

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

Identification of the substance or preparation

Trade name: Determine HIV 1&2 Ag/Ab Combo, Test Device

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

Company/undertaking identification:

Unipath Limited
 Priory Business Park,
 Bedford, MK44 3UP,
 United Kingdom
 Tel: +44 1234 835000
 Fax: +44 1234 835001
 Email: product.support@invmed.com

Further information obtainable from: www.determinetest.com

Emergency telephone: +44 (0)1234 835000

2. Hazards identification

Hazard description:

The test strip 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. 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 %

Additional information:

Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis and found to be non-reactive.

Devices are arranged in cards of 10 and packaged in a foil pouch.

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

4. First-aid measures

General Information:

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

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 components are swallowed seek medical attention.

5. Fire-fighting measures

Suitable extinguishing agents:

CO₂, 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, Carbon oxides (CO_x), Nitrogen oxides (NO_x).

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:

This product should be handled as a potentially infectious material, as no known test method can offer complete assurance that materials of human origin will not transmit infectious agents.

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 EU directive 2000/54/EC for handling biohazardous materials.

Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

Respiratory protection:

Not required, unless there is a risk of aerosol generation during sample handling.

Protection of hands:

Disposable gloves

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:

Safety glasses or face shield, where there is a risk of splashing during sample handling.

Body protection:

Lab coat

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

Form: The device is an article containing solid components

Appearance: Laminated test strip on a backing support card.

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: Contact with acids may liberate trace amounts of toxic (hydrazoic acid) gas.

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

Sensitisation: No sensitising 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 for professional user on request.

Note:

The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for 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.

Supersedes: N/A

* indicates altered data

Reason for update: Revision of supplier information in Section 1

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