

SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Paracetamol (Acetaminophen) Assay Kit
Product Code: K8003

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

Components of a kit for the quantitative measurement of Paracetamol concentration in serum and plasma. In Vitro Medical Diagnostic Device according to Directive (EC) 98/79/EC.

Kit content (name and label reference)

Enzyme Reagent	K7111
Enzyme Diluent	K7110
Colour Reagent	K7109
Paracetamol Calibrator	K7101
Paracetamol Sera Calibrator 1	K7001
Paracetamol Sera Calibrator 2	K7002

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
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 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 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.

Note: this product / product components are 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
Enzyme Reagent	1 vial	Tris Base, HCl, BSA, Lactose
Enzyme Diluent	20mL	o-Cresol
Colour Reagent B	100mL	CuSO ₄ , NH ₄ Cl, Na ₂ CO ₃
Paracetamol Calibrator	3mL	Paracetamol, NaN ₃ , CH ₃ COONa, CH ₃ CO ₂ H
Sera Calibrators	4 x 0.5mL	Paracetamol, Human Sera, Proclin 300

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.

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 o-cresol in the colour reagent A) are not classified as hazardous chemicals due to their physical and/or chemical nature and/or concentration in solution.

SAFETY DATA SHEET

Enzyme Reagent (K7111)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
HCl	231-595-7	7647-01-0	<0.01%	 H290
Enzyme Diluent (K7110)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
o-Cresol	202-423-8	95-48-7	0.1%	  H301 H311 H314, H318, H412
Colour Reagent B (K7109)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
Copper Sulphate	231-847-6	7558-98-7	<0.1%	  H302 H315 H319 H400 H410
Ammonium chloride	235-186-4	12125-02-9	<0.5%	 H302 H319
Sodium carbonate	207-838-8	497-19-8	<10%	 H319
Paracetamol Calibrator (K7101)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
Sodium azide	247-852-1	26628-22-8	<0.1%	  H300 H400 H410
Paracetamol	203-157-5	103-90-2	0.03%	 H302 H315 H319 H335
Glacial acetic acid	200-580-7	64-19-7	<0.2%	  H226 H314
Sera Calibrators (K7001/K7002)				
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008
Proclin 300	-	55965-84-9	0.015%	   H300 H314 H317 H332 H400 H411

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.

SAFETY DATA SHEET

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.

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).
 Except o-Cresol: TWA value 22 mg/m³ (91/322/EEC).

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
Enzyme Reagent	White, lyophilised powder	Odourless	8.60
Enzyme Diluent	Liquid, colourless	Faint odour	na
Colour Reagent	Liquid, pale blue colour	Odourless	10.60
Paracetamol Calibrator	Liquid, colourless	Odourless	5.00
Sera Calibrators	Liquid, pale yellow	Odourless	na

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	Not explosive
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.

SAFETY DATA SHEET

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

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.

o-Cresol:

LD50 Dermal - rabbit - 20 mg/kg

LD50 Oral - rat - 121 mg/kg

Remarks: Behavioural: Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration: Dyspnea. Gastrointestinal: Ulceration or bleeding from stomach.

LC50 Inhalation - rat - 1 h - >1,220 mg/m³

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Lacrimation. Behavioural: Somnolence (general depressed activity).

Glacial acetic acid:

LD50 Dermal - rabbit - 890 mg/kg

LD50 Oral - Rat - 3,310 mg/kg

LC50 Inhalation - Mouse - 1 h - 5620 ppm

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Conjunctive irritation.

Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Other. Blood: Other changes.

LC50 Inhalation - Rat - 4 h - 11.4 mg/l

LD50 Dermal - Rabbit - 1,112 mg/kg

Paracetamol:

LD50 Oral - Rat - 1,944 mg/kg

Ammonium chloride:

LD50 Oral - Rat - 1,650 mg/kg

Proclin 300:

no data available.

Skin corrosion/irritation

Sodium azide:

no data available

o-Cresol:

Skin - rabbit - Severe skin irritation - 24h - Draize Test

Glacial acetic acid:

no data available

Proclin 300:

Skin - rabbit - corrosive.

Serious eye damage/irritation

Sodium azide:

no data available

o-Cresol:

Eyes - rabbit - Severe eye irritation - Draize Test

Glacial acetic acid:

Eyes - Rabbit Result: Corrosive to eyes

Ammonium chloride:

Eyes - Rabbit Result: eye irritation

Proclin 300:

Eyes - rabbit - corrosive to eyes.

Respiratory or skin sensitisation

Sodium azide:

no data available

o-Cresol:

no data available

Glacial acetic acid:

no data available

Proclin 300:

may cause allergic skin reaction.

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.

SAFETY DATA SHEET

Reproductive toxicity

No data available.

Specific target organ toxicity (STOT) – single exposure

Sodium azide: no data available

o-Cresol: no data available

Proclin 300: 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.

o-Cresol

Inhalation May be fatal if inhaled. Causes respiratory tract irritation.

Ingestion Toxic if swallowed.

Skin Toxic if absorbed through skin. Causes skin irritation.

Eyes Causes eye burn.

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.

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

o-Cresol:

Toxicity to fish LC50 - Leuciscus idus (Golden orfe) - 10.00 mg/l - 96 h

Toxicity to daphnia and other aquatic invertebrates - EC50 - Daphnia magna (Water fea) - 9.2 mg/l - 48h

Toxicity to algae - EC50 - SELENASTRUM - 100.00 mg/l - 72h

Glacial acetic acid:

Toxicity to fish semi-static test LC50 - Oncorhynchus mykiss (rainbow trout) - > 1,000 mg/l - 96 h (OECD Test Guideline 203)

Toxicity to daphnia and other aquatic invertebrates – EC50 - Daphnia magna (Water flea) - > 300.82 mg/l - 48 h (OECD Test Guideline 202)

Paracetamol:

Toxicity to fish LC50 - Pimephales promelas (fathead minnow) - 814 mg/l - 96 h

Toxicity to daphnia and other aquatic invertebrates - Immobilisation EC50 - Daphnia magna (Water fea) - 15.8 mg/l - 48h

Ammonium chloride:

Toxicity to fish LC50 - Cyprinus carpio (Carp) - 209.00 mg/l - 96 h

LC50 - Oncorhynchus mykiss (rainbow trout) - > 3.98 mg/l - 96 h

NOEC - Oncorhynchus mykiss (rainbow trout) - > 57 mg/l - 96 h

Toxicity to daphnia and other aquatic invertebrates - EC50 - Daphnia magna (Water fea) - 161 mg/l - 48h

Proclin 300 - no data available.

SAFETY DATA SHEET

12.2 Persistence and degradability

Glacial acetic acid: Biodegradability aerobic - Exposure time 30 d Result: 99 % - Readily biodegradable
Remarks: Expected to be biodegradable
Biochemical Oxygen Demand (BOD) - 880 mg/g

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.
o-Cresol: 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

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.

15. Regulatory Information

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

The user has to observe the applicable regulations.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Commission Regulation (EU) 453/2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Commission Regulation (EU) 2015/830 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

SAFETY DATA SHEET

16. Other Information

The present MSDS has been compiled according to the ANNEX II of the Commission Regulation (EU) 2015/830 of 28 May 2015.

ANNEX II of Commission Regulation (EU) 2015/830 replaces

-Annex II ⁽¹⁾ of Regulation (EC) No 1907/2006

-Article 59(5) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council (amends ⁽¹⁾)

-Commission Regulation (EU) No 453/2010 (amends ⁽¹⁾)

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

H226	flammable liquid and vapour.
H290	may be corrosive to metals.
H300	fatal if swallowed.
H301	toxic if swallowed.
H302	harmful if swallowed.
H311	toxic in contact with skin.
H314	causes severe skin burns and eye damage.
H315	causes skin irritation.
H317	may cause an allergic skin reaction.
H318	causes serious eye damage.
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.
H412	harmful to aquatic life with long lasting effects.