LABSYSTEMS DIAGNOSTICS
speaking your language

Date of issue:
30 April, 2015

Material Safety Data Sheet – Chlamydia pneumoniae IgG/IgM and IgA MIFA According to regulations (EC) N:o 1907/2006 and (EU) N:o 453/2010

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

Chlamydia pneumoniae IgG/IgM MIFA and Chlamydia pneumoniae IgA MIFA

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 regulations (EC) N:o 1907/2006 and (EU) N:o 453/2010 has been generated for the kit component Mounting fluid as it contains 50 % glycerol.

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.

Product name	Article number
Chlamydia pneumoniae IgG/IgM MIFA	6108380
Chlamydia pneumoniae IgG/IgM MIFA	6108382
Chlamydia pneumoniae IgA MIFA	6108390
Chlamydia pneumoniae IgA MIFA	6108392
Chlamydia pneumonia Antigen dotted slides fot micro-IF	6108384

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	Article number
Chlamydia pneumoniae IgG/IgM MIFA	6108380
Chlamydia pneumoniae IgG/IgM MIFA	6108382
Chlamydia pneumoniae IgA MIFA	6108390
Chlamydia pneumoniae IgA MIFA	6108392
Chlamydia pneumonia Antigen dotted slides fot micro-IF assay	6108384

Component of these kits: Mounting fluid

Contains 50 % glycerol

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.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Classification according to EU Directives 67/548/EEC or 1999/45/EC
This substance is not classified as dangerous according to Directive 67/548/EEC.

2.2 Label elements

The product does not need to be labelled in accordance with EC directives.

2.3 Other hazards

-

SECTION 3: COMPOSITION / 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 in Mounting Fluid**
Glycerol	CAS: 56-81-5		-	50 %
Sodium azide	CAS: 26628-22-8 Index no.247-852-1		Acute Tox. 2; Aquatic Acute 1; Aquatic Chronic 1; H300; H400; H410; EUH032	<0,0975 %
Barbital sodium	CAS-No. 144-02-5 EC-No. 205-613-9		Acute Tox. 4; H302	0,52 %
Hazardous ingredients according to Directive 1999/45/EC				
Substance name	**CAS-, EC- or index number**	**REACH Registration No.**	**Classification**	**Concentration**
Glycerol	CAS: 56-81-5		-	50 %
Sodium azide	CAS: 26628-22-8		T+; N R: 28-32-50/53 S: (1/2-)28-45-60-61	<0,0975 %
Barbital sodium	CAS-No. 144-02-5		Xn, R22	0,52 %

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice

No special measures required.

If inhaled

Remove to fresh air and consult a doctor in case of symptoms.

In case of skin contact

Flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Consult a doctor if irritation develops.

In case of eye contact

Check for and remove any contact lenses**.** Flush eyes with plenty of water with the eyelid held wide open for at least 15 minutes, and then consult a doctor if irritation develops.

If swallowed

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 if irritation or symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

-

4.3 Indication of any immediate medical attention and special treatment needed

-

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Irritating and highly toxic gases may be generated by fire conditions. Vapors may be heavier than air. They can spread along the ground and collect in low or confined areas. Containers may explode when heated.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

No special precautions necessary if used correctly. Wash hands thoroughly after use. Use with adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid ingestion or inhalation.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

-

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

National occupational exposure limit values

Glycerol HTP: 20 mg/m3 (8 h) (Finland 2002)

Other limit values

Chemical Name	ACGIH	OSHA - Final PELs
Glycerine	10 mg/m3 TWA	15mg/m3 TWA (total dust) 5 mg/m^3 TWA (respirable dust)

8.2 Exposure controls

Appropriate engineering controls

Use adequate ventilation to keep concentrations below exposure limits. Eye wash and safety shower must be available.

Eye / face protection

Safety glasses.

Skin protection

Wear appropriate protective clothing to prevent skin exposure.

Hand protection
Handle with gloves.
Respiratory protection
Not required, if room is well ventilated.
Thermal hazards
-
Environmental exposure controls
Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES		
9.1	Information on physical and chemical properties	
	Appearance	clear colorless, slightly viscose liquid
	Odour	Faint odor
	Odour threshold	
	pH	8,5 at 23°C
	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)	Soluble in water
	Partition coefficient: n-octanol/water	
	Auto-ignition temperature	
	Decomposition temperature	
	Viscosity	
	Explosive properties	
	Oxidising properties	

9.2	Other information

The other physical and chemical properties of mounting fluid have not been investigated.

SECTION 10: STABILITY AND REACTIVITY	
10.1	Reactivity

-

10.2	Chemical stability

The products are stable.

10.3	Possibility of hazardous reactions

-

10.4	Conditions to avoid

Heat, ignition sources, incompatible materials.

10.5	Incompatible materials

Acetic anhydride, potassium permanganate, strong acids, strong basins, caustics, isocyanides, aliphatic amines, oxidizing agents.

10.3	Hazardous decomposition products

Carbon monoxide, carbon dioxide, irritating fumes and gases.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

The products contain 50 % glycerol. The following information refers to effects of 100 % glycerol.

Acute toxicity

LD50 Oral - Rat - 12.600 mg/kg

LD50 Dermal - Rabbit - > 10.000 mg/kg

Skin corrosion/irritation

Skin - Rabbit

Result: Mild skin irritation - 24 h

Serious eye damage/irritation

Eyes - Rabbit

Result: Mild eye irritation - 24 h

Respiratory or skin sensitisation

-

Germ cell mutagenicity

-

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

-

STOT-single exposure

-

STOT-repeated exposure

-

Aspiration hazard

-

Other information

Prolonged or repeated exposure may cause:, Nausea, Headache, Vomiting, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: ECOLOGICAL INFORMATION

Mounting fluid preparation contains ≥ 1 % (w/v) Glycerol. The following information refers to effects of 100 % (w/v) Glycerol.

12.1 Toxicity

Algae: LOEC=2900 mg/kg. Microcystis aeruginosa. Fish: CL_{50}> 5000mg/l, 24h, Carassius auratus.

12.2 Persistence and degradability

63% BOD, 14vrk, 100 mg/l, slurry 30 mg/l (MITI 1992). Biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Water soluble.

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 sections 2 and 3

Acute Tox. Acute toxicity

Aquatic Acute Acute aquatic toxicity

Aquatic Chronic Chronic aquatic toxicity

EUH032 Contact with acids liberates very toxic gas

H300 Fatal if swallowed

H300 + H310 Fatal if swallowed or in contact with skin

H302 Harmful if swallowed

Full text of R-phrases referred to under sections 2 and 3

N Dangerous for the environment

T+ Very toxic

Xn Irritative

R22 Harmful if swallowed

R27 Very toxic in contact with skin

R28 Very toxic if swallowed

R32 Contact with acids liberates very toxic gas

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

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 MSDS(s) of Sodium azide, Glycerol and Barbital sodium.

The date of issue of the Material Safety Data Sheet: 30.4.2015

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.