

SECTION 1. Product identification	
1.1. Trade name	Pylori-Strip, Pylori K-SeT Codes: C-1019, K-1219, K-1519
1.2. Manufacturer	Coris BioConcept, CREALYS Science Park, Rue Guillaume Fouquet, 11 5032 Gembloux, Belgium. Ph: +32/81 719 917 ; Fax: +32/81 719 919 ; E-Mail: <a href="mailto:info@corisbio.com">info@corisbio.com</a> - Web Site: <a href="http://www.corisbio.com">www.corisbio.com</a>
1.3. Kind of use	<i>In vitro</i> Rapid Diagnostic Test for the detection of <i>Helicobacter pylori</i> in human stool samples. <b>FOR MEDICAL DIAGNOSTIC USE ONLY</b> For details, see insert
SECTION 2. Health hazard data/risk identification	
Main exposure risks and symptoms	None with dried strip Buffer : This product is not hazardous and does not contain hazardous ingredients at concentrations used 'according to regulation (EC) No 1272/2008)
SECTION 3. Composition, information on ingredient	
3.1. Classification	<i>In vitro</i> Diagnostic device
3.2. Components	<p><b>Laminate:</b> Active matrix → nitrocellulose + mylar Plastic backing → Polyester</p> <p><b>Absorbent paper:</b> Sample PAD → glass fiber Absorbent paper → cellulose paper</p> <p><b>Release matrix:</b> Conjugate PAD → polyester fiber</p> <p><b>HC Dilution buffer:</b> Salts → restricted information Additive(s) → restricted information Conservative → Sodium Azide (&lt;0.1%) pH → 7.5 Molarity → restricted information</p>
3.3. Biologicals	<p><b>Specific reagent:</b> mouse monoclonal antibody directed against specific antigen of <i>Helicobacter pylori</i></p> <p><b>Control reagent:</b> Antichicken goat antiserum</p> <p><b>Conjugate:</b> Anti-<i>Helicobacter pylori</i>: mouse monoclonal antibody, latex coupled Chicken IgY: chicken polyclonal latex coupled</p>
3.4. Hazardous substance	Sodium Azide : < 0.1%                      CAS: 26628-22-8
3.5. Packaging material	Box → cardboard Buffer bottle → polyethylene-polypropylene Stick vial → PVC K-SeT → ABS Pouche → polyethylene aluminium foil plastic Faecal sampling system → polyethylene - polypropylene
3.6. Other information	-
SECTION 4. Emergency and first aid procedures	
4.1. Contact with eyes	Buffer: Immediately flush eyes thoroughly with water.
4.2. Contact with skin	Buffer: Immediately wash skin with soap and large volume of water.

<b>4.3. Ingestion</b>	Buffer: If swallowed, wash out mouth with water provided the person is conscious; seek medical advice (showing this document when possible); never give anything by mouth to an unconscious person; never try to make an unconscious person vomit.
<b>SECTION 5. Fire hazard data</b>	
<b>5.1. Flammability</b>	Contains combustible materials.
<b>5.2. Extinguishing</b>	Water, carbon dioxide, dry chemical powder or polymer foam. Use extinguishing media appropriate to surrounding fire conditions.
<b>5.3. Special Fire Fighting procedures</b>	For fires involving this material, do not enter any enclosed or confined fire space without proper protective equipment. This may include self-contained breathing apparatus to protect against the hazardous effects of normal products of combustion or oxygen deficiency.
<b>SECTION 6. Accidental release measures</b>	
<b>6.1. Precautionary measures</b>	Wear appropriate protective clothing (refer to point 8).
<b>6.2. Environment Precautions</b>	Buffer: Avoid flushing away in drainpipes. Collect samples in plastic bag and submit to sterilization procedures
<b>6.3. Released or spilled material</b>	Sweep up and collect in appropriate container for waste disposal (refer to point 13) clean the floor and all other contaminated objects with water.
<b>SECTION 7. Handling and storage</b>	
<b>7.1. Handling</b>	Wear appropriate protective clothing (refer to point 8); eliminate rapidly from eyes skin and clothes; wash hands and any other exposed zone with water and mild soap before eating, drinking, smoking and leaving workplace.
<b>7.2. Storage</b>	Store at room temperature, not above 30°C and not below 0°C.
<b>7.3. Additional information</b>	Refer to point 10.
<b>SECTION 8. Exposure controls and personal protection</b>	
<b>8.1. Hands protection</b>	Laboratory gloves.
<b>8.2. Skin protection</b>	Laboratory coat.
<b>8.3. Eyes protection</b>	Safety goggles.
<b>8.4. Ingestion</b>	Do not eat, drink or smoke during use.
<b>SECTION 9. Physical and chemical properties</b>	
<b>9.1. Form</b>	Strip → Dried; Buffer→ Liquid
<b>9.2. Critical temperature</b>	Min. 4°C - Not above 30°C; Do not frozen components.
<b>9.3. pH</b>	See point 3.2
<b>9.4. Vapour pressure</b>	Nil
<b>9.5. Solubility</b>	Nil
<b>9.6. Smell</b>	Nil
<b>SECTION 10. Stability and reactivity data</b>	
<b>10.1. Dangerous reaction</b>	Particular dangerous reactions not known.
<b>10.2. Dangerous properties</b>	Particular dangerous properties not known.

**10.3. Hazardous combustion or decomposition products**

Nature of decomposition products not known.

**SECTION 11. Toxicological information**

- Collect samples and used sticks in plastic bag and submit to sterilization procedures
- Rinse carefully polluted bench

**SECTION 12. Ecological information**

- Data not available for stick
- Avoid flushing away in drainpipes

**SECTION 13. Disposal considerations**

- Collect samples and used sticks in plastic bag and submit to sterilization procedures
- Rinse carefully polluted bench
- Contact a licensed professional waste disposal service to dispose of this material. Observe all federal state and regulations. Emptied bottles and vials may retain product residues: handle as if they were full.

**SECTION 14. Transport information**

Non classified.

**SECTION 15. Regulatory information**

From the European Communities Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CPL), this product is not hazardous and does not contain hazardous ingredients at concentrations used.

**SECTION 16. Other information**

Contents and format of this Safety Data Sheet comply with the European Communities Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Coris BioConcept shall not be held liable for any damage resulting from handling or from contact with the above product.