

Trade Name: Testosterone free ELISA

Doc: MYI015-9

Ed. 04/2015

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

1.1 Product identifier

Trade name: Testosterone free ELISA

Code: DE2924

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

Components of an *in vitro* Medical-Diagnostic Device according to Directive (EC) 98/79/EC.

Kit content (name):

Calibrators
Conjugate
Coated Microplate
TMB Substrate
Stop Solution
Conc. Wash Solution
Control 1
Control 2

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH

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24145 Kiel-Wellsee

Germany

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Fax: +49-(0)431 / 71922-55

E-Mail: info@demeditec.de,

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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Due to the low concentration of hazardous ingredients none of the listed components of this product may be classified as dangerous according to Directive 1999/45/EC, 67/548/EEC and Regulation (EC) 1272/2008.

2.2 Label elements

This product is not under labelling according to Regulation (EC) n. 1272/2008.

2.3 Other hazards

No one.

Note: this product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.

Safety Data Sheet

According to Regulation (EC) n. 1907/2006 (REACH)
and Regulation (EC) n. 453/2010

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3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

<i>Stop Solution</i>					
<i>Ingrediente</i>	<i>EC No</i>	<i>CAS No</i>	<i>Conc. (w/v)</i>	<i>Reg. 1272/2008</i>	<i>Dir. 67/548/CEE</i>
Sulphuric Acid	231-639-5	7664-93-9	< 5 %	H314	R35

3.2 Mixtures

Proclin 300 is a mixture of two substances (5-chloro-2-methyl-2H-isothiazol-3-one (EC 247-500-7) and 2-methyl-2H-isothiazol-3-one (EC 220-239-6)) mixed with the proportion 3:1.

<i>Calibrators - Controls - Conjugate - TMB Substrate - Conc. Wash Solution</i>					
<i>Ingrediente</i>	<i>EC No</i>	<i>CAS No</i>	<i>Conc. (%)</i>	<i>Reg. 1272/2008</i>	<i>Dir. 67/548/CEE</i>
Proclin 300	-	55965-84-9	< 0.0015 %	H302 - H314 H317 - H332 H400 - H411	R23/24/25 R34 - R35 R50/53

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: no special measures required. Consult a physician in case of complaints.
If inhaled: supply fresh air.
In case of skin contact: wash with plenty amounts of water.
In case of eye contact: rinse opened eye for few minutes with water.
If swallowed: contact the nearest first aid.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical a toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

No restriction.

5.2 Special hazards arising from the substance or mixture

To the best of our knowledge, can not be defined special hazards known.

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.

6.2 Environmental precautions

Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

Absorb with inert absorbent material and dispose of a waste (see section 13).

6.4 Reference to other sections

For disposal see section 13.

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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Use all reagents according to the Instruction For Use provided with the product.

7.2 Conditions for safe storage, including any incompatibilities

Store all reagents according to the Instruction For Use provided with the product.

7.3 Specific end use(s)

This product is intended for laboratory use by professional users only.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Component with exposure limits: it doesn't contain substances with exposure limit value.

8.2 Exposure controls

Handle in accordance with good industrial hygiene and safety practice.

Wash hands before breaks at the end of workday.

Personal protective equipment

Eye/face protection: goggles with UNI EN 166 (and subsequent updates), or other international standard certification

Skin protection: lab coats, gloves with UNI EN 374 (and subsequent updates), or other international standard certification

Body protection: lab coats

Respiratory protection: not required

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Component	a) Appearance	b) Odour	d) pH
Calibrators	liquid, faint brown	odorless	7.5
Conjugate	liquid, red	odorless	7.5
Microplate	solid, white	odorless	not applicable
TMB Substrate	liquid, colorless	odorless	3.2 - 3.8
Stop Solution	liquid, colorless	odorless	< 1
Control	liquid, faint brown	odorless	7.5
Conc. Wash Solution	liquid, colorless	odorless	7.4

For all components

c) odour threshold	no data available
e) melting point / freezing point	no data available
f) initial boiling point and boiling range	no data available
g) flash point	no data available
h) evaporation rate	no data available
i) flammability (solid, gas)	no data available
j) upper/lower flammability or explosive limits	no data available
k) vapour pressure	no data available
l) vapour density	no data available
m) relative density	no data available
n) solubility(ies)	no data available
o) partition coefficient: n-octanol / water;	no data available
p) auto-ignition temperature	no data available
q) decomposition temperature	no data available
r) viscosity	no data available
s) explosive properties	no data available
t) oxidising properties	no data available

9.2 Other informations

No other information available.

10. STABILITY AND REACTIVITY

10.1 **Reactivity:** no data available.

10.2 **Chemical stability:** no data available.

10.3 **Possibility of hazardous reactions:** no data available.

10.4 Conditions to avoid

For the functional stability and reactivity of "TMB Substrate" avoid its exposure to directed sunlight, metals or oxidants and do not freeze the solution.

10.5 **Incompatible materials:** no data available.

10.6 **Hazardous decomposition products:** no data available.

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11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

a) acute toxicity	no data available
b) skin corrosion/irritation	no data available
c) serious eye damage / irritation	no data available
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) STOT-single exposure	no data available
i) STOT-repeated exposure	no data available
j) aspiration hazard	no data available

Potential health effects

Inhalation	no data available
Ingestion	no data available
Skin	no data available
Eyes	no data available

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Additional Informations

No one.

12. ECOLOGICAL INFORMATION

- | | |
|---|--------------------|
| 12.1 Toxicity: | no data available. |
| 12.2 Persistence and degradabilità: | 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

Reagents must be disposed of in accordance with local regulations. Do not disposed of in wastewater. If appropriate, contact a licensed disposal company.

14. TRANSPORT INFORMATION

The product is not under transport regulations.

- | | |
|---|-------------------|
| 14.1 UN number: | no data available |
| 14.2 UN proper shipping name: | no data available |
| 14.3 Transport hazard class(es): | no data available |
| 14.4 Packing group: | no data available |
| 14.5 Environmental hazards: | no data available |
| 14.6 Special precautions for user: | no data available |
| 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: | no data available |

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15. REGULATORY INFORMATION

This Safety Data Sheet is according to Regulation (CE) n. 1907/2006 (REACH) and Regulation (EC) n. 453/2010; this product is classified and labelled according the Regulation (EC) n. 1272/2008 (CLP).

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

No data available.

15.2 Chemical safety assessment

No data available.

16. OTHER INFORMATION

- "H code" and "R Phrases" used in this Safety data sheet

<i>Reg. 1272/2008</i>	<i>Dir. 67/548/CEE</i>	
H302	/	Harmful if swallowed.
H314	/	Causes severe skin burns and eye damage.
H317	/	May cause an allergic skin reaction.
H332	/	Harmful if invale.
H400	/	Very toxic to aquatic life.
H411	/	Toxic to aquatic life with long lasting effects.
/	R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
/	R34	Causes burns.
/	R35	Causes severe burns.
/	R43	May cause sensitisation by skin contact.
/	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- Changing against the last version:**

Rev. 7: Updating to Regulation (CE) n. 1907/2006, Regulation (EC) n. 453/2010, and according to Regulation (EC) n. 1272/2008 (CLP).

Rev. 8: introduction of component "Conc. Wash Solution" and elimination of component "Incubation buffer"

Rev. 9: introduction of "Control 2" component

- Note:**

The information in this document is believed to be accurate and represents the best information currently available to us. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.