



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)

Name	Ref	Name	Ref
IFAB Wells	P4301	Sample Diluent	N7015D
IFAB Calibrator	N4303	IFAB Conjugate	N7123
IFAB Negative Control	N4302	TMB Substrate	N7304
IFAB Positive Control	N4301	Wash Buffer Concentrate	N7206D
TMB Stop Solution	N7706		

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
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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

Contents	Quantity	Ingredients
Sample Diluent	50mL	NaCl, Na ₂ HPO ₄ , NaH ₂ PO ₄ , BSA, NaN ₃ , Tween 20, Sunset Yellow Dye
Calibrator/Controls	1.5mL	NaCl, Na ₂ HPO ₄ , NaH ₂ PO ₄ , BSA, NaN ₃ , Tween 20, Sunset Yellow Dye, Human Sera
Conjugate	15mL	MOPS, Anti-human IgG HRP antibodies, Dye, MethylIsoThiazolones (MIT - preservative)
Substrate	15mL	TMB substrate
Stop Solution	15mL	Sulphuric Acid
Wash Buffer Conc	100mL	NaCl, KCl, Na ₂ HPO ₄ , KH ₂ PO ₄ , Tween 20
Microwell Plate	1	96 well breakable microplate coated with recombinant Intrinsic Factor

TMB = 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.


SAFETY DATA SHEET



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

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.

Conjugate (N7123)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
MIT		55965-84-9	<0.0015%	 H301 H311 H313 H314 H315 H317 H400 H410

Stop Solution (N7702)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
Sulphuric Acid	231-639-5	7664-93-9	2.5%	 H319 H315

Sample Diluent (N7015D), Calibrators (N4303), Controls (N4302, N4301)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
Sodium azide	247-852-1	26628-22-8	<0.1%	 H300 H400 H410
Sunset Yellow Dye	220-491-7	2783-94-0	0.04% (v/v)	 H315 H319 H335

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.

SAFETY DATA SHEET

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

Component	a) Appearance	b) Odour	d) pH
Sample diluent	Liquid, yellow	Odourless	7.4
Calibrator/Controls	Liquid, yellow	Odourless	7.4
Conjugate	Liquid, colourless	Odourless	6.5
Wash buffer concentrate	Liquid, colourless	Odourless	7.3
Substrate	Liquid, colourless	Odourless	4.0
Stop Solution	Liquid, colourless	Odourless	1.0

For all components

c) Odour threshold	no data available
e) Melting point / freezing point	similar to H ₂ O
f) Boiling point and boiling range	similar to H ₂ O
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.

SAFETY DATA SHEET

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

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
 no data available.
 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.

SAFETY DATA SHEET

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

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.

SAFETY DATA SHEET

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

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
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.