

	SAFETY INFORMATION CHORUS RF-G	Edition: 3 Date: 02-Sep-2015 Page: 1/7
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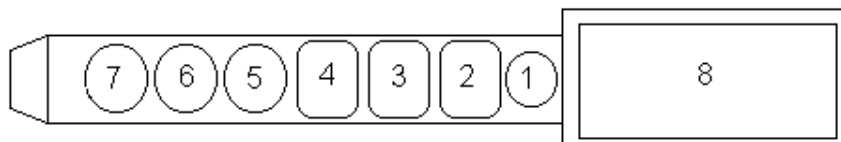
Chorus RF-G (REF 86038 and REF 86038/12) is an immunoenzymatic method for the semiquantitative determination of IgG Rheumatoid Factors (RF) in human serum.

REF 86038: each package contains 6 bags with 6 devices each (sufficient for 36 determinations of total).

REF 86038/12: 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 highly purified Fc fragment of human immunoglobulin (IgG)

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 0.3 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 in Tris <0.9%, containing Tween 20 and sodium azide 0.09%.

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 immunoglobulins labeled with horseradish peroxidase in phosphate-buffered saline containing BSA

Position 1: EMPTY WELL


In which the operator must place the undiluted serum

- CALIBRATOR 0.175 ml
Human serum diluted in phosphate-buffered saline containing BSA and sodium azide 0.09%.
- POSITIVE CONTROL 0.425 ml
Human serum diluted in phosphate-buffered saline containing BSA and sodium azide 0.09%.

The mixtures: Sample Diluent, Calibrator and Positive Control are not classified according to Regulation 1272/2008.

However, they contain substances classified as hazardous according to the Regulation and/or having occupational exposure limits for which it is required to develop of the material safety data sheet according to art. 31 of Regulation 1907/2006.

For these mixtures the material safety data sheet, prepared in accordance with EC regulations 1907/2006 and 453/2010, is available below.

	<p align="center">MATERIAL SAFETY DATA SHEET</p> <p align="center">SAMPLE DILUENT, CALIBRATOR/POSITIVE CONTROL</p> <p align="center">CHORUS RF-G</p> <p align="center">(According to Regulation (EC) No. 1907/2006 and 453/2010)</p>	<p>Edition: 3 Date: 02-Sep-2015 Page: 2/7</p>
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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIERS

Product name: SAMPLE DILUENT, CALIBRATOR/POSITIVE CONTROL
Product number: 86038
Brand: DIESSE

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

Identified use: Professional use as laboratory reagents.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: DIESSE Diagnostica Senese SpA

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

web: http://www.salute.gov.it/servizio/documenti/centri_antiveleni.pdf

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

Classification according to Regulation (EC) No. 1272/2008:

The mixtures are not classified according to Regulation 1272/2008.

However, they contain substances classified as hazardous according to the Regulation and/or having occupational exposure limits for which it is required to develop the material safety data sheet according to art. 31 of Regulation 1907/2006.

Hazard statement:

None

2.2 LABEL ELEMENTS

Pictograms: None


Signal word: None

Hazard statement(s): None

Precautionary statement(s): None

2.3 OTHER HAZARDS

None

	MATERIAL SAFETY DATA SHEET SAMPLE DILUENT, CALIBRATOR/POSITIVE CONTROL CHORUS RF-G (According to Regulation (EC) No. 1907/2006 and 453/2010)	Edition: 3 Date: 02-Sep-2015 Page: 3/7
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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES Not applicable

3.2 MIXTURES

International Chemical Identification	Concentration	Classification
Sodium azide	0.09%	Regulation EC/1272/2008
Cas No 26628-22-8		Acute Tox. 2 H300
EC No 247-852-1		Aquatic Acute 1 H400
Index No 011-004-00-7		Aquatic Chronic 1 H410
Substance with European exposure limit		EUH032

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. Do not cause vomiting or emesis. Call a physician immediately.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS

No data available

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

The mixture is not flammable, however in case of fire may release irritating and/or toxic gases (CO₂, CO, NO_x, SO_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.

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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:

Description	Type	TWA/8h		STEL/15min	
		mg/m ³	ppm	mg/m ³	ppm
Sodium azidel*	D.Lgs 81/2008	0.1		0.3	
*Note: Skin					

Other information:

None

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Liquid
Odor:	Odorless
Odor threshold:	Not pertinent
pH:	No data available
Melting point/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	Not pertinent
Evaporation rate	Not pertinent
Flammability	Not pertinent
Upper/lower flammability or explosive limit	Not pertinent
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Soluble in water
Partition coefficient: n-octano/water	No data available
Autoignition temperature	Not pertinent
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties:	Not explosive
Oxidizing properties	No data available

9.2 OTHER SAFETY INFORMATION

None

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

No data available

10.2 CHEMICAL STABILITY

Stable under the recommended transport, handling and storage conditions

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No data available

10.4 CONDITIONS TO AVOID

Avoid the strong heating of the mixture.

Sodium azide: Contact with acids liberates very toxic gas.

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

There is no information on toxicological effects of exposure to mixtures. These, however, might cause health effects in sensitive individuals.

In any case, it is recommended to handle them in accordance with the rules of good industrial hygiene.

Acute toxicity:	No data available
Skin irritation/corrosion:	No data available
Eye lesions/severe eye irritation:	No data available
Respiratory/skin sensitization:	No data available
Mutagenicity for germ cells:	No data available
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

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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.

12.2 PERSISTENCE AND DEGRADABILITY

No data available

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

H300 Fatal if swallowed

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH 032 Contact with acids liberates very toxic gas

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REFERENCES:

1. Directive 1999/45/EC and following amendments
2. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
3. Regulation (EC) 1272/2008 of the European Parliament (CLP) as amended
4. Commission Regulation (EU) 453/2010
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

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