

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

Chlamydia pneumoniae micro-IF assay

Each component of our products listed in the table below is evaluated in accordance with the directives 1999/45/EC and 1967/548/EC as well as with the Finnish "Vaarallisten aineiden luettelo" (ordinance on dangerous chemicals and preparations)

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

Material Safety data Sheet of mounting fluid (component no 6 in Chlamydia pneumoniae IgG/IgM and IgA micro-IF test kits) will be delivered to professional user on request. 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.

Product name	Article number
Chlamydia pneumonia IgG/IgM micro-IF test kit	6108380, 6108382
Chlamydia pneumonia IgA micro-IF test kit	6108390, 6108392
Chlamydia pneumonia Antigen dotted slides for micro-IF assay	6108384

For further health and safety information please contact:

Ani Labsystems Ltd. Oy

Tiilitie 3

FIN-01720 Vantaa

Finland

Telephone +358-20-155 7523

Telefax +358-20-155 7521

Material Safety Data Sheet - Chlamydia pneumoniae micro-IF assay According to 1907/2006/CE

1. Identification of Substance/Preparation and of the company

IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

Product name	Cat.number
Chlamydia pneumonia IgG/IgM micro-IF test kit	6108380, 6108382
Chlamydia pneumonia IgA micro-IF test kit	6108390, 6108392

Component of these kits: Mounting fluid

Contains more than 1% Glycerol

Application of the substance /preparation: For in vitro diagnostic use only

IDENTIFICATION OF THE COMPANY

Manufacturer: Ani Labsystems Ltd. Oy

Address: Tiilitie 3; 01720 Vantaa; Finland

Telephone: +358 20 1557523

Fax: +358 20 1557521

www.anilabsystems.com

Emergency telephone in Finland: 112

Telephone number of the official advisory body in Finland: Poison information center direct
09-471997 / 09-4711

2. Composition/information on Components

Description: Mounting fluid contains Glycerol

Name of ingredient for preparation not classified as dangerous: Glycerol

Concentration range: $\geq 1\%$ (w/v)

Ingredient classification: HTP(2002)=20mg/m³, 8h

EINECS: 200-289-5

CAS: 56-81-5

3. Hazards Identification

Mounting fluid preparation is not classified as dangerous according directives 1999/45/EC and 1967/548/EC

Emergency overview: Low hazard for usual handling

Potential health effects:

Eye: May cause eye irritation

Skin: May cause skin irritation

Ingestion: ingestion of large amounts may cause gastro-intestinal irritation or headache.

Inhalation: May cause respiratory tract irritation.

Chronic: Not known.

4. First Aid Measures

General information: No special measures required

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

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

After 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.

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 if irritation or symptoms occur.

5. Fire Fighting Measures

General information: : In case of burning of a larger amount wear self-contained breathing apparatus and full protective gear. 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.

Suitable extinguishing agents: Use water spray, dry chemical, carbon dioxide, or appropriate foam to extinguish fire. Use fire fighting measures that suit the environment.

6. Accidental Release Measures

Person-related safety precautions: Ensure supply fresh air in enclosed rooms.

Measures for environmental protection: -

Measures for cleaning/collecting: Wash off small quantities with plenty of water. Take up large quantities with fluid binders and dispose off in a suitable manner.

7. Handling and Storage

Handling:

Information 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.

Storage:

Requirements to be met by storerooms and containers: Keep containers tightly closed. Store in a cool dry well ventilated area away from incompatible substances.

8. Exposure Controls and Personal Protection

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

Personal Protective Equipment:

General protective and hygienic measures: The usual precautionary measures should be adhered to in handling the Chemicals. Avoid contact with eyes and skin. Instantly remove any soiled and impregnated garments. Do not eat or drink while working. Keep away from foodstuff, beverages and food. Wash hands during breaks and at the end of work.

Breathing equipment: Not required, if room is well ventilated.

Protective of hands: Protective gloves.

Eyes: Recommended protective eyeglasses

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Exposure Limits:

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

Consult local authorities for acceptable exposure limits

9. Physical and Chemical Properties

Physical State: Liquid

Appearance: clear colorless, slightly viscose liquid

Odor: Faint odor

pH: 8,5 at 23°C

Solubility: Soluble in water

Other information: The other physical and chemical properties of Mounting fluid, have not been investigated.

10. Stability and Reactivity

Stability: The product is stable

Conditions to be avoided: Heat, ignition sources, incompatible materials

Incompatibility with other material: Acetic anhydride, potassium permanganate, strong acids, strong basins, caustics, isocyanides, aliphatic amines, oxidizing agents.

Hazardous decomposition of products: Carbon monoxide, carbon dioxide, irritating fumes and gases.

11. Toxicological Information

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

Acute toxicity:

LD50 = 4090 mg/kg (oral mouse)

LD50 = 12600 mg/kg (oral rat)

Primary irritant effect: Irritating to eyes and skin. Fog irritates to respiratory system. If swallowed irritating to digestive system.

Empirical data on effects on humans: $TD_{LO} = 1428$ mg/kg (by mouth, human): have an influence central nervous system and digestive system. Mutagenic.

Further data: Animal experiment causes developmental disorder. The product should be handled with care like usual when dealing with chemicals.

12. Ecological Information

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

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

Mobility: Water soluble, drift with water

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

Bioaccumulation potential: Not known

13. Disposal Considerations

General notes: In general laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations.

The disposal should be carried out according to the existing local laws and the existing local regulation governing water pollution.

14. Transport Information

Pacaging category: Not subject to transport regulation.

15. Regulatory Information

Name of the ingredient: Glycerol

Mounting fluid preparation is not classified as dangerous

16. Other Information

List of used Risk-phrases and safety-phrases:

R-phrases: -

S-phrases: -

Training advice: 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 1907/2006/CE, 1999/45/EC and 1967/548/EC as well as to the Finnish "Vaarallisten aineiden luettelo" (ordinance on dangerous chemicals and preparations) and material safety data for Glycerol.

The date of issue of the Material Safety Data Sheet: 25.6.2009/TVi

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.

Ani Labsystems Ltd. Oy

Tiilitie 3

FIN-01720 Vantaa

Finland

Telephone +358-20-155 7523

Telefax +358-20-155 7521

e-mail : tiina.vilkkinen@anilabsystems.com