SAFETY DATA SHEET

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

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

1.1 Product Identifier

Product Name: AUTOZYME™ IFAB Elisa Kit
Product Code: Z4396

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

Components of a kit for the quantitative measurement of anti-intrinsic factor antibodies in serum and plasma. In Vitro Medical Diagnostic Device according to Directive (EC) 98/79/EC.

Kit content (name and label reference)

<table>
<thead>
<tr>
<th>Name</th>
<th>Ref</th>
<th>Name</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>IFAB Wells</td>
<td>P4301</td>
<td>Sample Diluent</td>
<td>N7015D</td>
</tr>
<tr>
<td>IFAB Calibrator</td>
<td>N4303</td>
<td>IFAB Conjugate</td>
<td>N7123</td>
</tr>
<tr>
<td>IFAB Negative Control</td>
<td>N4302</td>
<td>TMB Substrate</td>
<td>N7304</td>
</tr>
<tr>
<td>IFAB Positive Control</td>
<td>N4301</td>
<td>Wash Buffer Concentrate</td>
<td>N7206D</td>
</tr>
<tr>
<td>TMB Stop Solution</td>
<td>N7706</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1.3 Details of the supplier of the safety data sheet

Cambridge Life Sciences Ltd.
14 St. Thomas’ Place, 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

Due to the low concentration of hazardous ingredients, the listed components of this product are not classified as dangerous according to Regulation (EC) 1272/2008 (CLP).

2.2 Label Elements

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

2.3 Other Hazards

The sample diluent, calibrators and controls contain 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. The sera although found negative when tested for HIV-1 and HIV-2 antibodies, HCV and hepatitis B surface antigen, no test can guarantee their absence. Therefore, the sera should be handled using the same safety precautions employed when handling any potentially infectious material. The product components contain preservatives which may possess in their given concentration, skin-sensitizing and slightly polluting properties.

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>50mL</td>
<td>NaCl, Na₃H₂PO₄, NaH₂PO₄, BSA, NaN₃, Tween 20, Sunset Yellow Dye</td>
</tr>
<tr>
<td>Calibrator/Controls</td>
<td>1.5mL</td>
<td>NaCl, Na₃H₂PO₄, NaH₂PO₄, BSA, NaN₃, Tween 20, Sunset Yellow Dye, Human Sera</td>
</tr>
<tr>
<td>Substrate</td>
<td>15mL</td>
<td>MOPS, Anti-human IgG HRP antibodies, Dye, MethylIsoThiazolones (MIT - preservative)</td>
</tr>
<tr>
<td>Stop Solution</td>
<td>15mL</td>
<td>Sulphuric Acid</td>
</tr>
<tr>
<td>Wash Buffer Conc</td>
<td>100mL</td>
<td>NaCl, KCl, Na₃H₂PO₄, KH₂PO₄, Tween 20</td>
</tr>
<tr>
<td>Microwell Plate</td>
<td>1</td>
<td>96 well breakable microplate coated with recombinant Intrinsic Factor</td>
</tr>
</tbody>
</table>

MIT = 3,3’ ,5,5’-Tetramethyl-benzidine

MIT is a mixture of two substances (5-Chloro-2-Methyl-3(2H)-isothiazolone with 2-Methyl-3(2H)-isothiazolone) mixed with the proportion 3:1.
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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>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>Conjugate (N7123)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MIT</td>
<td></td>
<td>55965-84-9</td>
<td>&lt;0.0015%</td>
<td></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>Sulphuric Acid</td>
<td>231-639-5</td>
<td>7664-93-9</td>
<td>2.5%</td>
<td></td>
</tr>
</tbody>
</table>

Sample Diluent (N7015D), Calibrators (N4303), Controls (N4302, N4301)

<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>Sodium azide</td>
<td>247-852-1</td>
<td>26628-22-8</td>
<td>&lt;0.1%</td>
<td></td>
</tr>
<tr>
<td>Sunset Yellow Dye</td>
<td>220-491-7</td>
<td>2783-94-0</td>
<td>0.04% (v/v)</td>
<td></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
The severity of the symptoms described will vary dependant of the concentration and the length of exposure.

4.3 Indication of any immediate medical attention and special treatment needed
No recommendation given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this chemical. If in doubt, get medical attention promptly.

5. Firefighting Measures
Non-flammable aqueous solutions.

5.1 Extinguishing Media
Water, carbon dioxide, dry chemical powder or foam. Use extinguishing media appropriate to surrounding fire conditions.

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.

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
Contain spill to prevent migration. Avoid discharge into drains.

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 good laboratory procedures and wear appropriate protective clothing, see section 8.
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According to Regulation (EC) 1907/2006 (REACH) and Regulation (EC) 453/2010

7.2 Conditions for safe storage, including any incompatibilities
Store all components according to instructions given on the label 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.
Except sodium azide: TWA value 0.1 mg/m³ (in EU).
Sulphuric Acid: TWA value 0.05 mg/m³ (in EU); STEL value EU: na.
Values according to Directive 98/24/EC + Article 2(3) of Commission Decision 2 014/113/EU
TWA: Time Weighted Average, i.e. the average exposure to a contaminant to which workers may be exposed without adverse effect over a period such as in an 8-hour day or 40-hour week (an average work shift). They are usually expressed in units of ppm (volume/volume) or mg/m³.
STEL: Short Term Exposure Limit; i.e. the acceptable average exposure over a short period of time, usually 15 minutes as long as the time-weighted average is not exceeded.

8.2 Exposure Controls
Avoid contact with skin, eyes and clothing. 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>Calibrator/Controls</td>
<td>Liquid, yellow</td>
<td>Odourless</td>
<td>7.4</td>
</tr>
<tr>
<td>Conjugate</td>
<td>Liquid, colourless</td>
<td>Odourless</td>
<td>6.5</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</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.
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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
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.
CMIT/MIT: LD50 Dermal - rabbit - 20 mg/kg
Sulphuric acid: no data available
Sunset Yellow: LD50 Oral – rat > 10,000mg/kg
Remarks: Diarrhoea

Skin corrosion/irritation
Sodium azide: no data available
CMIT/MIT: Skin – rabbit - corrosive.
Sulphuric acid: no data available
Sunset Yellow: no data available

Serious eye damage/irritation
Sodium azide: no data available
CMIT/MIT: Eyes – rabbit – corrosive to eyes.
Sulphuric acid: no data available
Sunset Yellow: no data available

Respiratory or skin sensitisation
Sodium azide: no data available
CMIT/MIT: may cause allergic skin reaction.
Sulphuric acid: no data available
Sunset Yellow: no data available

Germ cell mutagenicity
No data available.

Carcinogenicity
Sulphuric Acid: IARC 1 Group 1: carcinogenic
No other 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
Sodium azide: no data available
CMIT/MIT: no data available
Sulphuric acid: no data available
Sunset Yellow: no data available

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
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.
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CMIT/MIT
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.

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:
Sodium azide:
Toxicity to daphnia and other aquatic invertebrates - EC50 - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h
CMIT/MIT - no data available.
Sulphuric acid - no data available
Sunset Yellow - 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
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects
Sodium azide: Very toxic to aquatic life with long lasting effects.
CMIT/MIT: Toxic to aquatic life
Sulphuric Acid: Harmful to aquatic organisms

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
The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1 UN number
No data available.

14.2 UN proper shipping name
Not dangerous goods.

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 data sheet is according to 2015/830EC, Registration, evaluation, authorisation and restriction of chemicals regulation (REACH), 1272/2008/EC, Classification, labelling and packaging regulation (CLP), 453/2010/EC, Compilation of safety data sheets regulations (SDS).

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 chemical safety assessment has been carried out.

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 from section 3:
Reg. 1272/2008
H300 fatal if swallowed.
H301 toxic 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
H322 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.