SAFETY INFORMATION

CHORUS TG EXTENDED RANGE

Compilation date: 16 June 2021 Edition: 1

Chorus Tg Extened Range (REF: 86110) is an immunoenzymatic method for the quantitative determination of human thyroglobulin (Tg) in human serum, using a disposable device applied on the Chorus TRIO instruments.

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

Each kit consists of:

DEVICE

Position 9: Space for application of bar code label

Position 8: STREPTAVIDIN-POD 0.150 ml

The substance 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: Streptavidin conjugated to peroxidase, in phosphate buffer solution containing phenol 0.05% and Bronidox 0.02%.

Position 7: MICROPLATE WELL

Coated with anti-Tg monoclonal antibodies

Position 6: MICROPLATE WELL

Coated with anti-Tg monoclonal antibodies

Position 5: TMB SUBSTRATE 0.250 ml

The substance 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 4: SAMPLE DILUENT 0.200 ml

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

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

Contents: Saline proteic solution with Proclin (0.1%)

Position 3: STOP SOLUTION 0.350 ml

The substance 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: 0.3 M sulfuric acid solution

Position 2: CONJUGATE 0.250 ml

The substance 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-Tg monoclonal antibodies labeled with Biotin, in phosphate buffer containing phenol 0.05% and Bronidox 0.02%.

Position 1: EMPTY WELL

In which the sample is transferred

CALIBRATOR

CALIBRATOR 0.500 ml

Contents: Buffer containing Tg and preservative. Liquid, ready to use.

POSITIVE CONTROL

CONTROL + 1 ml

Contents: Buffer containing Tg and preservative. Liquid, ready to use.

Both mixtures are classified as **dangerous** according to Regulation 1272/2008/EC.
For these mixtures the material safety data sheet, prepared in accordance with EC Regulation 1907/2006, is available below.

MATERIAL SAFETY DATA SHEET

SAMPLE DILUENT – DT20

CALIBRATOR/POSITIVE 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: 1. SAMPLE DILUENT – DT20
2. CALIBRATOR/POSITIVE CONTROL

Product code: 1. PF30212
2. PF86410-C1 (CALIBRATOR); PF86410-C2 (POSITIVE CONTROL)

Brand: DIESSE

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

Identified use: Professional use as laboratory reagent.
DT20: Proteic solution used for dilution of samples.
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 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: Skin Sensitizer– Category 1

Hazard statement: H317 – May cause an allergic skin reaction.

2.2 LABEL ELEMENTS

Pictograms: GHS07

Signal word: Warning

Hazard statement(s):
H317 – May cause an allergic skin reaction.

Precautionary statement(s):
Prevention:
P261 – Avoid breathing dust/fume/gas/mist/vapors/spray.
P272 – Contaminated work clothing should not be allowed out of the workplace.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.
Response:
P302+P352 – IF ON SKIN: Wash with plenty of soap and water.
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:
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	
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

No data available

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: 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

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:	Odorless
Odor threshold:	Not pertinent
pH:	See it at the first page
Melting point/freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash point	Not applicable
Evaporation rate	Not determined
Flammability	Not flammable
Upper/lower flammability or explosive limit	Not applicable
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Water solubility	Soluble in water
Partition coefficient: n-octano/water	Not determined
Autoignition temperature	Not applicable
Decomposition temperature	Not determined
Viscosity	Not determined
Explosive properties	Not explosive
Oxidizing properties	Not determined

9.2 OTHER SAFETY INFORMATION

None

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

In the normal condition, no risk of reactivity is present.

10.2 CHEMICAL STABILITY

Stable until the expire date under the recommended transport, handling and storage conditions

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

The mixture could react with the basic and/or oxidizing substances

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

There is no known information on toxicological effects from exposure to the mixtures.
However, it's recommended to operate according to the good operational practices.
Nevertheless, the mixture can cause mild health effects on sensitive people by inhalation, cutaneous absorption, contact eyes or on ingestion.

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
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 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
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