Chorus Mycoplasma pneumoniae IgM (REF 81035) is an immunoenzymatic method for the qualitative determination of IgM-class antibodies to Mycoplasma pneumoniae in human serum.

Each package contains 6 bags with 6 devices each (sufficient for 36 determinations of total).

Each kit consists of:

- **Device:**
  - Position 8: Space for application of bar code label
  - Position 7: Empty
  - Position 6: MICROPLATE WELL
    Coated with Mycoplasma pneumoniae antigens.
  - Position 5: MICROPLATE WELL
    Uncoated
  - Position 4: TMB SUBSTRATE 0.35 ml.
    The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
    For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
    Contents: Tetramethylbenzidine 0.26 mg/mL and H2O2 0.01% stabilized in 0.05 mol/L citrate buffer (pH 3.8)
  - Position 3: SAMPLE DILUENT 0.35 ml
    The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
    For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
    Contents: Proteic solution containing anti-human IgG, phenol 0.05%, Bronidox 0.02% and an indicator to reveal the presence of the serum.
  - Position 2: CONJUGATE 0.35 ml
    The substance is not classified as dangerous according to Regulation 1272/2008 and European Directive 1999/45/CE and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
    For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
    Contents: anti-human IgM monoclonal antibodies labeled with peroxidase in phosphate buffer containing phenol 0.05% and Bronidox 0.02%.
  - Position 1: EMPTY WELL
    In which the operator must place the undiluted serum
    - CALIBRATOR 0.175 ml
      Diluted human serum containing Proclin and Gentamycin. Ready for use.
    - POSITIVE CONTROL 0.425 ml
      Diluted human serum containing Proclin and Gentamycin. Ready for use.

Both mixtures are classified as **dangerous** according to Regulation 1272/2008/EC and Directive 1999/45/EC.
For these mixtures the material safety data sheet, prepared in accordance with EC regulations 1907/2006 and 453/2010, is available below.
1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIERS

Product name: CALIBRATOR/POSITIVE CONTROL
Product number: PF 30144-C
Brand: DIESSE

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCES OR MIXTURE AND USES ADVISED AGAINST

Identified use: Professional use as laboratory reagent. Calibrator: diluted human serum, necessary for the calibration of the instrument. Positive Control: diluted human serum, used to verify the correctness of the obtained results and for the subsequent validation of the test.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: DIESSE Diagnostica Senese SpA
Registered office: Via A. Solari 19
20144 Milan, Italy
Tel: +39 02 4859121
Fax: +39 02 48008530
Production plant: Via delle Rose, 10 – Loc. Tognazza
53035 Monteriggioni (SI), Italy
Tel: +39 0577 319560/61
Fax: +39 0577 318763

1.4 EMERGENCY TELEPHONE NUMBER

Emergency number: DIESSE Diagnostica Senese SpA
Tel: +39 0577 587143
e-mail: letizia.rovai@diesse.it

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

Classification according to Regulation (EC) No. 1272/2008:
Acute Toxicity – Category 4 (Oral)
Skin Sensitizer – Category 1

Hazard statement:
H302 – Harmful if swallowed
H317 – May cause an allergic skin reaction.

Classification according to European Directive 67/548/EEC and 1999/45/EC:
Xn; R22
Xi; R43

R-phrases:
R22 – Harmful if swallowed
R43 – May cause sensitization by skin contact

2.2 LABEL ELEMENTS

Pictograms: GHS07
Signal word: Warning

Hazard statement(s):
H302 – Harmful if swallowed
H317 – May cause an allergic skin reaction.

Precautionary statement(s):
Prevention:
P261 – Avoid breathing dust/fume/gas/mist/vapors/spray.
P264 – Wash ... thoroughly after handling
P272 – Contaminated work clothing should not be allowed out of the workplace.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.
Response:
P301+P312 – IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302+P352 – IF ON SKIN: Wash with plenty of soap and water.
P330 – Rinse mouth
P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.
P363 – Wash contaminated clothing before reuse.

Disposal:
P501- Dispose of contents/container in accordance with local regulation

Contains:
Ethylene glycol
Index. No 603-027-00-1

Reaction mass of: 5-chloro-2-methyl-4-iso-thiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1);
Index No: 613-167-00-5

2.3 OTHER HAZARDS
None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES
Not applicable

3.2 MIXTURES

<table>
<thead>
<tr>
<th>International Chemical Identification</th>
<th>Concentration</th>
<th>Directive</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene glycol</td>
<td>25-35%</td>
<td>Xn R22</td>
<td>Acute Tox. 4</td>
</tr>
<tr>
<td>Cas No 107-21-1</td>
<td></td>
<td></td>
<td>H302</td>
</tr>
<tr>
<td>EC No 203-473-3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Index No 603-027-00-1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reaction mass of: 5-chloro-2-methyl-</td>
<td>0.0015-0.06%</td>
<td>T R23/24/25</td>
<td>Acute Tox. 3</td>
</tr>
<tr>
<td>4-iso-thiazolin-3-one [EC no. 247-</td>
<td></td>
<td></td>
<td>H331</td>
</tr>
<tr>
<td>500-7] and 2-methyl-2H -isothiazol-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-one [EC no. 220-239-6] (3:1);</td>
<td></td>
<td></td>
<td>Acute Tox. 3</td>
</tr>
<tr>
<td>Cas No 55965-84-9</td>
<td>C R34</td>
<td>Skin Corr. 1B</td>
<td>H314</td>
</tr>
<tr>
<td>Index No 613-167-00-5</td>
<td>Xi R43</td>
<td>Skin Sens. 1</td>
<td>H317</td>
</tr>
<tr>
<td></td>
<td>N R50/53</td>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

The entire text of Hazard Statements and R-phrases is reported at Section 16 of the sheet.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice: Move the person from the exposure to open air. Consult a physician immediately and show this Material Safety Datasheet.

Skin contact: Wear off the contaminated clothes and wash with copious amounts of water.

Eye contact: If present, remove immediately contact lenses. Wash with plenty of water at least 15 minutes, keeping eyelids opened. Consult an oculist if the irritation persists.

Inhalation: Consult a physician

Ingestion: Rinse mouth immediately and drink a copious amounts of water. Do not cause vomiting or emesis. Call a physician immediately.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS

Ingestion of the product can cause nausea, vomiting and CNS disorders.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available
5. FIREFIGHTING MEASURES

5.1 EXTINGUISH MEDIA

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Not Suitable extinguishing media: None.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

If heated, the mixture may release combustible vapors which diffuse along floors. The mixture is not flammable, however in case of fire may release irritating and/or toxic gases (CO\textsubscript{2}, CO, NO\textsubscript{x}, SO\textsubscript{x}, HCl).

5.3 ADVICE FOR FIREFIGHTERS

In case of fire wear self-contained breathing apparatus. Avoid that fire extinguishing water contaminates surface water and/or groundwater.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Keep people not involved in the intervention operations away. Avoid inhalation contact with vapors/aerosols. Ensure an adequate ventilation of the affected area. Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid the contamination of surface water, soil and the dispersion in the air. Do not let product enter into drains. Discharge into the environment must be avoided.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Contain the leakages with earth and sand. Collect the spilled material with mechanical means avoiding raising of dust and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers.

6.4 REFERENCE TO OTHER SECTIONS

For further information see section 8 and 13.

7. HANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING

Work in well ventilated areas and in the presence of ventilation systems or personal protective equipment. Do not inhale vapors or mists. Avoid contact with eyes and skin.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep the containers tightly closed and labeled in a cool, well-ventilated area, away from heat sources and from direct sunlight. Keep the containers vertically avoiding the possibility of falls and leakage.

7.3 SPECIFIC END USE

None

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Applicable exposure limits:

<table>
<thead>
<tr>
<th>Description</th>
<th>Type</th>
<th>TWA/8h mg/m\textsuperscript{3}</th>
<th>STEL/15min mg/m\textsuperscript{3}</th>
<th>ppm</th>
<th>ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene glycol*</td>
<td>D.Lgs 81/2008</td>
<td>52</td>
<td>104</td>
<td>20</td>
<td>40</td>
</tr>
</tbody>
</table>

*Note: Skin

Other information: Ethylene glycol

Derived no effect level (IUCLID)
8.2 EXPOSURE CONTROLS

Work and handle according to the usual precautionary measures for handling chemicals. Do not eat, drink or smoke while handling the product; wash hands thoroughly with soap and water before meals and after the work shift. Immediately remove all contaminated clothing.

Appropriate engineering controls:
Ensure an adequate ventilation of the working area.

Personal Protective Equipment:
The suggestions on the use of specific PPE are indicative. Their choice should be made according to the use of the product and the instructions given by the supplier of the device.

Hand protections:
Chemical-resistant gloves, compliant with EN 374. Suitable material: nitrile rubber (thickness: 0.11 mm).
Gloves have to be checked by the user, before using.
Dispose the used gloves according to good laboratory practices and to law.
Clean and dry the hands after the use.

Eye protections:
Side Shields Safety Goggles compliant with EN 166

Body protections:
Work outfits.

Respiratory protections:
Based on the results of the risk assessment the use a full face mask with combined filter type AP (EN 14387) may be need.

8.3 ENVIRONMENTAL EXPOSURE CONTROLS:
Do not discard residuals in the environment. Discard the empty containers as hazardous waste.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor:</td>
<td>Characteristic</td>
</tr>
<tr>
<td>Odor threshold:</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>197.6°C (Ethylene glycol)</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>111°C (Ethylene glycol)</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Flammability</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limit</td>
<td>3.2-15.3 % v/v (Ethylene glycol)</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>0.053 hPa at 20°C (Ethylene glycol)</td>
</tr>
<tr>
<td>Vapor density</td>
<td>2.14 (Ethylene glycol)</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Partition coefficient: n-octano/water</td>
<td>Log P_{ow} = -1.36 (Ethylene glycol)</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>200-250°C (Ethylene glycol)</td>
</tr>
<tr>
<td>Viscosity</td>
<td>21 mPa.s (Ethylene glycol)</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
</tr>
</tbody>
</table>
9.2 Other safety information

None

10. Stability and Reactivity

10.1 Reactivity
In case of a strong heating, the product could form vapors, which are flammable if mixed with air.

10.2 Chemical Stability
Stable under the recommended transport, handling and storage conditions

10.3 Possibility of Hazardous Reactions
Information about the contained substances:

Ethylene glycol
Risk of explosion in case of contact with aluminum and perchloric acid.
Risk of fire or formation of flammable gases in case of contact with chromium chloride, strong oxidizing agents, chlorate, potassium permanganate and peroxides.
Exothermic reactions with chlorosulfonic acid, sodium hydroxide and sulfuric acid are possible.

10.4 Conditions to Avoid
Avoid the strong heating of the mixture.

10.5 Incompatible Materials
Strong oxidizing and reducing agents.

10.6 Hazardous Decomposition Products
When heated or in case of fire, vapors potentially dangerous to health may be produced.

11. Toxicological Information

11.1 Information on Toxicological Effects
The product is harmful if swallowed.

Toxicological properties of the substances

Ethylene glycol
- Acute toxicity: No data available
- Skin irritation/corrosion: Results of tests performed using rabbits: Not corrosive; slight irritation of skin with reversible effects within 72h with completely reversible effects
- Eye lesions/severe eye irritation: Patch test results: Negative
- Respiratory/skin sensitization:
- Mutagenicity for germ cells: Results of in vitro genotoxicity tests (Ames test with metabolic activation): Negative
- Carcinogenicity: No data available
- Reproductive toxicity: No data available
- Toxicity for target organs (single and repeated exposures): No data available
- Hazards in case of inhalation: No data available
- Additional information: No data available

12. Ecological Information

12.1 Toxicity
Use according to the good working practices, avoiding the disposal in the environment. In case the product reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

Toxic properties of the substances

Ethylene glycol
- Fishes (Oncorhynchus mykiss, 96h): CL50 > 18500 mg/l
- Invertebrates (Daphnia magna, 24h): EC50 74000 mg/l
- Algae (Scenedesmus quadricauda, 7d): IC5 > 10000 mg/l
12.2 **PERSISTENCE AND DEGRADABILITY**

- **Ethylene glycol:** readily biodegradable (OECD TG 301C)

12.3 **BIOACCUMULATIVE POTENTIAL**

No data available

12.4 **MOBILITY IN SOIL**

No data available

12.5 **RESULTS OF PBT AND vPvB ASSESSMENT**

No data available

12.6 **OTHER ADVERSE EFFECTS**

No data available

### 13. DISPOSAL CONSIDERATIONS

13.1 **WASTE TREATMENT METHODS**

The product and its containers should be considered special waste. Their transport and disposal should be performed by authorized specialized companies according to the law.

### 14. TRANSPORT INFORMATION

Not hazardous good according to the transport regulations.

### 15. REGULATORY INFORMATION

15.1 **SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE**

Hazard labeling under directives 1272/2008 (EC) and its subsequent amendments.

- **Legislative Decree 81/2008:**
  
  The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk

- **European Standard 1907/2006/EC:**
  
  Not applicable

- **Directive 96/82/EC (Seveso Directive):**
  
  Not applicable

15.2 **CHEMICAL SAFETY ASSESSMENT**

Not performed for the product

### 16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

**Text of the hazard statements present at point 3**

- H301 Toxic if swallowed
- H302 Harmful if swallowed
- H311 Toxic in contact with skin
- H314 Causes severe skin burns and eye damage
- H317 May cause an allergic skin reaction
- H331 Toxic if inhaled.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

**Text of the Risk phrases present at point 3**

- R22 – Harmful if swallowed
- R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
- R34 Causes burns
- R43 May cause sensitization by skin contact
- R50/53 Very toxic to aquatic organisms, May cause long-term adverse effects in the aquatic environment

SAFETY INFORMATION – Chorus Mycoplasma pneumoniae IgM (REF: 81035)
REFERENCES:
1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and technical adjustments
7. The Merck Index.
8. Handling Chemical Safety
9. NIOSH - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique

DIESSE Diagnostica Senese SpA declares that the information contained in this data sheet is based on the knowledge available to us on the date of the last version. Users must verify the suitability and accuracy of the provided information according to the specific use of the product. The document has not be accepted as a guarantee of any specific product property. Because of the use of this product is not subject to our direct control, the users, under their own responsibility, must observe the laws and regulations relating to health and safety. We accept no responsibility for improper use.

This data sheet supersedes each previous edition.