

**1. Identification of the substance/preparation and of the company/undertaking****Identification of the substance or preparation**Trade name: **Inverness Medical TESTPACK + Plus hCG Combo with OBC, Test Device**

Reference No.: 505805 (ROW) and 506048 (Canada)

Use of the substance / the preparation: In vitro diagnostic medical device. For professional use only.

**Company/undertaking identification:**

Unipath Ltd.,  
 Priory Business Park,  
 MK44 3UP,  
 United Kingdom.  
 Tel: +44 (0)1234 835000  
 Fax: +44 (0)1234 835009  
 Email: product.support@invmed.com

Further information obtainable from: [www.unipath.com](http://www.unipath.com)

Emergency telephone: +44 (0)1234 835000

**2. Hazards identification****Hazard description:**

The test strip contained in the device is not classified as dangerous according to directive 99/45/EC

**Information concerning particular hazards for human and environment:**

Under the recommended conditions of use, there is no risk of exposure to any of the materials contained in the device.

**Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

**3. Composition/information on ingredients****Chemical characterisation****Description:**

In vitro diagnostics medical device containing test strip impregnated with dried chemical / biochemical reagents.

**Dangerous components:**

Component	CAS No.	EINECS No.	Classification	Concentration
Tris (hydroxymethyl) aminomethane	77-86-1	201-064-4	Xi, R 36/37/38	1 – 2 %
Tris (hydroxymethyl) aminomethane Hydrochloride	1185-53-1	214-684-5	Xi, R 36/37/38	1 – 2 %

**Additional information:**

Each device also contains a desiccant tablet.

For the wording of the listed risk phrases refer to section 16.

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**4. First-aid measures****General Information:**

The following first aid measures are only relevant in the event of serious misuse, whereby the device is opened and there is exposure to the contents.

**After skin contact:**

Wash with soap and water and rinse thoroughly.

**After eye contact:**

Rinse opened eye for several minutes under running water.

**After ingestion:**

If desiccant tablets or other components are swallowed seek medical attention.

**5. Fire-fighting measures****Suitable extinguishing agents:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire-extinguishing methods suitable to surrounding conditions.

**Special hazards caused by the substance, its products of combustion or resulting gases:**

In case of fire, the following can be released: Hazardous fumes and vapours.

**Protective equipment:**

Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

**Additional information:**

The device contains combustible materials.

**6. Accidental release measures****Person-related safety precautions:**

Refer to Section 8 for protective measures when handling the spillage.

**Measures for environmental protection:**

Avoid release to the environment.

**Measures for cleaning/collecting:**

Collect material and dispose of as waste according to Section 13.

**7. Handling and storage****Information for safe handling:**

Keep out of reach of children.

**Storage:**

Store in the original container at 2...30°C.

**Requirements to be met by storerooms and receptacles:**

No special requirements.

**8. Exposure controls/personal protection****Ingredients with limit values that require monitoring in the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

**Additional information:**

The lists valid during the creation of this MSDS were used as a basis for this assessment.



**Personal protective equipment:****General protective and hygienic measures:**

- Adhere to good laboratory practices (GLP).
- Wash hands before breaks and at the end of work.

**Respiratory protection:**

Not required

**Protection of hands:**

Disposable gloves (for sample handling)

**Material of gloves:** Latex/natural rubber.

**Penetration time of glove material:** Glove resistance is not critical as the gloves are intended to provide protection against the sample material.

**Eye protection:**

Not required

**Body protection:**

Lab coat

**9. Physical and chemical properties****General Information**

- Form:** The device is an article containing solid components
- Colour (outer casing):** white
- Odour:** Odourless
- Flash point:** Not applicable.
- Self-igniting:** Product is not self-igniting.
- Danger of explosion:** Product does not present an explosion hazard.

**10. Stability and reactivity**

- Stability:** The product is stable in accordance with the recommended storage conditions.
- Materials to be avoided:** None
- Hazardous reactions:** No dangerous reactions known.
- Hazardous decomposition products:** No dangerous decomposition products known.

**11. Toxicological information****Acute toxicity:**

Quantitative data on the toxic effects of this product is not available.

**Primary effects:**

- After skin contact:** No irritating effects known.
- After eye contact:** No irritating effects known
- Sensitization:** No sensitizing effects known.

**12. Ecological information****Environmental Toxicity:**

Quantitative data on the toxic effects of this product is not available.

**Persistence and Degradability:**

The device contains plastic and other components that are not readily degradable.



### 13. Disposal considerations

**Product:**

Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

**European waste catalogue:**

18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

**Packaging:**

Disposal must be made in accordance with local waste management regulations. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

### 14. Transport information

**Land transport ADR/RID (cross-border)**

Not regulated for transport.

**Maritime transport IMDG:**

Not regulated for transport.

**Marine pollutant:** No

**Air transport ICAO-TI and IATA-DGR:**

Not regulated for transport.

### 15. Regulatory information

**Labelling according to EU guidelines:**

Safety data sheet available to professional user on request.

**Note:** Exemption from the labelling requirements is possible on the basis that the preparation is contained in an article from which there is no risk of exposure under normal use.

### 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

**Relevant R-phrases**

36/37/38 Irritating to eyes, respiratory system and skin.

**Reason for Update:**

Email contact missing from Section 1 & to be REACH compliant

\* Indicates altered section.

**Supersedes:** SDS 016.03

