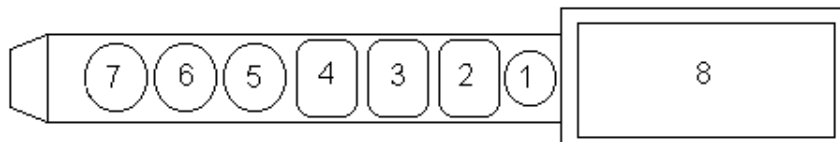


Chorus ft3 (REF 86518) is an immunoenzymatic method for the quantitative determination of triiodothyronine (ft3) in human serum, using a disposable device applied on the Chorus TRIO instruments.
Each package contains 6 bags with 6 devices each (sufficient for 36 determinations of total).

Each kit consists of:

- Device:



Position 8: Space for application of bar code label

Position 7: Empty

Position 6: MICROPLATE WELL
Coated with anti-T3 monoclonal antibodies

Position 5: Empty

Position 4: TMB SUBSTRATE 0.400 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 H2O2 0.01% stabilized in 0.05 mol/L citrate buffer.

Position 3: STOP SOLUTION 0.400 ml
According to the volume of solution filled in the device and the relative concentration, 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: Sulfuric acid 0.3M.

Position 2: CONJUGATE 0.200 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: T3 labelled with horse radish peroxidase, in phosphate buffer containing phenol 0.05% and Bronidox 0.02%.

Position 1: EMPTY WELL
In which the undiluted serum must be added

- CALIBRATOR 0.250 ml
Diluted human serum containing ft3 and preservative. Liquid, ready for use.
- POSITIVE CONTROL 0.500 ml
Diluted human serum containing ft3 and preservative. Liquid, ready for 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 CALIBRATOR/POSITIVE CONTROL – CHORUS FT3 (According to Regulation (EC) No. 1907/2006)	Edition: 0 Date: 19-Jun-2018 Page: 2/7
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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIER

Product name: CALIBRATOR/POSITIVE CONTROL
Product number: PF 86718-C1
 PF 86718-C2
Brand: DIESSE

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

Identified use: Professional use as laboratory reagent.
 Calibrator: diluted human serum containing FT3 necessary for the calibration of the instrument.
 Positive Control: diluted human serum containing FT3 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

<u>Registered office:</u> Via A. Solari 19 20144 Milan, Italy Tel: +39 02 4859121 Fax: +39 02 48008530	<u>Production plant:</u> Via delle Rose, 10 – Loc. Tognazza 53035 Monteriggioni (SI), Italy Tel: +39 0577 587111 Fax: +39 0577 318690
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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 SUBSTANCE 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: Caution

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:





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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	H331
		Acute Tox. 3	H311
		Acute Tox. 3	H301
		Skin Corr. 1B	H314
		Skin Sens. 1	H317
		Aquatic Acute 1	H400
Aquatic Chronic 1	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. If irritation persist consult a physician.

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: Move the person from the exposure to open air. 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 BOTH ACUTE AND DELAYED

If swallowed, the product can cause nausea, vomiting and disorders of the Central Nervous System.

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



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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 to avoid contacts with skin and eyes.
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 and evacuate the area, keeping people not involved in the intervention operations away. Ensure an adequate ventilation of the affected area. Avoid inhalation contact with vapors/aerosols. 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 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. Limit repeated exposure.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep at 2-8°C in a cool, well-ventilated area, away from heat sources and from humidity.
Keep the containers vertically and well-closed 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: The product contains no substances with occupational exposure limit value.

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 (0.11 mm)

Eye protections:

Side Shields Safety Glasses compliant with EN 166



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Body protections:
Work outfits.

Respiratory protections:
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

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	No data available
Evaporation rate	Not pertinent
Flammability	Not pertinent
Upper/lower flammability or explosive limit	No data available
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:	No data available
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 until the expiration date

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No data available.

10.4 CONDITIONS TO AVOID

Avoid the formation and dispersion of powders.
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.



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11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

The product in case of skin contact may cause an allergic reaction.

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 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 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



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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

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.