

SAFETY DATA SHEET

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

1.1 Product Identifier

Trade Name	Product Code	Country
Pantozol [®] Hp Test	U1001	Germany
Controloc [®] Hp Test	U1008	Bosnia and Herzegovina
Panto Hp Test	U1019	Cyprus
Endosc Hp [®] Test	U1021	UK
Urease Hp Test	U1023	Serbia

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.

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 none of the listed components of this product may be classified as dangerous according to Regulation (EC) 1272/2008 (CLP) or EU Directive 67/548/EEC, Directive 1999/45/EC.

2.2 Label Elements

The labelling for these products is not classified as hazardous according to Regulation (EC) 1272/2008 (CLP).

2.3 Other Hazards

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





Contents	Quantity	Ingredients
Hp Buffer Ampoule	4 vials of 1.65mL	Sterile Water

3.2 Mixtures

Contents	Quantity	Ingredients
Phenol Red Tablets	8 tablets	Urea, Phenol Red, Citric Acid, Sodium Phosphate, Sodium crosscarmellose

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.

Phenol Red Tablets					
Ingredients	EC No.	CAS No	Conc (w/v)	Reg. 1272/2008	Dir. 67/548/EEC
Phenol Red	143-74-8	205-609-7	<1.0%	 H315 H319 H335	 R36/37/38
Citric Acid Monohydrate	77-92-9	201-069-1	<1.0%	 H319	 R36

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4. First Aid Measures

4.1 Description of first aid measures

Inhalation: Move affected person to fresh air. If not breathing, provide artificial respiration and get medical attention.

Skin Contact: In case of skin contact, immediately wash thoroughly with soap and water. Remove contaminated clothing and shoes.

Eye contact: Rinse eyes for a few minutes with water while lifting the eye lids. If irritation persists, consult a physician.

Ingestion: Rinse mouth with water. If irritation or discomfort occurs, seek medical attention.

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

Flammable properties: Components are not combustible.

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 fire fighting 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.

See section 8 for information on personal protection equipment.

6.2 Environmental precautions

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 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. 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.

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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
Sterile Water	Liquid, colourless	Odourless	6.00
Hp Buffer	Tablet, orange	Odourless	5.90

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

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

Citric Acid: LD50 Intraperitoneal - rat - 375 mg/kg
 Urea: LD50 Oral - rat – 8,471mg/kg

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Skin corrosion/irritation

Citric acid: no data available
Phenol red: no data available
Urea: rabbit - no skin irritation

Serious eye damage/irritation

Citric Acid: Eyes – rabbit – corrosive to eyes.
Phenol red: no data available
Urea: rabbit - no skin irritation

Respiratory or skin sensitisation

Citric acid: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.
Phenol red: no data available
Urea: 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

Citric acid: no data available
Phenol red: Inhalation - May cause respiratory irritation
Urea: 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

No data available.

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

Citric acid RTECS: GE7810000 - Vomiting, Diarrhoea, Damage to tooth enamel, Dermatitis
Phenol red RTECS: SJ7490000 - To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Urea RTECS: YR6250000 - To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. Ecological Information

- 12.1 Toxicity:** Citric acid: no data available
Phenol red: no data available.
Urea: Toxicity to fish LC50 - *Poecilia reticulata* (guppy) - 17,500 mg/l - 96 h
Toxicity to daphnia and other aquatic invertebrates - EC50 - *Daphnia magna* (Water flea) - 3,910 mg/l - 48 h
- 12.2 Persistence and degradability**
No data available.
- 12.3 Bioaccumulative potential**
No data available.

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12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

No data available.

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

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. There is no labelling requirement.

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:

Reg. 1272/2008

H315 causes skin irritation
H319 causes serious eye irritation
H335 may cause respiratory irritation

Dir. 67/548/CEE

R36 irritating to eyes.
R36/37/38 irritating to eyes, respiratory system and skin.