.

12.2 **Persistence and degradability**  
-  

12.3 **Bioaccumulative potential**  
Low bioaccumulation potential.

12.4 **Mobility in soil**  
-  

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

12.6 **Other adverse effects**  
-  

### SECTION 13: DISPOSAL CONSIDERATIONS

13.1 **Waste treatment methods**  
In general laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations. The disposal of liquid effluents should be carried out according to the existing local laws and the existing local regulation governing water pollution.

### SECTION 14: TRANSPORT INFORMATION

Not subject to transport regulation.

14.1 **UN number**  
-  

14.2 **UN proper shipping name**  
-  

14.3 **Transport hazard class(es)**  
-  

14.4 **Packing group**  
-  

14.5 **Environmental hazards**  
-  

14.6 **Special precautions for user**  
-  

14.7 **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**  
-  

### SECTION 15: REGULATORY INFORMATION

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

15.2 **Chemical safety assessment**  
-

SECTION 16: OTHER INFORMATION

Indication of changes

Abbreviations and acronyms

Key literature references and sources for data

Used method in evaluating classification

List of relevant R-phrases and H-statements

Full text of H-Statements referred to under section 3.
H290 May be corrosive to metals
H314 Causes severe skin burns and eye damage
Met. Corr. Corrosive to metals
Skin Corr. Skin corrosion

Full text of R-phrases referred to under section 3.
C Corrosive
R35 Causes severe burns

Training advice for workers: It is recommended to train the laboratory employees before use of this preparation.

Instructions for use: Each kit contains instructions for use.


The date of issue of the Material Safety Data Sheet: 17.2.2015

The information and recommendations above are believed to be accurate and represents the best information currently available for us, but shall not be taken as be all inclusive and shall be used only as a guide. Health and safety precautions in this data sheet may not be adequate for all individuals and/or situations. All chemicals and preparations may present unknown hazards and should be used with caution. It is user’s obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. No statement made in this data sheet shall be constructed as a permission or recommendation for the use of any product in a manner that might infringe existing patents. Not warranty is made, either expresses or implied.