

**Material Safety Data Sheet – Infectious Diseases Real-Time PCR
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

**M. pneumoniae + C. pneumoniae Duplex Real-Time PCR and
B. pertussis + B. parapertussis Duplex Real-Time PCR**

Each component of our products listed in the table below is evaluated in accordance with the 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.

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
M. pneumoniae + C. pneumoniae Duplex Real-Time PCR	8100100, 8101100 and 8100101
B. pertussis + B. parapertussis Duplex Real-Time PCR	8100200, 8101200

For further health and safety information please contact:

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SAFETY DATA SHEET

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

1.1 Product identifier

Product name	Article number
M. pneumoniae + C. pneumoniae Duplex Real-Time PCR	8100100, 8101100 and 8100101
B. pertussis + B. parapertussis Duplex Real-Time PCR	8100200, 8101200

REACH Registration number

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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 product

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

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2.3 Other hazards

None

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SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Components of these kits:

1 Amplification mix This product is a mixture:

Component	Concentration
Sodium azide CAS-No. 26628-22-8 EC-No. 247-852-1	0 – 0,1%
Magnesium Chloride CAS-No. 7786-30-3 EC-No. -	1 % - 10 %
Gelatin CAS-No. 9000-70-8 EC-No. -	1 – 10 %
Glycerin CAS-No. 56-81-5 EC-No. 200-289-5	10 – 30 %
1,3-propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride CAS-No. 1185-53-1 EC-No. -	10 – 30 %

2 Negative control

No dangerous ingredients.

3 Positive control

No dangerous substances.

The product contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact: Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed: Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician

4.2 Most important symptoms and effects, both acute and delayed

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4.3 Indication of any immediate medical attention and special treatment needed

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas, Magnesium oxide

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary. Use water spray to cool unopened containers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided

6.3 Methods and material for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

6.4 Reference to other sections

For disposal see section 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Keep away from sources of ignition - No smoking. Keep away from heat and sources of ignition. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

7.3 Specific end use(s)

no data available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

National occupational exposure limit values

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Other limit values

-

DNEL

-

PNEC

-

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8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday

Eye / face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace

Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards

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Environmental exposure controls

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES	
9.1	Information on physical and chemical properties
Appearance	No information available
Odour	No information available
Odour threshold	No information available
pH	No information available
Melting point/freezing point	No information available
Initial boiling point and boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available

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Upper/lower flammability or explosive limits	No information available
Vapour pressure	No information available
Vapour density	No information available
Relative density	No information available
Solubility(ies)	No information available
Partition coefficient: n-octanol/water	No information available
Auto-ignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available
Explosive properties	No information available
Oxidising properties	No information available

9.2 Other information

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

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10.2 Chemical stability

Stable under normal condition

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use

10.4 Conditions to avoid

-

10.5 Incompatible materials

-

10.3 Hazardous decomposition products

None under normal use

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Sodium azide LD50 (oral) = 27 mg/kg (rat)

Glycerin LD50 (oral) = 12600 mg/kg (rat/mouse)

Skin corrosion/irritation

May cause irritation with susceptible persons

Serious eye damage/irritation

May cause irritation with susceptible persons

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Respiratory or skin sensitisation

May be harmful by inhalation

Germ cell mutagenicity

no data available

Carcinogenicity

none

Reproductive toxicity

none

STOT-single exposure

no known effects under normal use conditions

STOT-repeated exposure

no known effects under normal use conditions

Aspiration hazard

no data available

Other information

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SECTION 12: ECOLOGICAL INFORMATION	
12.1	Toxicity No data available
12.2	Persistence and degradability Inherently biodegradable
12.3	Bioaccumulative potential Does not bioaccumulate
12.4	Mobility in soil No data available
12.5	Results of PBT and vPvB assessment No data available
12.6	Other adverse effects Glycerin 56-81-5; Daphnia magna EC50>500 mg/L (24 h); logPow-1.76

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	
14.1	UN number -
14.2	UN proper shipping name

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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

Land transport ADR/RID and GGVS/GGVE(cross-border/domestic)

ADR/RID-GGVS/E Class: -
 Remarks: not restricted

Marine transport IMDG/GGVSea

IMDG/GGV Sea Class: -
 Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA Class: -
 Remarks: not restricted

Additional information: Because of small volume and concentration, no classification as dangerous goods according to above regulations

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

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 regulations (EC) No 1907/2006, (EC) No 1272/2008 and (EU) No 453/2010.

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The date of issue of the Material Safety Data Sheet: 1.10.2015

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.