Chorus Treponema IgM (REF 81051 and REF 81051/12) is an immunoenzymatic method for the qualitative determination of IgM-class antibodies to Treponema pallidum in human serum.

REF 81051: each package contains 6 bags with 6 devices each (sufficient for 36 determinations of total).
REF 81051/12: each package contains 2 bags with 6 devices each (sufficient for 12 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 anti-human IgM monoclonal antibodies.

  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, it is not necessary to develop a material safety data sheet.
  Contents: Tetramethylbenzidine 0.26 mg/mL and H$_2$O$_2$ 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, it is not necessary to develop a material safety data sheet.
  Contents: Proteic solution containing 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, it is not necessary to develop a material safety data sheet.
  Contents: mixture of recombinant proteins of Treponema pallidum labelled with HRP 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 92053-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, at known concentration of antibodies, necessary for the calibration of the instrument.
Positive Control: diluted human serum, at known concentration of antibodies, 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:
Centro Antiveleni, Ospedale Niguarda Ca’ Granda - Milano
Tel: +39 02 66101029

Centro Antiveleni, Azienda Ospedaliera “S.G.Battista” – Molinette di Torino - Torino
Tel: +39 011 6637637

Centro Antiveleni – U.O. Tossicologia Medica, Azienda Ospedaliera Careggi – Firenze
Tel: +39 055 4277238

Centro Antiveleni, Policlinico A. Gemelli – Università Cattolica del Sacro Cuore - Roma
Tel: +39 06 3054343

Centro Antiveleni, Azienda Ospedaliera A. Cardarelli – Napoli
Tel: +39 081 7472870


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

2.2 LABEL ELEMENTS

Pictograms: GHS07
Signal word: Caution

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>Classification</th>
<th>Regulation EC/1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene glycol</td>
<td>25-35%</td>
<td></td>
<td>Acute Tox. 4 H302</td>
</tr>
<tr>
<td>Cas No 107-21-1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC No 203-473-3</td>
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<td>Index No 603-027-00-1</td>
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<tr>
<td>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);</td>
<td>0.0015-0.06%</td>
<td>Acute Tox. 3 H311</td>
<td></td>
</tr>
<tr>
<td>Cas No 55965-84-9</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Index No 613-167-00-5</td>
<td></td>
<td></td>
<td>Aquatic Chronic 1 H410</td>
</tr>
</tbody>
</table>

The entire text of Hazard Statements 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. Call a physician immediately. Do not cause vomiting.

#### 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 (water, CO₂ foam, powder) 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 (CO₂, CO, NOₓ, SOₓ, 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 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 in a cool, well-ventilated area, away from heat sources and humidity. Close accurately the containers and keep them 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/m³</th>
<th>STEL/15min mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene glycol*</td>
<td>D.Lgs 81/2008</td>
<td>52</td>
<td>104</td>
</tr>
</tbody>
</table>

*Note: Skin
Other information: Ethylene glycol

Derived no effect level (IUCLID)

PNEC
Fresh water: 10 mg/L
Marine water: 1 mg/L
Intermittent release: 10 mg/L

STP 199.5 mg/L
Sediments (Fresh water): 20.9 mg/kg sediment dw
Soil: 1.53 mg/kg soil dw

DNEL (Workers)
Long-term exposure - systemic effects - dermal: 106 mg/kg bw/day
Long-term exposure - systemic effects - inhalation: 35 mg/m³

DNEL (Population)
Long-term exposure - systemic effects - dermal: 53 mg/kg bw/day
Long-term exposure - systemic effects - inhalation: 7 mg/m³

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:
In case of vapors/aerosol, the use a full face mask with combined filter type AP (EN 14387) may be needed.

8.3 ENVIRONMENTAL EXPOSURE CONTROLS:
Do not discard residuals in the environment.
9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: Liquid
- **Odor**: Characteristic
- **Odor threshold**: Not pertinent
- **pH**: No data available
- **Melting point/freezing point**: 197.6°C (Ethylene glycol)
- **Initial boiling point and boiling range**: No data available
- **Flash point**: 111°C (Ethylene glycol)
- **Evaporation rate**: Not pertinent
- **Flammability**: Not pertinent
- **Upper/lower flammability or explosive limit**: 3.2-15.3 % v/v (Ethylene glycol)
- **Vapor pressure**: 0.053 hPa at 20°C (Ethylene glycol)
- **Vapor density**: 2.14 (Ethylene glycol)
- **Relative density**: No data available
- **Water solubility**: Soluble in water
- **Partition coefficient: n-octano/water**: Log P<sub>ow</sub> = -1.36 (Ethylene glycol)
- **Autoignition temperature**: Not pertinent
- **Decomposition temperature**: 200-250°C (Ethylene glycol)
- **Viscosity**: 21 mPa·s (Ethylene glycol)
- **Explosive properties**: Not explosive
- **Oxidizing properties**: No data available

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 (boron hydroxide, COx) may be produced.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

The product is harmful if swallowed.
- The product can cause an allergic reaction in case of contact with skin.
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
Eye lesions/severe eye irritation: Results of tests performed using rabbits: slightly irritating with completely reversible effects
Respiratory/skin sensitization: Patch test results: Negative
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 classification and 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.
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.

References:

1. Directive 1999/45/EC and following amendments
2. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
5. ECHA European Chemicals Agency www.echa.europa.eu
6. The Merck Index.
7. Handling Chemical Safety
8. NIOSH - Registry of Toxic Effects of Chemical Substances
9. 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.