

SAFETY DATA SHEET

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

1.1 Product Identifier

Trade Name	Product Code
Paracetamol (Acetaminophen) Sera Calibrator Kit	K8100

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)

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, 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

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), Directive 1999/45/EC or EU Directive 67/548/EEC.

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 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	Ingredients
Sera	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 are not classified as hazardous chemicals due to their physical and/or chemical nature and/or concentration in solution.

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

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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.

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.

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9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Component Sera	a) Appearance Liquid, pale yellow	b) Odour Odourless	d) pH 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		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

Proclin 300: no data available.

Skin corrosion/irritation

Proclin 300: Skin – rabbit - corrosive.

Serious eye damage/irritation

Proclin 300: Eyes – rabbit – corrosive to eyes.

Respiratory or skin sensitisation

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.

Reproductive toxicity

No data available.

Specific target organ toxicity (STOT) – single exposure

Proclin 300: no data available

Specific target organ toxicity (STOT) – repeated exposure

No data available.

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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.

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: Proclin 300 - no data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

Proclin 300: 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.

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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.
H314	causes severe burns and eye damage.
H317	may cause an allergic skin reaction.
H332	harmful if inhaled.
H400	very toxic to aquatic life.
H411	toxic to aquatic life with long lasting effects.