 <p style="text-align: center;">TRINITY BIOTECH plc</p>	<p>MSDS</p> <p>NAME OF PRODUCT: Mini-Quant D-Dimer Product Code: 1479</p>
<p>MATERIAL SAFETY DATA SHEET</p>	<p>Effective date: 10 September 2004 Version Number 1</p>

<p>Written By: Yvonne Kenny Date: 10 September 04</p>	<p>Approved by: Rachel Creane Date: 10 September 04</p>
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1-PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Mini-Quant D-Dimer

SUPPLIER:

<p>Name: Trinity Biotech Plc Address: IDA Business Park, Bray, Co. Wicklow, Ireland. Phone number: + 353 1 276 9800 Fax number: + 353 1 276 9888</p>	<p>Emergency phone number: Contact National Poisons Unit. Ireland: 01-837 9964 Belgium (+31) 30 2748888 France (+331) 40.37.04.04 USA 1800-603 8076</p>
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2-COMPOSITION / INFORMATION ON COMPONENTS


There are 6 reagents in this kit:

- Minutex[®] D-Dimer Latex
- Saline Solution
- Minutex D-Dimer Positive Control Plasma
- Minutex D-Dimer Negative Control Plasma
- Test Cards
- Mixing Sticks

PREPARATION/SUBSTANCE: Preparation

COMPONENTS CONTRIBUTING TO THE HAZARD:

Components	Hazardous Ingredient	Percentage By Weight	Cas No.	Ec No.
Minutex [®] D-Dimer Latex	Sodium Azide	0.02%	26628-22-8	247-852-1
Saline Buffer Solution	Sodium Azide	0.02%	26628-22-8	247-852-1
Minutex D-Dimer Positive Control Plasma	Human lyophilized plasma enriched with fibrin D-Dimer	100%	---	---
Minutex D-Dimer Negative Control Plasma	Human lyophilized plasma.	100 %	---	---

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3-HAZARD IDENTIFICATION

Minutex D-Dimer Negative Control Plasma - Human lyophilized plasma.

This product is prepared from human blood. All blood products should be treated as potentially infectious, and handled as if capable of transmitting infectious agents. Each donor unit used for this preparation has been tested and found negative for the presence of HBsAg, anti-HIV I + II, anti-HCV and syphilis.

Minutex D-Dimer Positive Control Plasma - Human lyophilized plasma enriched with fibrin D-Dimer.

This product is prepared from human blood. All blood products should be treated as potentially infectious, and handled as if capable of transmitting infectious agents. Each donor unit used for this preparation has been tested and found negative for the presence of HBsAg, anti-HIV I + II, anti-HCV and syphilis.

Minutex[®] D-Dimer Latex - Sodium Azide – Sodium Azide is very poisonous. Irritation in contact with skin/eyes. Ingestion/inhalation may cause irritation, shortness of breath, headache and dizziness. High concentrations may cause shock

Saline Solution - liquids containing **Sodium Azide** as preservative are poisonous and irritating in contact with skin/eyes. Ingestion/inhalation may cause irritation, shortness of breath, headache and dizziness. High concentrations may cause shock.

Mixing Sticks - Non Hazardous

Test Cards - Non Hazardous

4-FIRST-AID MEASURES

Skin Contact: For Minutex D-dimer positive and negative Control Plasma, wash at once thoroughly with soap and water followed by disinfection with 70 % isopropanol or ethanol. If irritation develops obtain medical attention. For Saline Solution and Minutex D-dimer latex, take off contaminated clothes. If symptoms remain, obtain medical attention.

Eye Contact: Immediately flush/wash thoroughly with water for 15 minutes and notify medical personnel. Ensure adequate flushing by separating eyelids with fingers. Keep the eyes wide open. Flush immediately with plenty of water. If irritation develops obtain medical attention.

Inhalation: Immediately remove to fresh air, Rinse nose, mouth and throat with water and notify medical personnel. If not breathing, give artificial respiration. If breathing difficult, give oxygen. If symptoms remain, obtain medical attention.

Ingestion: Never give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Do not induce vomiting. Have victim drink 200-400 mL to dilute. If breathing has stopped trained personnel should begin artificial respiration immediately, or if heart has stopped begin CPR immediately. Obtain medical attention.

5-FIRE-FIGHTING MEASURES

Extinguishing Media:

Minutex D Dimer Latex: Fire is put out with chemical dry powder, carbon dioxide or spread water beam. Vials nearby fire shall be moved and/or cooled down with water. May be explosive when heated


Hazardous Combustion Products: May emit toxic fumes under fire conditions.

Special Procedures:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes

6-ACCIDENTAL RELEASE MEASURES

Personal Precautions:

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If material is released or spilled, take proper precautions to minimise exposure by using appropriate personal protective equipment

Cleaning Methods:

Carefully sweep or vacuum up into a suitable waste container for disposal. Wipe the contaminated surface with disinfectant.

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.

7-HANDLING AND STORAGE

See kit insert.

8-EXPOSURE CONTROL / PERSONAL PROTECTION

Safety goggles and disposable gloves are recommended. Use good hygienic practices. Wash thoroughly with soap and water after handling

9-PHYSICAL AND CHEMICAL PROPERTIES

- **Minutex D-Dimer Negative Control Plasma:**
Before reconstitution: Lyophilized yellow plug
After reconstitution: Light yellow, slightly cloudy
- **Minutex[®] D-Dimer Latex** White solution.
- **Saline Solution** Clear colourless solution.
- **Minutex D-Dimer Positive Control Plasma:**
Before reconstitution: Lyophilized yellow plug
After reconstitution: Light yellow, slightly cloudy

10-STABILITY AND REACTIVITY

Saline Solution: Reactivity: Sodium Azide in contact with acid forms very poisonous gases. Sodium Azide may react with copper and lead plumbing. Sodium Hydroxide may be used as a cleaning agent.

Minutex[®] D-Dimer Latex


Stability: See kit insert.

Reactivity: Sodium Azide in contact with acid forms very poisonous gases. Sodium azide may react with copper and lead plumbing. Sodium Hydroxide may be used as a cleaning agent.

Minutex D-Dimer Negative Control Plasma – See Kit Insert

Minutex D-Dimer Positive Control Plasma – See Kit Insert

11-TOXICOLOGICAL INFORMATION Refer to Section 3 for Additional Information on Health Hazards

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LD₅₀/LC₅₀ Sodium Azide: (oral-rat)= 27 mg/kg

All wastes containing biological material should be properly labelled and stored separately from other wastes. Dispose of all waste materials according to prescribed international, national and local regulations. Follow Universal Precautions for Disposal/ Handling.

12-ECOLOGICAL INFORMATION

N/A

13-DISPOSAL CONSIDERATIONS

Dispose of in accordance with local regulations.

14-TRANSPORT INFORMATION

N/A

15-REGULATORY INFORMATION

The product contains Sodium Azide at concentrations below the Hazard Concentration Threshold = 0.1%. All components containing biological material must be treated as potentially biohazardous. There are no other materials present which may be a hazard.

16-OTHER INFORMATION

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do 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.