 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 02.04.2017
	Item Title: Free T3 Elisa kit, 96T/Kit	Item Code: 8.12.04.0.0096	Issue Level: 1.1


Contents

1. Amendment Record.
2. General Information.
3. Composition, Information on Active Ingredients.
4. Hazard Information.
5. Health Hazard Data.
6. Fire & Explosion Hazard Data.
7. Accidental release measures.
8. Handling and Storage.
9. Exposure control and personal gear.
10. Physical and chemical properties.
11. Stability and Reactivity Data.
12. Toxicological information.
13. Ecological information.
14. Waste disposal information.
15. Transport information.
16. Regulatory information.
17. Other information.
18. Disclaimer.

1. Amendment Record

Issue Level	Date Issued	Summary of Amendment	Reviewed by
1.1	02.04.2017	General Review	Amani

PMX8.12.04.0.0096D.11	Issued for Date:	Prepared by. QA Date:	Reviewed by. QA Date:	Approved by. QA Date:	Page 1 of 7
-----------------------	-------------------------	---------------------------------	---------------------------------	---------------------------------	----------------

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 02.04.2017
	Item Title: Free T3 Elisa kit, 96T/Kit	Item Code: 8.12.04.0.0096	Issue Level: 1.1


2. General Information.

Trade Names & Synonyms:	Free T4 Elisa kit, 96T/Kit
Chemical Family:	In Vitro Diagnostic Test kit (ELISA KITS).
Formula:	Not Applicable.
Manufacturer:	Atlas Medical.
Manufacturer's address:	William James House Cowley Road Cambridge, CB4 0WX, UK.
Manufacturer's phone:	+44 (0) 1223 858 910
Manufacturer's Fax:	+44 (0) 1223 858 524
Email:	info@atlas-site.co.uk

3. Composition, Information on Active Ingredients.


REAGENTS	INITIAL CONCENTRATION	CLASSIFICATION
STD 1 FT3 1.0 mL		
FT3	0 pmol/L	
Proclin300	0.20%	
Serum free of hormones	N/A	
Sodium azide	0.1%	
STD 2 FT3 1.0 mL		NOT DANGEROUS
FT3	2.0 pmol/L	
Proclin300	0.20%	
Serum free of hormones	N/A	
Sodium azide	0.1%	
STD 3 FT3 1.0 mL		NOT DANGEROUS

PMX8.12.04.0.0096D.11	Issued for	Prepared by. QA	Reviewed by. QA	Approved by. QA	Page 2 of 7
	Date:	Date:	Date:	Date:	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 02.04.2017
	Item Title: Free T3 Elisa kit, 96T/Kit	Item Code: 8.12.04.0.0096	Issue Level: 1.1

FT3	5.0 pmol/L	
Proclin300	0.20%	
Serum free of hormones	N/A	
Sodium azide	0.1%	
STD 4 FT3 1.0 mL		NOT DANGEROUS
FT3	10 pmol/L	
Proclin300	0.20%	
Serum free of hormones	N/A	
Sodium azide	0.1%	
STD 5 FT3 1.0 mL		NOT DANGEROUS
FT3	20 pmol/L	
Proclin300	0.20%	
Serum free of hormones	N/A	
Sodium azide	0.1%	
STD 6 FT3 1.0 mL		NOT DANGEROUS
FT3	50 pmol/L	
Proclin300	0.20%	
Serum free of hormones	N/A	
Sodium azide	0.1%	
ENZYME CONJUGATE		NOT DANGEROUS
Tris	0.05mol/L	
BSA	1%	
Proclin 300	0.2%	
Anti-T3	1:4000	
COATED MICROPLATE		NOT DANGEROUS
Coated with T3 structural analog	1:10000	
Other ingredients		
TMB SUBSTRATE		NOT DANGEROUS
3,3',5,5'- tetramethylbenzidine	0.03%	

PMX8.12.04.0.0096D.11	Issued for	Prepared by. QA	Reviewed by. QA	Approved by. QA	Page 3 of 7
	Date:	Date:	Date:	Date:	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 02.04.2017
	Item Title: Free T3 Elisa kit, 96T/Kit	Item Code: 8.12.04.0.0096	Issue Level: 1.1

Hydrogen peroxide 0.015%
 Other ingredients

WASH SOLUTION

PBS 0.01M NOT DANGEROUS
 TWEEN 20 0.05%

STOP SOLUTION

Sulphuric Acid 1M NOT DANGEROUS

4. Hazard Information.

Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3.

Label elements

Not a hazardous substance or mixture.

5. Health Hazard Data.

Sodium Azide:

Spill: Not applicable.
 Exposure Controls: Not applicable.
 Personal Protection: Not applicable.
 Physical Properties: Not applicable.
 Stability/Reactivity: Stable. Non-reactive in this test.
 Toxicological Information: Exposure above acceptable limits may be harmful

6. Fire & Explosion Hazard Data.

Non-flammable


Using the reagents according to protocol should not incur a fire or explosion hazard. In case of fire, use water, foam, carbon dioxide, or dry chemical, as suitable for the surrounding fire and materials.

7. Accidental release measures.

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Refer to protective measures listed in sections 7 and 8.

PMX8.12.04.0.0096D.11	Issued for	Prepared by. QA	Reviewed by. QA	Approved by. QA	Page 4 of 7
	Date:	Date:	Date:	Date:	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 02.04.2017
	Item Title: Free T3 Elisa kit, 96T/Kit	Item Code: 8.12.04.0.0096	Issue Level: 1.1

Environmental precautions

Environmental precautions: Local authorities should be advised if significant spillages cannot be contained.

Methods and material for containment and cleaning up

Methods for cleaning up: Wipe up with absorbent material (e.g. cloth, fleece).

Keep in suitable, closed containers for disposal

8. Handling and Storage.

Handling

Handling

No special requirements.

Conditions for safe storage

Storage

Store in tightly closed containers

under cool conditions.

9. Exposure control and personal gear.

Exposure controls

Eye protection: Safety glasses.

Hand protection: Protective gloves.

Wash hands before breaks and at the end of work. Skin and body protection

Protective Sui


Respiratory protection: No personal respiratory protective equipment normally required.

10. Physical and chemical properties.

General Information

Triiodothyronine is one of the thyroid hormones present in serum which regulates metabolism. Determination of this hormone concentration is important for the diagnostic differentiation of euthyroid, hyperthyroid, and hypothyroid states. The major fraction of total triiodothyronine is bound to the transport proteins (TBG, prealbumin, albumin). Free triiodothyronine (fT3) is the physiologically active form of the thyroid hormone triiodothyronine (T3). The determination of free T3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins; additional determination of a binding parameter (T-uptake, TBG) is therefore

PMX8.12.04.0.0096D.11	Issued for	Prepared by. QA	Reviewed by. QA	Approved by. QA	Page 5 of 7
	Date:	Date:	Date:	Date:	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 02.04.2017
	Item Title: Free T3 Elisa kit, 96T/Kit	Item Code: 8.12.04.0.0096	Issue Level: 1.1

unnecessary. (1, 2, 3)

In normal thyroid function, as the concentrations of the carrier proteins alter, the total T3 level changes so that the FT3 concentration remains constant. (4) Thus, measurements of FT3 concentrations correlate more reliably with clinical status than total T3 levels. For example, the increase in total T3 levels associated with pregnancy, oral contraceptives and estrogen therapy result in higher total T3 levels while the FT3 concentration remains basically unchanged. (5) In addition, it has been found that the mean FT3 value has a gradient decreasing from young to older. (6)

Odor: Odorless.

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

11. Stability and Reactivity Data.

Stability: The product is stable in accordance with the recommended storage conditions.

Materials to be avoided: None.

Hazardous reactions: No dangerous reactions known.

Hazardous decomposition products: No dangerous decomposition products known.

These products should not be used if turbid, and should **not** be diluted. Stable until expiry date stated on the vial if stored according to manufacturers recommendation

12. Toxicological information.

Acute toxicity: Quantitative data on the toxic effects of this product is not available.

Primary effects:

After skin contact: No irritating effects known.

After eye contact: No irritating effects known.

Sensitization: No sensitizing effects known.

13. Ecological information.

Environmental Toxicity:

Quantitative data on the toxic effects of this product is not available.

Incorrect sample and used kit disposable:


Bio-hazards may exert cumulative environmental effects due to chemicals and biological materials present in the test kit.

14. Waste disposal information.

Product:

When disposing of reagents that contain Sodium azide, flush down the drain with copious amounts of tap water to prevent the build-up of explosive residues in the

PMX8.12.04.0.0096D.11	Issued for	Prepared by.	Reviewed by.	Approved by.	Page 6 of 7
	Date:	QA Date:	QA Date:	QA Date:	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 02.04.2017
	Item Title: Free T3 Elisa kit, 96T/Kit	Item Code: 8.12.04.0.0096	Issue Level: 1.1

plumbing. As this reagent is of animal origin care must be taken during disposal, as there is a potential infection risk. Follow local and national guidelines

Packaging:

Disposal must be made in accordance with local waste management regulations. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

15. Transport information.

The product is not subject to transport regulations. Product should be shipped with ice pack. A label should be affixed to the outside of the package - "Refrigerate Upon Arrival".

16. Regulatory information.

NA.

17. Other information.

The product is for in-vitro use only.

18. Disclaimer.

The information above is believed to be accurate represents the best information currently available to us.

However we make no warranty of merchantability or any other warranty expressed or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company be liable for any claims, losses or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

PMX8.12.04.0.0096D.11	Issued for Date:	Prepared by. QA Date:	Reviewed by. QA Date:	Approved by. QA Date:	Page 7 of 7
-----------------------	-------------------------	---------------------------------	---------------------------------	---------------------------------	----------------