

## Material Safety Data Sheet

IDENTIFICATION OF THE PREPARATION AND COMPANY NAME.

**Product Name:** Anti CCP ELISA  
**Catalog No:** 3175-17  
**Synonyms:** N/A  
**Intended Use:** Laboratory Use

### 1. 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 and label reference):**

<b>Calibrators</b>	<b>DCE002/117(06-10)-0</b>
<b>Conjugate</b>	<b>DCE002/11702-0</b>
<b>Sample Diluent</b>	<b>DCE053/11753-0</b>
<b>Coated Microplate</b>	<b>DCE002/11703-0</b>
<b>TMB Substrate</b>	<b>DCE004/11704-0</b>
<b>Stop Solution</b>	<b>DCE005/11705-0</b>
<b>Conc. Wash Solution</b>	<b>DCE054/11754-0</b>
<b>Positive Control</b>	<b>DCE045/11702-0</b>

### 2. HAZARDS IDENTIFICATION

▪ **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.

▪ **Label elements**

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

▪ **Other hazards**

None.

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

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

- Substances

<b>Stop Solution</b>				
<i>Ingredient</i>	<i>EC No</i>	<i>CAS No</i>	<i>Conc. (w/v)</i>	<i>Reg. 1272/2008</i>
Sulphuric Acid	231-639-5	7664-93-9	< 5 %	H314

<b>Standards - Controls - Sample Diluent</b>				
<i>Ingredient</i>	<i>EC No</i>	<i>CAS No</i>	<i>Conc. (w/v)</i>	<i>Reg. 1272/2008</i>
Sodium Azide	011-00400-7	26628-22-8	< 0.1 %	H300 - H400 - H410

- 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.

<b>Conjugate - TMB Substrate - Conc. Wash Solution</b>				
<i>Ingredient</i>	<i>EC No</i>	<i>CAS No</i>	<i>Conc. (%)</i>	<i>Reg. 1272/2008</i>
Proclin 300	-	55965-84-9	< 0.0015 %	H302 - H314 H317 - H332 H400 - H411

### 4. FIRST AID MEASURES

- 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 with the eye open for few minutes with water.  
 If swallowed: contact the nearest first aid.

- Most important symptoms and effects, both acute and delayed

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

- Indication of any immediate medical attention and special treatment needed

No data available.

### 5. FIREFIGHTING MEASURES

- Extinguishing media

No restriction.

- Special hazards arising from the substance or mixture

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

- Advice for firefighters

Wear self contained breathing apparatus for fire fighting, if necessary.

## 6. ACCIDENTAL RELEASE MEASURES

- **Personal precautions, protective equipment and emergency procedures**  
Use appropriate personal protective equipment.
- **Environmental precautions**  
Do not let product enter drains. Discharge into the environment must be avoided.
- **Methods and materials for containment and cleaning up**  
Absorb with inert absorbent material and dispose in the waste (see section 13).
- **Reference to other sections.**  
For disposal see section 13.

## 7. HANDLING AND STORAGE

- **Precautions for safe handling**  
Use all reagents according to the Instruction For Use provided with the product.
- **Conditions for safe storage, including any incompatibilities** Store all reagents according to the Instruction For Use provided with the product.
- **Specific end use(s)** This product is intended for laboratory use for professional use only.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

- **Control parameters**  
Component with exposure limits: it doesn't contain substances with exposure limit value.
- **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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Information on basic physical and chemical properties**

Component	a) Appearance	b) Odour	d) pH
Calibrators	liquid, blue	odorless	/
Positive Control	liquid, blue	odorless	/
Conjugate	liquid, red	odorless	/
Microplate	solid, white	odorless	not applicable
TMB Substrate	liquid, colorless	odorless	3.2 - 3.8
Stop Solution	liquid, colorless	odorless	< 1
Sample Diluent	liquid, red	odorless	7.4
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

▪ **Other informations**

No other information available.

## 10. STABILITY AND REACTIVITY

- **Reactivity:** no data available.
- **Chemical stability:** no data available.
- **Possibility of hazardous reactions:** no data available.
- **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.
- **Incompatible materials:** no data available.
- **Hazardous decomposition products:** No data available.

## 11. TOXICOLOGICAL INFORMATION

- **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 sensitization	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**

- **Toxicity:** no data available.
- **Persistence and degradability:** no data available.
- **Bioaccumulative potential:** no data available.
- **Mobility in soil:** no data available.
- **Results of PBT and vPvB assessment:** no data available.
- **Other adverse effects:** no data available.

**13. DISPOSAL CONSIDERATIONS**

▪ **Waste treatment methods**

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

**14. TRANSPORT INFORMATION**

The product is not under transport regulations.

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

**15. REGULATORY INFORMATION**

This Safety Data Sheet is according to Regulation (CE) n. 1907/2006 (REACH) and Regulation (EC) n. 1272/2008 (CLP).

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
 No data available.
- **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>	
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H332	Harmful if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

**Changing against the last version:**

Updating to Regulation (CE) n. 1907/2006, Regulation (EC) n. 453/2010, and according to Regulation (EC) n. 172/2008 (CLP).

**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.

**Quality Control**

Diagnostic Automation/Cortez Diagnostics, Inc.  
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