SECTION 1. Product identification	
1.1. Trade name	C. diff-Strip; Clostridium K-SeT Codes: C-1020, K-1220, K-1520
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: info@corisbio.com - Web Site: www.corisbio.com
1.3. Kind of use	*In vitro* Rapid Diagnostic Device for detection of *Clostridium difficile* in human stool samples. **FOR MEDICAL DIAGNOSTIC USE ONLY** 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	*In vitro* Diagnostic device
3.2. Components	**Laminate:** Active matrix → nitrocellulose + mylar Plastic backing → Polyester **Absorbent paper:** Sample PAD → glass fiber Absorbent paper → cellulose paper **Release matrix:** Conjugate PAD → polyester fiber **HC Dilution buffer:** Salts → restricted information Additive(s) → restricted information Conservative → Sodium Azide (<0.1%) pH → 7.5 Molarity → restricted information
3.3. Biologicals	**Specific reagent:** mouse monoclonal antibody directed against specific *Clostridium difficile* antigen (Glutamate Deshydrogenase GDH) **Control reagent:** Antichicken goat polyclonal antibody **Conjugate:** Anti-*Clostridium difficile*: mouse monoclonal antibody, gold colloïd coupled Chicken IgY: chicken polyclonal gold colloid coupled
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	Latex free
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.

4.3. Ingestion	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.
SECTION 5. Fire hazard data	
5.1. Flammability	Contains combustible materials.
5.2. Extinguishing	Water, carbon dioxide, dry chemical powder or polymer foam. Use extinguishing media appropriate to surrounding fire conditions.
5.3. Special Fire Fighting procedures	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.
SECTION 6. Accidental release measures	
6.1. Precautionary measures	Wear appropriate protective clothing (refer to point 8).
6.2. Environment Precautions	Buffer: Avoid flushing away in drainpipes. Collect samples in plastic bag and submit to sterilization procedures
6.3. Released or spilled material	Sweep up and collect in appropriate container for waste disposal (refer to point 13) clean the floor and all other contaminated objects with water.
SECTION 7. Handling and storage	
7.1. Handling	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.
7.2. Storage	Store at room temperature, not above 30°C and not below 0°C.
7.3. Additional information	Refer to point 10.
SECTION 8. Exposure controls and personal protection	
8.1. Hands protection	Laboratory gloves.
8.2. Skin protection	Laboratory coat.
8.3. Eyes protection	Safety goggles.
8.4. Ingestion	Do not eat, drink or smoke during use.
SECTION 9. Physical and chemical properties	
9.1. Form	Strip → Dried; Buffer→ Liquid
9.2. Critical temperature	Min. 4°C - Not above 30°C; Do not frozen components.
9.3. pH	See point 3.2
9.4. Vapour pressure	Nil
9.5. Solubility	Nil
9.6. Smell	Nil
SECTION 10. Stability and reactivity data	
10.1. Dangerous reaction	Particular dangerous reactions not known.
10.2. Dangerous properties	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.