Chorus Rubella IgG (REF 81030) is an immunoenzymatic method for the quantitative determination of IgG-class antibodies to Rubella virus 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 Rubella antigen
  - 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 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: 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 0.425 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 30002-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
- **Production plant:** Via delle Rose, 10 – Loc. Tognazza
  53035 Monteriggioni (SI), Italy
- **Tel:** +39 02 4859121
- **Fax:** +39 02 48008530
- **Tel:** +39 0577 319560/61
- **Fax:** +39 0577 318763

1.4 EMERGENCY TELEPHONE NUMBER
- **Emergency number:** DIESSE Diagnostica Senese SpA
  Tel: +39 0577 587143
  email: letziaroval@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:** 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.
  - **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
P331+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></th>
<th></th>
<th></th>
<th></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>
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<td></td>
<td></td>
</tr>
<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>T R23/24/25</td>
<td>Acute Tox. 3</td>
</tr>
<tr>
<td>Cas No 55965-84-9</td>
<td></td>
<td></td>
<td>H311</td>
</tr>
<tr>
<td>Index No 613-167-00-5</td>
<td></td>
<td></td>
<td></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. 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</th>
<th>STEL/15min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene glycol*</td>
<td>D.Lgs 81/2008</td>
<td>52</td>
<td>104</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20</td>
<td>40</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 need.  

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</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&lt;sub&gt;n-oct/w&lt;/sub&gt; - 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 mPas (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 (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.
Material Safety Data Sheet
Calibrator/Positive Control
Chorus Rubella IgG


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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 reaches waterways or sewers or contaminates 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 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.

SAFETY INFORMATION – Chorus Rubella IgG (REF: 81030)
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

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 been 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.