

SAFETY DATA SHEET

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

1.1 Product Identifier

Trade Name	Product Code
AUTOZYME™ RF IgA Elisa Kit	Z9196
AUTOZYME™ RF IgM Elisa Kit	Z9296
AUTOZYME™ RF IgG Elisa Kit	Z9396

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)

Name	Ref	Name	Ref
Rheumatoid Factor Wells	P9103	RF IgG Positive Control	N9104G
RF IgA Calibrators x 5	Y9102A	RF Sample Diluent	N7015D
RF IgM Calibrators x 6	Y9202M	RF IgA Conjugate	N7120D
RF IgG Calibrators x 5	Y9302G	RF IgM Conjugate	N7121D
RF IgM 15U/mL Calibrator	Y9215	RF IgG Conjugate	N7122D
RF Negative Control	N9102D	Substrate Solution	N7301
RF IgA Positive Control	N9104A	Wash Buffer Concentrate	N7206D
RF IgM Positive Control	N9104M	Stop Solution	N7702

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

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

Signal Word: Warning

Hazard Statements:

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

Precautionary Statements:

P280 - Wear protective gloves/ eye protection/ face protection.

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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.

SAFETY DATA SHEET

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
Calibrators/Controls	1.5mL	NaCl, Na ₂ HPO ₄ , NaH ₂ PO ₄ , BSA, NaN ₃ , Tween 20, Sunset Yellow Dye, Human Sera
Conjugates	15mL	NaCl, Na ₂ HPO ₄ , KH ₂ PO ₄ , BSA, K ₃ Fe(CN) ₆ , Bromophenol Blue, Proclin 300, Sunset Yellow Dye, Anti-human F(ab') ₂ IgA/IgM/IgG HRP antibodies
Substrate	15mL	ABTS [®] substrate
Stop Solution	15mL	Oxalic 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 purified antigen

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.

Sample Diluent (N7015D), Calibrators (Y9102A/Y9202M/Y9302G/Y9215), Controls (N9102D, N9104A/M/G)				
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
Conjugates (N7120D/N7121D/N7122D)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
Proclin 300	-	55965-84-9	0.015%	 H300 H314 H317 H332 H400 H411
Substrate (N7301)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
ABTS [®]	30931-67-0	250-396-6	<0.1%	 H315 H319 H335
Stop Solution (N7702)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
Oxalic Acid	144-62-7	205-634-3	2.25%	 H302 H312

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.

SAFETY DATA SHEET

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

Component	a) Appearance	b) Odour	d) pH
Sample diluent	Liquid, yellow	Odourless	7.4
Calibrators/Controls	Liquid, yellow	Odourless	7.4
Conjugate	Liquid, blue	Odourless	7.1
Wash buffer concentrate	Liquid, colourless	Odourless	7.3
Substrate	Liquid, colourless / v pale green	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

SAFETY DATA SHEET

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.

LD50 Dermal - rabbit - 20 mg/kg

Oxalic Acid: LD50 Oral – rat 1400mg/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

SAFETY DATA SHEET

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 - 48 h
 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.

SAFETY DATA SHEET

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.