SAFETY INFORMATION

CHORUS RUBELLA IgG AVIDITY

Compilation date: 27 May 2021 Edition: 4

Chorus Rubella IgG Avidity (REF 81095) kit is an immunoenzymatic method for the qualitative determination of the avidity of IgG-class antibodies against Rubella virus in human serum, using a disposable device applied on the Chorus and Chorus TRIO instruments.

Each package contains 2 bags with 6 devices each (sufficient for the total of 12 determinations).

Each kit consists of:

DEVICE

Position 8: Space for application of bar code label

Position 7: AVIDITY BUFFER 0.200 ml
The mixture is not classified as dangerous according to Regulation 1272/2008 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 Regulation 1907/2006, is not necessary to develop a material safety data sheet.
Contents: Urea in saline buffer solution containing phenol (0.05%) and Bronidox (0.02%)

Position 6: MICROPLATE WELL
Coated with Rubella virus

Position 5: MICROPLATE WELL
Coated with Rubella virus

Position 4: TMB SUBSTRATE 0.450 ml
The mixture is not classified as dangerous according to Regulation 1272/2008 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 Regulation 1907/2006, is not necessary to develop a material safety data sheet.
Contents: Tetramethylbenzidine 0.26 mg/ml and H_2O_2 0.01% stabilized in 0.05 mol/L citrate buffer (pH 3.8)

Position 3: SAMPLE DILUENT 0.400 ml
The mixture is not classified as dangerous according to Regulation 1272/2008 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 Regulation 1907/2006, 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 0.450 ml
The mixture is not classified as dangerous according to Regulation 1272/2008 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 Regulation 1907/2006, is not necessary to develop a material safety data sheet.
Contents: Anti-human IgG monoclonal antibodies labelled with horseradish peroxidase, in phosphate buffer containing phenol 0.05% and Bronidox 0.02%.

Position 1: EMPTY WELL
In which the sample is transferred

HIGH AVIDITY CONTROL

CONTROL HIGH 0.300 ml

The mixture is classified as **dangerous** according to Regulation 1272/2008/EC.

For this mixture the material safety data sheet, prepared in accordance with EC Regulation 1907/2006, is available

Contents: Diluted human serum, containing high avidity antibodies and Proclin and Gentamycin as preservatives. Liquid ready for use.

SAMPLE DILUENT

SAMPLE DILUENT 1.5 ml

The mixture is not classified as dangerous according to Regulation 1272/2008 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 Regulation 1907/2006, is not necessary to develop a material safety data sheet.

Contents: IgG negative serum to be used as sample diluent for samples which give a result over range.

MATERIAL SAFETY DATA SHEET

HIGH AVIDITY CONTROL

(According to Regulation (EC) No. 1907/2006)

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIERS

Product name: HIGH AVIDITY CONTROL

Product code: PF91094-C2

Brand: DIESSE

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

Identified use: Professional use as laboratory reagent.
High Avidity Control: Diluted human serum, containing high avidity 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 S.p.A

Registered office:
Via A. Solari 19
20144 Milan, Italy
Tel: +39 02 4859121
Fax: +39 02 48008530

Production plant:
Strada dei Laghi, 39
53035 Monteriggioni (SIENA), Italy
Tel: +39 0577 307100
e-mail: contatti@diesse.it

1.4 EMERGENCY TELEPHONE NUMBER

Emergency number:

Centro Antiveleni, Ospedale Niguarda Ca' Granda - Milan
Tel: +39 02 66101029

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

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

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

Centro Antiveleni, Azienda Ospedaliera A. Cardarelli – Naples
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

International Chemical Identification	Concentration	Classification Regulation EC/1272/2008	
Ethylene glycol Cas No 107-21-1 EC No 203-473-3 Index No 603-027-00-1	25-35%	Acute Tox. 4	H302
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); Cas No 55965-84-9 Index No 613-167-00-5	0.0015-0.06%	Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H314 H317 H400 H410

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. In case of needs consult a physician immediately and show this Material Safety Datasheet. Eyewash and shower for the treatment of emergency have to be present in the workplace.

Skin contact: Wear off the contaminated clothes and wash with copious amounts of water (for at least 15 minutes). If irritation persists consult a physician.

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

Inhalation: Move the person from the exposure to open air. If irritation occurs consult a physician.

Ingestion: Rinse mouth immediately and drink a copious amount 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, other than point 4.1

5. FIREFIGHTING MEASURES

5.1 EXTINGUISH MEDIA

Suitable extinguishing media: Use extinguishing measures (CO_2, foam, dry powder, water) 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

The mixture is not flammable, however in case of fire may release irritating and/or toxic gases.

5.3 ADVICE FOR FIREFIGHTERS

Wear appropriate personal protective equipment and clothing. In case of fire, wear self-contained breathing apparatus and avoid that fire extinguishing water contaminates surface water and/or groundwater.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Avoid the contact with skin and eyes and evacuate the area, keeping people not involved in the intervention operations away. 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 the contact with eyes, skin and clothes. Limit repeated exposure.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep the containers at 2-8°C in a cool, well-ventilated area, away from heat sources and humidity.

7.3 SPECIFIC END USE

None

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Applicable exposure limits:

Description	Type	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
Ethylene glycol* *Note: Skin	D.Lgs 81/2008	52	20	104	40

Other information: 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

Eye protections:
Side Shields Safety Goggles compliant with EN 166

Body protections:
Work outfits

Respiratory protections:
Not required under normal work activities

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 Po/w: - 1.36 (Ethylene glycol)
Autoignition temperature	Not pertinent
Decomposition temperature	200-250°C (Ethylene glycol)
Viscosity	21 mPas (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 until the expire date 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 storage at temperature different from that are advised

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.
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 samples and all the used reagents have to be handled as potentially infected.
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, labeling and packaging under Regulation 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

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

REFERENCES:
1. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
2. Regulation (EC) 1272/2008 of the European Parliament (CLP) as amended
3. ECHA European Chemicals Agency www.echa.europa.eu
4. The Merck Index.
5. Handling Chemical Safety
6. NIOSH - Registry of Toxic Effects of Chemical Substances
7. INRS - Fiche Toxicologique

This sheet supersedes any previous edition.