

MATERIAL SAFETY DATA SHEET

Section 1: IDENTIFICATION

Name: Strep B Device

Description: For Use With Vaginal/Rectal Swabs For Women Or Swabs For New Born

Manufacturer: **Prestige Diagnostics U.K Ltd.,
40/41 Ballymena Business Centre
Galgorm, Co.Antrim, BT42 1FL
+44(0)28 2564 2100**

Cat No. : RADSTB1

Section 2: CHEMICAL COMPOSITION

All components contain preparations and are therefore not listed in CAS

COMPONENT	SIZE	DESCRIPTION
Test Device	20 test devices, individually sealed in pouches.	This product comprises a mixture of components in an <i>in vitro</i> diagnostic medical device. Each test device is impregnated with dry chemicals and biochemical reagents.

Section 3: HAZARDS IDENTIFICATION

Hazardous components	None
Physical Hazards	None
Potential Health Effects Summary	None
Product Hazard Classifications	None

Section 4: FIRST AID MEASURES

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 device.

After skin contact	Not Applicable
After eye contact	Not Applicable
After ingestion	Not Applicable

Section 5: FIRE FIGHTING MEASURES

Flash Point:	Not Applicable
Flammable Limits:	Not Applicable
Autoignition Temperature:	Not Applicable
Extinguisher Media:	Not Applicable
Special Fire and Explosion Hazards:	Not Applicable
Hazardous Combustion Products:	Not Applicable
Protective Equipment for Firefighter:	Not Applicable

Section 6: ACCIDENTAL RELEASE MEASURES

Personal safety precautions	Not Applicable
Spill and leak procedures	Not Applicable
Environmental precautions	Not Applicable

Section 7: HANDLING AND STORAGE

Precautions to be taken in handling and storage	Not Applicable
Requirements to be met by storage conditions	Store at 2 – 30°C
Other precautions/Special Hazards	Not Applicable

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Exposure Limits US OSHA, ACGIH, DFG MAK:	Not Applicable
Personal protective equipment	Chemical resistant gloves, safety glasses, other protective clothing
Engineering controls:	Not Applicable
Skin Protection:	Not Applicable

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Solid
Appearance	Laminated test device
Odour	Odourless
Flash Point	Not Applicable
Self-ignition	The product is not self-igniting
Danger of explosion	The product does not present an explosion hazard
Melting Point/Boiling Point	Not Applicable / Not Applicable
Vapour Pressure	Not Applicable
Density (20 °C)	Not Applicable
pH value at 20 °C	Not Applicable
Solubility in water	Not soluble

Section 10: STABILITY AND REACTIVITY

Stability	Stable under conditions of use until the expiration date on the corresponding label
Hazardous Decomposition Products	None known

Section 11: TOXICOLOGICAL INFORMATION

Toxicity data for hazardous ingredients	Not Applicable
Primary routes of exposure	Not Applicable
Potential effects of acute exposure	Not Applicable
Potential effects of chronic exposure	Not Applicable
Symptoms of exposure	Not Applicable
Chronic Toxicity / Carcinogenicity	Not Applicable
Other effects	Not Applicable

Section 12: ECOLOGICAL INFORMATION

Environmental precautions	Not Applicable
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Section 13: DISPOSAL CONSIDERATIONS

General requirements	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
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Section 14: TRANSPORT INFORMATION

The product is not affected by the current rules for transport of hazardous goods (GGVS/ADR, GGVE/RID, IMDG, IATA/ICAO).

Section 15: REGULATORY INFORMATION

The product is not classified as a dangerous preparation according to 1999/45/EC and 67/548/EEC and 2001/58/EC.

Section 16: OTHER INFORMATION

The above mentioned information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Prestige Diagnostics UK Ltd shall not be held liable for any damage resulting from handling or from contact with the above product.