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: 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
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
Enzyme Diluent K7110 is classified as Acute Tox. 3; H301, H311 and Skin Corr. 1B, H314
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
Enzyme Diluent K7110 labelling according to Regulation (EC) 1272/2008 (CLP).

Pictogram
Signal Word: Danger
Hazard Statements: H301 - Toxic if swallowed
                  H311 - Toxic in contact with skin
                  H314 - Causes severe skin burns and eye damage
Precautionary Statements: P280 - Wear protective gloves/ eye protection/ face protection.
                          P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician.
                          P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
                          P310 – Immediately call a POISON CENTRE or doctor/physician.

The labelling for the other 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.
SAFETY DATA SHEET
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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>Enzyme Reagent</td>
<td>1 vial</td>
<td>Tris Base, HCl, BSA, Lactose</td>
</tr>
<tr>
<td>Enzyme Diluent</td>
<td>20mL</td>
<td>o-Cresol</td>
</tr>
<tr>
<td>Colour Reagent B</td>
<td>100mL</td>
<td>CuSO₄, NiCl₂, Na₂CO₃</td>
</tr>
<tr>
<td>Paracetamol Calibrator</td>
<td>3mL</td>
<td>Paracetamol, NaN₃, CH₃COONa, CH₃COOH</td>
</tr>
<tr>
<td>Sera Calibrators</td>
<td>4 x 0.5mL</td>
<td>Paracetamol, Human Sera, Proclin 300</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Enzyme Reagent (K7111)</th>
<th>EC No.</th>
<th>CAS No</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCl</td>
<td>231-595-7</td>
<td>7647-01-0</td>
<td>&lt;0.01%</td>
<td>H290</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enzyme Diluent (K7110)</th>
<th>EC No.</th>
<th>CAS No</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>o-Cresol</td>
<td>202-423-8</td>
<td>95-48-7</td>
<td>0.1%</td>
<td>H301 H311 H314</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Colour Reagent B (K7109)</th>
<th>EC No.</th>
<th>CAS No</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper Sulphate</td>
<td>231-847-6</td>
<td>7558-98-7</td>
<td>&lt;0.1%</td>
<td>H302 H315 H319 H400 H410</td>
</tr>
<tr>
<td>Ammonium chloride</td>
<td>235-186-4</td>
<td>12125-02-9</td>
<td>&lt;0.5%</td>
<td>H302 H319</td>
</tr>
<tr>
<td>Sodium carbonate</td>
<td>207-838-8</td>
<td>497-19-8</td>
<td>&lt;10%</td>
<td>H319</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paracetamol Calibrator (K7101)</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>H300 H400 H410</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>203-157-5</td>
<td>103-90-2</td>
<td>0.03%</td>
<td>H302 H315 H319 H335</td>
</tr>
<tr>
<td>Glacial acetic acid</td>
<td>200-580-7</td>
<td>64-19-7</td>
<td>&lt;0.2%</td>
<td>H226 H314</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sera Calibrators (K7001/K7002)</th>
<th>EC No.</th>
<th>CAS No</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proclin 300</td>
<td>-</td>
<td>55965-84-9</td>
<td>0.015%</td>
<td>H300 H314 H317 H332 H400 H411</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.
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.
SAFETY DATA SHEET

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

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.

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

<table>
<thead>
<tr>
<th>Component</th>
<th>a) Appearance</th>
<th>b) Odour</th>
<th>d) pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzyme Reagent</td>
<td>White, lyophilised powder</td>
<td>Odourless</td>
<td>8.60</td>
</tr>
<tr>
<td>Enzyme Diluent</td>
<td>Liquid, colourless</td>
<td>Faint odour</td>
<td>na</td>
</tr>
<tr>
<td>Colour Reagent</td>
<td>Liquid, pale blue</td>
<td>Odourless</td>
<td>10.60</td>
</tr>
<tr>
<td>Paracetamol Calibrator</td>
<td>Liquid, colourless</td>
<td>Odourless</td>
<td>5.00</td>
</tr>
<tr>
<td>Sera Calibrators</td>
<td>Liquid, pale yellow</td>
<td>Odourless</td>
<td>na</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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For all components

c) Odour threshold
   no data available

e) Melting point / freezing point
   similar to H_2O

f) Boiling point and boiling range
   similar to H_2O

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
   ~1 g/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

Sodium azide:
   LC50 Inhalation - rat - 37 mg/m^3
   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
   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 – 1h - >1,220 mg/m^3

   LD50 Dermal - rabbit - 890 mg/kg
   LD50 Oral - Rat - 3,310 mg/kg
   LC50 Inhalation – Mouse - 1 h - 5620 ppm

   Paracetamol:
   LD50 Dermal - Rabbit - 1,112 mg/kg
   LD50 Oral - Rat - 1,944 mg/kg

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
   LD50 Oral - Rat - 1,944 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.
SAFETY DATA SHEET
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**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.

**Reproductive toxicity**
No data available.

**Specific target organ toxicity (STOT) – single exposure**
- Sodium azide: no data available
- o-Cresol: no data available
- Glacial acetic acid: 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.
SAFETY DATA SHEET
According to Regulation (EC) 1907/2006 (REACH) and Regulation (EC) 453/2010

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 flea) - 9.2 mg/l - 48 h
  - Toxicity to algae - EC50 - SELENASTRUM - 100.00 mg/l - 72 h
- 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 flea) - 15.8 mg/l - 48 h
- 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 flea) - 161 mg/l - 48 h
- Proclin 300 - no data available.

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

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 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 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
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.
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.