SAFETY DATA SHEET

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUTOZYME™ TAB Anti-Thyroglobulin Elisa Kit</td>
<td>Z2196</td>
</tr>
<tr>
<td>AUTOZYME™ TAB Anti-Thyroid Peroxidase Elisa Kit</td>
<td>Z2396</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Ref</th>
<th>Name</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thyroglobulin Wells</td>
<td>P2101A</td>
<td>TAB Sample Diluent</td>
<td>N7013</td>
</tr>
<tr>
<td>Thyroid Peroxidase Wells</td>
<td>P2301A</td>
<td>Anti-Tg Conjugate</td>
<td>N7110</td>
</tr>
<tr>
<td>Anti-Tg Calibrators x 6</td>
<td>Y2102</td>
<td>Anti-TPO Conjugate</td>
<td>N7115</td>
</tr>
<tr>
<td>Anti-TPO Calibrators x 6</td>
<td>Y2302</td>
<td>Substrate Solution</td>
<td>N7301</td>
</tr>
<tr>
<td>TAB Negative Control</td>
<td>N2105</td>
<td>Wash Buffer Concentrate</td>
<td>N7203</td>
</tr>
<tr>
<td>TAB Positive Control</td>
<td>N2104</td>
<td>Stop Solution</td>
<td>N7702</td>
</tr>
</tbody>
</table>

1.3 Details of the supplier of the safety data sheet

Cambridge Life Sciences Ltd.
14 St. Thomas’ Place, Cambridgeshire Business Park, Ely, Cambridgeshire, CB7 4EX, UK
T: +44 (0)1353 645200
F: +44 (0)1353 645250
E: support@clsdiagnostics.com

1.4 Emergency telephone number:

Cambridge Life Sciences Ltd. (only office hours): +44 (0) 1353 645200

2. Hazards Identification

2.1 Classification of the substance or mixture

Stop Solution N7702 is classified as Acute Tox. 4; H302, H312

Due to the low concentration of hazardous ingredients, the other listed components of this product are not classified as dangerous according to Regulation (EC) 1272/2008 (CLP), Directive 1999/45/EC or EU Directive 67/548/EEC.

2.2 Label Elements

Stop Solution N7702 labelling according to Regulation (EC) 1272/2008 (CLP).

Pictogram

<table>
<thead>
<tr>
<th>Signal Word: Warning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Statements: H302 - Harmful if swallowed</td>
</tr>
<tr>
<td>H312 - Harmful in contact with skin</td>
</tr>
<tr>
<td>Precautionary Statements: P280 - Wear protective gloves/ eye protection/ face protection.</td>
</tr>
<tr>
<td>P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</td>
</tr>
</tbody>
</table>

The labelling for the other listed components are not classified as hazardous according to Regulation (EC) 1272/2008 (CLP).

2.3 Other Hazards

The sample diluent, calibrators and controls contains small amounts of sodium azide which may react with lead and copper plumbing to form highly explosive metal azides. It may also develop toxic and explosive hydrogen azide in contact with acid. Rapidly absorbed through skin.

Note: this product is intended for laboratory use by professional users only. Use appropriate personal protective equipment while working with the reagents provided.
3. Composition/information on ingredients

3.1 Substances
Not applicable.

3.2 Mixtures

<table>
<thead>
<tr>
<th>Contents</th>
<th>Quantity</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Diluent</td>
<td>100mL</td>
<td>NaCl, Na₂HPO₄, NaH₂PO₄, BSA, NaN₃, Tween 20, Sunset Yellow Dye</td>
</tr>
<tr>
<td>Calibrators/Controls</td>
<td>1.5mL</td>
<td>NaCl, Na₂HPO₄, NaH₂PO₄, BSA, NaN₃, Tween 20, Sunset Yellow Dye, Human Sera</td>
</tr>
<tr>
<td>Conjugates</td>
<td>15mL</td>
<td>NaCl, Na₂HPO₄, KH₂PO₄, BSA, K₃Fe(CN)₆, Bromophenol Blue, Proclin 300,</td>
</tr>
<tr>
<td>Substrate</td>
<td>15mL</td>
<td>ABTS® substrate</td>
</tr>
<tr>
<td>Stop Solution</td>
<td>15mL</td>
<td>Oxalic Acid</td>
</tr>
<tr>
<td>Wash Buffer Conc</td>
<td>100mL</td>
<td>NaCl, Na₂HPO₄, NaH₂PO₄</td>
</tr>
<tr>
<td>Microwell Plate</td>
<td>1</td>
<td>96 well breakable microplate coated with purified / recombinant antigen</td>
</tr>
</tbody>
</table>

Proclin 300 is a mixture of two substances (5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one) mixed with the proportion 3:1. ABTS® = 2,2’-azino-bis (3-ethylbenziazoline-6-sulphonic) acid

Hazardous Ingredients
The Hazard Classification listed refers to the chemical at a pure concentration. It has been determined that the remaining ingredient(s) of these components (except oxalic acid in the stop solution) are not classified as hazardous chemicals due to their physical and/or chemical nature and/or concentration in solution.

<table>
<thead>
<tr>
<th>Sample Diluent (N7013), Calibrators (Y2102/Y2302), Controls (N2104, N2105)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredients</td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>Sodium azide</td>
</tr>
<tr>
<td>Sunset Yellow Dye</td>
</tr>
</tbody>
</table>

Conjugates (N7110/N7115)

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>EC No.</th>
<th>CAS No</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proclin 300</td>
<td>-</td>
<td>55965-84-9</td>
<td>0.015%</td>
<td>H300 H314 H317 H332 H400 H411</td>
</tr>
</tbody>
</table>

Substrate (N7301)

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>EC No.</th>
<th>CAS No</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABTS®</td>
<td>30931-67-0</td>
<td>250-396-6</td>
<td>&lt;0.1%</td>
<td>H315 H319 H335</td>
</tr>
</tbody>
</table>

Stop Solution (N7702)

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>EC No.</th>
<th>CAS No</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxalic Acid</td>
<td>144-62-7</td>
<td>205-634-3</td>
<td>2.25%</td>
<td>H302 H312</td>
</tr>
</tbody>
</table>

4. First Aid Measures

4.1 Description of first aid measures

General advice: No special measures required. Consult a physician in case of complaints.

After Inhalation: Remove affected person to fresh air and get medical attention if necessary.

After Skin Contact: In case of skin contact, immediately wash thoroughly with soap and water. Remove contaminated clothing and shoes and wash before reuse.

After Eye contact: Rinse eyes for a few minutes with water while lifting the eye lids. If irritation persists, consult a physician.

After swallowing: Rinse mouth with water. Immediately 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
Water, carbon dioxide, dry chemical powder or foam.

5.2 Special hazards arising from the substance or mixture
No defined special hazards are known.

5.3 Advice for firefighters
Wear fully protective suit and self-contained breathing apparatus for firefighting if necessary.
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6. Accidental Release Measures
6.1 Personal precautions, protective equipment and emergency procedures
Wear appropriate protective clothing, such as laboratory coat, gloves and safety glasses/goggles.

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
Soak up and remove with absorbent materials and dispose of as hazardous waste. Clean floor and all other contaminated objects with water.

6.4 Reference to other sections
See section 8 for information on personal protection equipment.
See section 13 for disposal information.

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 at 2 – 8°C. Protect from light.

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
Components with exposure limits: it does not contain substances with exposure limit values.

8.2 Exposure Controls
Handle in accordance with good industrial hygiene and safety practice.
Wash hands before breaks and at the end of the work day.

Personal protective equipment
Eye/face protection: goggles with UN EN166 (and subsequent updates), or other international standard certification.
Skin protection: laboratory coats, gloves with UN EN374 (and subsequent updates), or other international standard certification.
Body protection: laboratory 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>Sample diluent</td>
<td>Liquid, yellow</td>
<td>Odourless</td>
<td>7.4</td>
</tr>
<tr>
<td>Callibrators/Controls</td>
<td>Liquid, yellow</td>
<td>Odourless</td>
<td>7.4</td>
</tr>
<tr>
<td>Conjugate</td>
<td>Liquid, blue</td>
<td>Odourless</td>
<td>7.1</td>
</tr>
<tr>
<td>Wash buffer concentrate</td>
<td>Liquid, colourless</td>
<td>Odourless</td>
<td>7.3</td>
</tr>
<tr>
<td>Substrate</td>
<td>Liquid, colourless / v pale green</td>
<td>Odourless</td>
<td>4.0</td>
</tr>
<tr>
<td>Stop Solution</td>
<td>Liquid, colourless</td>
<td>Odourless</td>
<td>1.0</td>
</tr>
</tbody>
</table>

For all components

c) Odour threshold: no data available
e) Melting point / freezing point: similar to H₂O
f) Boiling point and boiling range: similar to H₂O
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: ~1g/ml
n) Solubility in / miscibility with water: soluble
o) Partition coefficient: n-octanol/water: no data available
p) Autoignition 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 information
No other information available

10. Stability and Reactivity
10.1 Reactivity
No data available

10.2 Chemical stability
Stable under the recommended storage conditions.

10.3 Possibility of hazardous reactions
Not known when used appropriately.

10.4 Conditions to avoid
Freezing and high temperature.

10.5 Incompatible materials
No data available.

10.6 Hazardous decomposition products
No data available.

11. Toxicological Information

11.1 Information to toxicological effects

Acute toxicity
- Sunset Yellow: LD50 Oral – rat > 10,000mg/kg
  Remarks: Diarrhoea
- Proclin 300: no data available.
- Sodium azide: LC50 Inhalation - rat - 37 mg/m³
  Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Other. Behavioural: Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration: Structural or functional change in trachea or bronchi.
- Oxalic Acid: LD50 Dermal - rabbit - 20 mg/kg
- ABTS: no data available.

Skin corrosion/irritation
- Sunset Yellow: no data available
- Proclin 300: Skin – rabbit - corrosive.
- Sodium azide: no data available
- Oxalic acid: no data available
- ABTS: no data available

Serious eye damage/irritation
- Sunset Yellow: no data available
- Proclin 300: Eyes – rabbit – corrosive to eyes.
- Sodium azide: no data available
- Oxalic acid: no data available
- ABTS: no data available

Respiratory or skin sensitisation
- Sunset Yellow: no data available
- Proclin 300: may cause allergic skin reaction.
- Sodium azide: no data available
- Oxalic acid: no data available
- ABTS: no data available

Germ cell mutagenicity
No data available.

Carcinogenicity
No component of these products present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
No data available.

Specific target organ toxicity (STOT) – single exposure
- Sunset Yellow: may cause respiratory irritation
- Proclin 300: no data available
- Sodium azide: no data available
- Oxalic acid: no data available
- ABTS: no data available
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Specific target organ toxicity (STOT) – repeated exposure
No data available.

Aspiration Hazard
No data available.

Information on likely routes of exposure: routes of entry anticipated
Oral, dermal, inhalation.

Symptoms related to the physical, chemical and toxicological characteristics

Proclin 300
Inhalation   Harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.
Ingestion    Harmful if swallowed.
Skin         May be harmful if absorbed through skin. Causes skin burns.
Eyes         Causes eye burns.

Sodium Azide
Inhalation   May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion    May be fatal if swallowed.
Skin         May be fatal if absorbed through skin. May cause skin irritation.
Eyes         May cause eye irritation.

Oxalic acid:
Inhalation   no symptoms.
Ingestion    there may be irritation of the throat.
Skin         there may be mild irritation at the site of contact.
Eyes         there may be irritation and redness.

ABTS
Inhalation   May be harmful and cause irritation.
Ingestion    May be harmful.
Skin         May be harmful and cause irritation.
Eyes         May cause irritation.

Delayed and immediate effects as well as chronic effects from short and long-term exposure
No data available.

Effects of chronic exposure
No data available.

Additional Information
No other information available.

12. Ecological Information

12.1 Toxicity:
Sunset Yellow: no data available
Proclin 300 - no data available.
Sodium azide - Toxicity to daphnia and other aquatic invertebrates; EC50 - Daphnia pulex (Water flea) - 4.2 mg/l - 48h
Oxalic acid – no data available
ABTS – no data available

12.2 Persistence and degradability
No data available.

12.3 Bioaccumulative potential
Sunset Yellow: no data available
Proclin 300: no data available
Sodium azide: no data available
Oxalic acid: no data available
ABTS: 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
Very toxic to aquatic life.

13. Disposable Considerations

13.1 Waste treatment methods
Waste should be disposed of in accordance with federal, state and local environmental control regulations. If appropriate, contact a licensed disposal company.
14. Transport Information
This product is not subject to official 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 data sheet is according to 1907/2006/EC, Registration, evaluation and authorisation of chemicals regulation (REACH), 1272/2008/EC, Classification, labelling and packaging regulation (CLP), 453/2010/EC, Compilation of safety data sheets regulations (SDS), amending 1907/2006/EC. This product is classified and labelled according to EU regulations 1272/2008.

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
Disclaimer: To the best of our knowledge, the above information is believed to be accurate but does not purport to be all inclusive and shall be used only as a guide and is provided without warranty of any kind. The recipient of the product is responsible for observing all applicable laws and regulations.

Relevant phrases:
Reg. 1272/2008
H300 fatal if swallowed.
H302 harmful if swallowed.
H312 harmful in contact with skin
H314 causes severe burns and eye damage.
H315 causes skin irritation
H317 may cause an allergic skin reaction.
H319 causes serious eye irritation
H332 harmful if inhaled.
H335 may cause respiratory irritation
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.