



SAFETY DATA SHEET

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ALPCO Name: Free Thyroxine (fT4) ELISA

ALPCO Product Number: 25-FT4HU-E01

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

1.1 Product identifier

ALPCO Name: Free Thyroxine (fT4) ELISA

ALPCO Product Number: 25-FT4HU-E01

Kit Components:

1. Ab Coated Microtiter Plate (96 wells)
2. Reference Standard Set
3. Enzyme Conjugate Reagent
4. Color A Reagent
5. Color B Reagent
6. Stop Solution

1.2 Relevant identified uses of the substance or mixture and uses advised against

Components of an *in-vitro* diagnostic device

1.3 Details of the supplier of the safety data sheet

Address: 26-G Keewaydin Drive
Salem, NH, 03079, USA

Phone: 1-603-893-8914

1.4 Emergency phone: 911 if in USA. Use relevant local phone number if outside of the USA.

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Some components in this kit contain Proclin 300: Skin Sens. 1; H317, at concentration provided, according to the European Regulation 1272/2008/EC.

2.2 Label elements



Pictogram: H317

Signal Word: Warning

Hazard statement: H317: May cause an allergic skin reaction

Precautionary Statement Prevention:

P261: Avoid breathing mist

P272: Contaminated work clothing should not be allowed out of the workplace

P280: Wear protective gloves

Precautionary Statement Response:

If on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: get medical attention. Wash contaminated clothing before reuse.

2.3 Other hazards

TMB Reagent and Stop Solution

An irritant effect to the skin cannot be ruled out because of the low pH value.

A corrosive effect to the eye cannot be ruled out because of the low pH value.



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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixture

Hazardous Ingredients:

Chemical name	CAS No. (EC No.) [index No.]	Amount (%) in the mixture	Classification according to Regulation (EC) No 1272/2008 [CLP] (related to the concentrated form)	
			Hazard class/ Hazard categories	Hazard statement
Kit component: Stop Solution				
Hydrochloric acid %	--- 231-595-7 017-002-01-X	< 3.65%	Skin Corr. 1B STOT SE 3	H314 H335
Kit component: TMB Reagent				
3,3',5,5'-Tetramethylbenzidin	54827-17-7 259-364-6 ---	< 0.05%	Skin Irrit. 2 Eye Irrit 2 STOT SE 3	H315 H319 H335
Kit components: Reference Standard Set and Enzyme Conjugate Reagent				
Proclin 300* - modified alkyl carboxylate	55965-84-9 --- 613-167-00-5	< 0.1%	Aquatic Chronic 4	H413
Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4 isothiazolin-3-one [EC no. 220-239-6] (3:1)		< 0.05% ♣	Acute Tox. 3 *	H331
			Acute Tox. 3 *	H311
			Acute Tox. 3 *	H301
			Skin Corr. 1B	H314
			Skin Sens. 1	H317
			Aquatic Acute 1	H400
*ProClin 300 is used as preservative in the listed reagents.			Aquatic Chronic 1	H410

♣ **Proclin 300 contains active ingredients:** mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4 isothiazolin-3-one [EC no. 220-239-6] (3:1). The Classification of this mixture at the contained concentration of < 0.05% ($0.0015\% \leq C \leq 0.06\%$) is Skin Sensitization (Category 1), H317.

All the other ingredients listed above or not listed are not classified as hazardous substances in the contained concentrations according to Regulation (EC) No 1272/2008 (CLP).

Full text of H- phases: see section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General information	No special measures required.
If inhaled	Supply fresh air. Consult doctor in case of complaints.
Following skin contact	Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.
Following eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Continue rinsing eyes during transport to hospital.



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If swallowed

Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

No further relevant information available.

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use appropriate personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 Environmental precautions

Dilute with plenty of water.

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Soak up with insert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Refer to section 8 for information on personal protection equipment.

Refer to section 13 for disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid direct contact with the reagents. Use all reagents in accordance with the relevant package insert.

7.2 Conditions for safe storage, including any incompatibilities

Store all reagents at 2 °C - 8 °C as instructed in the relevant package insert.

7.3 Specific end use

For professional in vitro diagnostic use only



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection Not required

Hand protection Protective gloves

Eye protection Safety goggles or glasses recommended during dispensing or refilling

Skin and body protection Lab coat

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Kit Component	Standard Set and Conjugate Reagent	TMB Reagent (3,3',5,5'-Tetramethylbenzidine)	Stop Solution (1N HCl)
(a) Appearance: Form: Color	Liquid	Liquid	Liquid
	Diverse (has no influence to the properties of the mixture)		
(b) Odor	odorless		
(c) Odor threshold	no data available		
(d) pH	7.0 – 7.4	3.35 – 3.75	< 1.0
(e) Melting point/freezing point	no data available	no data available	no data available
(f) Initial boiling point and boiling range	no data available	no data available	no data available
(g) Flash point	no data available	no data available	no data available
(h) Evaporation rate	no data available	no data available	no data available
(i) Flammability (solid, gas)	no data available	no data available	no data available
(j) Upper/lower flammability or explosive limits	no data available	no data available	no data available
(k) Vapor pressure	no data available	no data available	no data available
(l) Vapor density	no data available	no data available	no data available
(m) Relative density	no data available	no data available	no data available
(n) Solubility(ies)	no data available	no data available	no data available
(o) Partition coefficient: n-octanol/water	no data available	no data available	no data available
(p) Auto-ignition temperature	no data available	no data available	no data available
(q) Decomposition temperature	no data available	no data available	no data available
(r) Viscosity	no data available	no data available	no data available
(s) Explosive properties	no data available	no data available	no data available
(t) Oxidising properties	no data available	no data available	no data available

9.2 Other information

No other information available.



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10. STABILITY AND REACTIVITY

- | | |
|---|---|
| 10.1 <u>Reactivity</u> | No data available. |
| 10.2 <u>Chemical stability</u> | Stable under recommended storage conditions |
| 10.3 <u>Possibility of hazardous reactions</u> | No data available. |
| 10.4 <u>Conditions to avoid</u> | No data available |
| 10.5 <u>Incompatible materials</u> | No materials known. |
| 10.6 <u>Hazardous decomposition products</u> | No dangerous decomposition products known. |

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

- | | |
|---|---|
| a) Acute toxicity: | No data available |
| b) Skin corrosion/irritation | Inconclusive data. Due to its low pH value an irritant effect to the skin cannot be ruled out for <i>TMB Reagent</i> and <i>Stop Solution</i> . |
| c) Serious eye damage/irritation: | Inconclusive data. Due to its low pH value a corrosive effect cannot be ruled out for <i>TMB Reagent</i> and <i>Stop Solution</i> . |
| d) Respiratory or skin sensitisation: | No data available |
| e) Germ cell mutagenicity: | No data available |
| f) Carcinogenicity: | No data available |
| g) Reproductive toxicity: | No data available |
| h) Specific target organ toxicity-single exposure: | No data available |
| i) Specific target organ toxicity-repeated exposure | No data available |
| j) Aspiration hazard | No data available |

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

- | | |
|---|---|
| 12.1 <u>Toxicity</u> | No further relevant information available |
| 12.2 <u>Persistence and degradability</u> | No further relevant information available |
| 12.3 <u>Bioaccumulative potential</u> | No further relevant information available |
| 12.4 <u>Mobility in soil</u> | No further relevant information available |
| 12.5 <u>Results of PBT and vPvB assessment</u> | Not applicable |
| 12.6 <u>Other adverse effects</u> | No further relevant information available |



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13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product:

Dispose of waste according to applicable local, state, and federal regulations.

Contaminated packaging:

Dispose of waste according to applicable local, state, and federal regulations.

14. TRANSPORT INFORMATION

This product is not subject to official transport regulations.

14.1 <u>UN number</u>	None
14.2 <u>UN proper shipping name</u>	None
14.3 <u>Transport hazard class(es)</u>	None
14.4 <u>Packing group</u>	None
14.5 <u>Environmental hazards</u>	None
14.6 <u>Special precautions for user</u>	Not applicable
14.7 <u>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</u>	Not applicable

15. REGULATORY INFORMATION

This Safety Data Sheet is according to:

1907/2006/EC Registration, evaluation and authorization of chemicals regulation (REACH)

1272/2008/EC Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EEC and 1999/45/EC, amending 1907/2006/EC

453/2010/EC Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

15.2 Chemical safety assessment

Not applicable



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16. OTHER INFORMATION

16.1 "H code" used in this Safety Data Sheet

H301	Toxic if swallowed.
H303	May be harmful if swallowed
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H331	Toxic if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H413	May cause long-lasting harmful effects to aquatic life

Note: H317 is the Hazard Statement Code for the components that contain Proclin 300.

All the other H codes above are supplied for reference only as they are valid for the concentrated chemical only and are **not applicable to the concentrations supplied**.