 TRINITY BIOTECH plc	MSDS	
	NAME OF PRODUCT: Uni-Gold™ Recombigen® HIV Product Code: 1206506 MSDS Number: U-0003	
MATERIAL SAFETY DATA SHEET	Effective date: March 2005	Version Number 03

Written By: Y. Kenny	Date: 22 March 2005	Approved by: F. Campbell	Date: 22 March 2005
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1-Product and Company Identification

PRODUCT NAME: Uni-Gold™ Recombigen® HIV

SUPPLIER:

Name: Trinity Biotech Plc,
Address: IDA Business Park,
Bray, Co. Wicklow,
Ireland.

Phone number: +353 1 276 9800

Fax number: +353 1 276 9888

NAME AND INTENDED USE

Uni-Gold™ Recombigen® HIV is a single use rapid immunoassay, for the qualitative detection of antibodies to HIV-1 in serum, plasma and whole blood (venipuncture and fingerstick). Uni-Gold™ Recombigen® HIV is intended for use in point of care settings as an aid in the diagnosis of infection with HIV-1.

This test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results.


2-Composition / information on components

KIT COMPONENTS:

Description	Quantity
1-Test Device: (Individually pouched with desiccant).	20 Tests
2-Wash Reagent: (For use with all sample types).	5.0 ml
3-Package Insert: Procedural instructions.	1
4. Subject information leaflet	20
5- Pipettes for use with serum, plasma or venipuncture whole blood. To be used also with Controls (Catalogue number 1206530)	20
6. Disposable Fingerstick Sample Collection and Transfer Pipettes	20

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For use with fingerstick whole blood	
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PREPARATION/SUBSTANCE: Preparation
COMPONENTS CONTRIBUTING TO THE HAZARD:

Chemical	Concentration	Units	% Concentration	CAS	EC Hazard symbol	R&S phrases
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Ingredient Notes: This product does not contain any hazardous ingredients above the trigger limits (e.g. above 0.1 or 1% depending on the hazard).

In the preparation of this device, the following components are used: Bovine Serum Albumin (certified USA source), buffered aqueous solutions, colloidal solutions, concentrated antigens to HIV. All these components have been coated onto a laminated membrane and are therefore not present in liquid form in the kit.

Intended use: In vitro diagnostic for professional use.

3-Hazard Identification

WARNING STATEMENT

All components containing biological material must be treated as potentially hazardous. Patient specimens and all fluid wastes should be handled as if they contain infectious materials, in accordance with national guidelines for Biosafety/Hazard Group 2. All material of animal or human origin is certified as "non-infectious" but should be treated as potentially hazardous.

Do not eat – FOR In vitro diagnostic use

For single use only / do not reuse

ADVERSE HUMAN HEALTH EFFECTS:

The following general hazard warnings apply to all the kit components:

Potential Routes of Exposure: Skin contact, eye contact, accidental ingestion, and inhalation.

Eye: Direct contact may cause eye irritation.

Skin: Direct or repeated contact may cause skin irritation.


Inhalation: Inhalation of dusts or mists may irritate the respiratory tract. However, inhalation is not expected to be a significant route of exposure under normal conditions of use.

Accidental ingestion: Relatively non-toxic.

Chronic Toxicity: None identified.

Carcinogenicity: None identified.

Medical Conditions Aggravated by Exposure: None identified.

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4-First-aid measures

The following general first aid measures apply to all components of the Uni-gold™ HIV kit and in general when handling potentially infectious materials (patient blood samples).

Eye contact: Immediately flush eyes with copious amounts of water for at least 15 minutes and notify medical personnel.

Skin contact: Immediately wash skin thoroughly with soap and water for 15 minutes and notify medical personnel. Remove and wash contaminated clothing and shoes.

Inhalation: Immediately move to fresh air and notify medical personnel.

Ingestion: If swallowed, do not induce vomiting, wash out mouth with water provided person is conscious. Call a physician immediately.

Notes to a physician: If at all possible, show all labels to physician of chemicals that you may have come into contact with.

5-Fire-fighting measures

The following general measures apply to all components of the Uni-gold™ HIV kit.

Extinguishing media: Water, carbon dioxide, dry chemical powder or appropriate foam.

Specific hazards: Closed containers exposed to heat may explode.

Specific methods of fire fighting: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Use water spray to cool fire-exposed containers.

6-Accidental release measures


The following general first measures apply to all components of the Uni-gold™ HIV kit.

Personal precautions: Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Methods of cleaning up: Cordon off spill area and minimise the spreading of spilled material. Soak up material with absorbent. Wash spill area thoroughly with soap and water.

Environmental precautions: Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations. Prevent runoff into sewers, storm drains, surface waters, and soil.

Decontamination: Decontaminate all surface area with a 10% sodium chlorite or equivalent solution when any material is spilled containing biological material.

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7-Handling and storage

Avoid contact with skin, eyes or clothing. Wear appropriate personal protective equipment (see section 8). Wash thoroughly after handling. Store at temperatures between 2-27°C. Keep away from combustible materials, heat, sparks and open flame.

8-Exposure control / Personal protection

The following general first aid measures apply to all components of the Uni-gold™ HIV kit.

Personal protective equipment:

Eye and Face protection: Wear suitable safety goggles. In the case of exposure to eyes an eye bath should be installed.

Skin and body protection: Wear gloves, lab coat, or other protective over garment if skin contact is likely. The choice of skin protection should be based on the job activity and potential for exposure to the skin.

Hygiene measures: Wash hands immediately after handling this material (especially before eating, drinking or smoking). Decontaminate or discard disposable protective equipment after each use.

9-Physical and chemical properties

Kit potentially hazardous components are presented in buffered aqueous solution or on the test device.

10-Stability and reactivity

The Uni-gold™ HIV kit should only be used as instructed in the package insert. See package insert for further information on kit stability.

Stability: Stable under normal conditions of use. Hazardous polymerisation is not expected to occur.

Hazardous Decomposition Products: None identified

Incompatibility: None identified

11-Toxicological information

See section 3 for Additional Information on Health Hazards.

Inhalation: No data available for this product


Skin (Irritancy and Acute Toxicity): No data available for this product

Eye (Irritancy and Acute Toxicity): No data available for this product

Ingestion: No data available for this product

Chronic Toxicity or Long-Term Toxicity: No data available for this product

Carcinogenicity : No data available for this product

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Reproductive and Developmental Toxicity : No data available for this product
 Mutagenicity : No data available for this product

12-Ecological information

Persistence and Degradability: No data available.
 Aquatic Toxicity: No data available.

13-Disposal considerations

All wastes containing the material should be properly labelled and stored separately from the other waste. Dispose of waste material according to prescribed national and local regulations.

14-Transport information


Land transport ARD / RID: Not regulated
 - ARD / RID class: N/A
 - Danger code: N/A
 - UN number: N/A
 - Hazard label: N/A
 - Description of goods: In vitro diagnostic testing kit
 Inland waterways ADN / ADNR: Not regulated
 Sea IMDG: Not regulated
 Air CAO / IATA: Not regulated

NOTE: Packaging "absorbent material" and "up arrows" should be considered for all shipments.

15-Regulatory information

EINECS Status:
 This product does not contain any hazardous ingredients above trigger levels (0.1% or 1.0%)

EC Classification and Labelling:
 None required.

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16-Other information

Recommended use: This product is an in vitro diagnostic testing kit and should only be used according to its package insert instructions.

The above information is based on data available to Trinity Biotech Plc and is believed to be correct. Since the information may be applied under conditions beyond the control of Trinity Biotech Plc and with which the company may be unfamiliar, Trinity Biotech Plc does not assume any responsibility for the results of its use and all persons receiving it shall make their own determination of the effects, properties, and protections, which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.