

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

Infectious diseases I

Each component of our products listed in the table below is evaluated in accordance with the directives 1999/45/EC and 1967/548/EEC, regulations (EC) N:o 1907/2006, (EC) N:o 1272/2008 and (EU) N:o 453/2010.

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

Product name	Product name abbreviation	Article number
Chlamydia pneumonia IgG EIA	CPG	6111300
Chlamydia pneumonia IgA EIA	СРА	6111310
Chlamydia pneumonia IgM EIA	СРМ	6111320
Mycoplasma pneumonia IgG EIA	MPG	6111400
Mycoplasma pneumonia IgA EIA	МРА	6111410
Mycoplasma pneumonia IgM EIA	МРМ	6111420
Bordetella pertussis IgG EIA	BPG	6111500
Bordetella pertussis IgA EIA	ВРА	6111510
Bordetella pertussis IgM EIA	ВРМ	6111520
Chlamydia trachomatis IgG EIA	СТБ	6111101
Chlamydia trachomatis IgA EIA	СТА	611111

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

Product name	Product name abbreviation	Company product code
Chlamydia pneumonia IgG EIA	CPG	6111300
Chlamydia pneumonia IgA EIA	СРА	6111310
Chlamydia pneumonia IgM EIA	СРМ	6111320
Mycoplasma pneumonia IgG EIA	MPG	6111400
Mycoplasma pneumonia IgA EIA	MPA	6111410
Mycoplasma pneumonia IgM EIA	MPM	6111420
Bordetella pertussis IgG EIA	BPG	6111500
Bordetella pertussis IgA EIA	ВРА	6111510
Bordetella pertussis IgM EIA	BPM	6111520
Chlamydia trachomatis IgG EIA	CTG	6111101
Chlamydia trachomatis IgA EIA	СТА	6111111

Component of these kits: Stopping solution

Contains \geq 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		
	Street address	Tiilitie 3	
	Postcode and post office	FIN-01720 Vantaa	
	Telephone number	+358-20-155 7530	
	Telefax	+358-20-155 7521	
	E-mail address	www.labsystemsdx.com	

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.



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

2.1

Labelling according Regulation (EC) No 1272/2008

Labelling according to European Directive 67/548/EEC

2.3 Other hazards

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SECTION 3: COMPOSIT	ION / INFORMATION ON	INGREDIENTS		
Hazardous ingredients according to Regulation (EC) No 1272/2008				
Substance name	CAS-, EC- or index number	REACH Registration No.	Classification	Additional information Concentration
Sulfuric acid	EINECS: 231-639-5 CAS: 7664-93-9		Met. Corr. cat. 1; Skin corr. cat. 1A, H290, H314	<u>≥</u> 1 % - <5 %
Hazardous ingredients according to Directive 1999/45/EC Substance name CAS-, EC- or index number REACH Registration No. Classification		Classification	Additional information Concentration	
Sulfuric acid	CAS: 7664-93-9		C; R 35	<u>></u> 1 % - <5 %

SECTION 4	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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SECTIO	N 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.
SECTIO	N 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

SECTIO	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/PERSONAL PROTECTION

8.1 Control parameters

National occupational exposure limit values

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HTP (Sulfuric acid) 0,05 mg/m<sup>3</sup> /8 h
0,1 mg/m<sup>3</sup> /15 min
Other limit values
-
DNEL
-
PNEC
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Viscosity

Explosive properties Oxidising properties

Material Safety Data Sheet - Infectious diseases I According to regulations (EC) N:o 1907/2006 and (EU) N:o 453/2010

8.2	Exposure controls		
	Appropriate engineering controls		
		ontrol 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 si Hand protection	kin exposure.	
	Protective gloves.		
	Respiratory protection		
	Not required, if room is well ventilated.		
	Thermal hazards		
	- Environmental exposure controls		
	- ·		
	N 9: PHYSICAL AND CHEMICAL PROPERTIES		
9.1	Information on physical and chemical properties		
	Appearance	clear colourless	
	Odour	odourless	
	Odour threshold	acidic	
	рН	easily soluble in water	
	Melting point/freezing point		
	Initial boiling point and boiling range		
	Flash point		
	Evaporation rate		
	Flammability (solid, gas)		
	Upper/lower flammability or explosive limits		
	Vapour pressure		
	Vapour density		
	Relative density		
	Solubility(ies)		
	Partition coefficient: n-octanol/water		
	Auto-ignition temperature		
	Decomposition temperature		



9.2	Other information
	-
SECTION 1	0: STABILITY AND REACTIVITY
10.1	Reactivity
	-
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
	-
10.3	Hazardous decomposition products
	Hydrochloric acid and chlorine may be formed during thermal decomposition.
SECTION 2	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

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Reproductive toxicity

STOT-single exposure

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STOT-repeated exposure

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Aspiration hazard

Other information

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SECTION	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.

Sources of key data used to compile the Material Safety Data Sheet: The collected information is based on the directives 1999/45/EC and 67/548/EEC, regulations (EC) No 1907/2006, (EC) No 1272/2008 and (EU) No 453/2010 and the material safety data sheet for H2SO4.

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.