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

1.1 Product identifier

*Trade name:* Anti Cardiolipin IgM  
*Diametra Code:* DKO112

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 and label reference):*

- Calibrators: DCE002/112(06-10)-0
- Conjugate: DCE002/11202-0
- Sample Diluent: DCE053-0
- Coated Microplate: DCE002/11203-0
- TMB Substrate: DCE004-0
- Stop Solution: DCE005-0
- Conc. Wash Solution: DCE054-0
- Negative Control: DCE045/11201-0
- Positive Control: DCE045/11202-0

1.3 Details of the supplier of the safety data sheet

**DiaMetra S.r.l.**

- **Headquarter:** 20090 Segrate – Milano – Italy  
  Via Calabria, 15  
  Tel. +39.02.21.39.184 / +39.02.26.92.15.95  
  Fax. +39.02.21.33.354
- **R&D Manufacturing:** 06038 Spello – Perugia – Italy  
  Via Pozzuolo, 14  
  Tel. +39.0742.24.851 / +39.0742.32.04.53  
  Fax. +39.0742.31.61.97
- **Email:** massini@diametra.com

1.4 Emergency telephone number

+ 39 06-3054343 (Centro antiveleli - Policlinico Gemelli Roma)

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 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.
3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>EC No</th>
<th>CAS No</th>
<th>Conc. (w/v)</th>
<th>Reg. 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphuric Acid</td>
<td>231-639-5</td>
<td>7664-93-9</td>
<td>&lt; 5 %</td>
<td>H314</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>EC No</th>
<th>CAS No</th>
<th>Conc. (w/v)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Azide</td>
<td>011-00400-7</td>
<td>26628-22-8</td>
<td>&lt; 0.1 %</td>
</tr>
</tbody>
</table>

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.

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.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Component</th>
<th>a) Appearance</th>
<th>b) Odour</th>
<th>d) pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrators</td>
<td>liquid, blue</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>Controls</td>
<td>liquid, blue</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>Conjugate</td>
<td>liquid, red</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>Microplate</td>
<td>solid, white</td>
<td>odorless</td>
<td>not applicable</td>
</tr>
<tr>
<td>TMB Substrate</td>
<td>liquid, colorless</td>
<td>odorless</td>
<td>3.2 - 3.8</td>
</tr>
<tr>
<td>Stop Solution</td>
<td>liquid, colorless</td>
<td>odorless</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Sample Diluent</td>
<td>liquid, blue</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>Conc. Wash Solution</td>
<td>liquid, colorless</td>
<td>odorless</td>
<td>7.4</td>
</tr>
</tbody>
</table>
### 9.2 Other informations

No other information available.

### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity: no data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability: no data available</td>
</tr>
<tr>
<td>Possibility of hazardous reactions: no data available</td>
</tr>
</tbody>
</table>

#### 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.

### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

<table>
<thead>
<tr>
<th>Toxicological effects: no data available</th>
</tr>
</thead>
</table>

| 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 |
Safety Data Sheet
According to Regulation (EC) n. 1907/2006 (REACH) and Regulation (EC) n. 453/2010

Trade Name: Anti Cardiolipin IgM
Doc: MYI112-3
Ed. 01/2015

i) STOT-repeated exposure  no data available
j) aspiration hazard      no data available

<table>
<thead>
<tr>
<th>Potential health effects</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>no data available</td>
</tr>
<tr>
<td>Ingestion</td>
<td>no data available</td>
</tr>
<tr>
<td>Skin</td>
<td>no data available</td>
</tr>
<tr>
<td>Eyes</td>
<td>no data available</td>
</tr>
</tbody>
</table>

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

Additional Information
No one.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: no data available.
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
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
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" used in this Safety Data Sheet

<table>
<thead>
<tr>
<th>Reg. 1272/2008</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H300</td>
<td>Fatal if swallowed.</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage.</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>H332</td>
<td>Harmful if inhaled.</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life.</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects.</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

- Changing against the last version:
  Rev. 3: change in Headquarter address

- 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.