

MATERIAL SAFETY DATA SHEET

Section 1: IDENTIFICATION

Name: Plasma Controls

Manufacturer: **Prestige Diagnostics U.K Ltd.,
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Cat No. QCCPCL1/ QCCPCL2/ QCCPCC1

Section 2: CHEMICAL COMPOSITION

These products contain several different chemical components, see below for biological and chemical hazard information.

Section 3: HAZARDS IDENTIFICATION

Potential Biohazard:

The components of the device are formulated with constituents from animal serum, human serum and potentially infectious components. The human sera are tested by a licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product. All bovine products and goat sera originate from countries where BSE has not been reported.

Chemical Hazard:

None of the above are hazardous substances or mixtures according to Regulation (EC) No. 1272/2008. These substances/mixtures contain no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. Avoid contact with eyes, skin, inhalation and ingestion. Handle with the precautions listed in Sections 4, 5, 7 and 8. The following Hazard statements apply to the neat form of the chemical although the components are used in diluted form in the preparation of the device.

Hazard and Precaution Statements

P102 – Keep out of reach of children

P405 – Store locked up

Section 4: FIRST AID MEASURES

Description of First aid measures

Emergency first aid: Call an internal first aider where available or else contact a physician immediately.

After Inhalation: Supply fresh air, consult doctor in case of complaints

After Skin contact: Immediately wash with water and soap and rinse thoroughly

Generally the product does not irritate the skin

After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing: Rinse mouth with water. Seek medical device and appropriate follow-up.

Section 5: FIRE FIGHTING MEASURES

Extinguishing media: No restrictions – Water spray, carbon dioxide, dry chemical powder, alcohol-resistant foam or appropriate form.

Thermal decomposition: Gases that are damaging to health do not form in dangerous quantities.

Section 6: ACCIDENTAL RELEASE MEASURES

After spillage: Treat material as you would human body fluids. Disposal should therefore include autoclaving at 121°C for 20 minutes prior to appropriate disposal with regard to local regulations. Alternatively, decontamination using a 0.1% sodium hypochlorite is acceptable. Perform this type of decontamination in a fume hood.

Absorbent material: No restrictions.

Section 7: HANDLING AND STORAGE

Handling: Normal precautions for handling chemicals must be observed.

Storage: Store at 2-8°C.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: None

Eye protection: protective glasses

Hand protection: Standard laboratory nitrile or latex gloves.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid
Colour: Yellow
Odour: Not determined
pH value: Not determined
Boiling Point: Not determined
Melting Point: Not determined
Flash Point: Not determined
Substance does not have any oxidising properties: Not determined
Ignition Temperature: Not determined
Explosion limits: Not determined
Vapour pressure: Not determined
Density: Not determined
Solubility in water: Soluble
Viscosity: Not determined

Section 10: STABILITY AND REACTIVITY

Hazardous Reactions – None when used appropriately
Hazardous decomposition products – None when used appropriately.

Section 11: TOXICOLOGICAL INFORMATION

LD50 Oral: Not Known
LD 50 Intraperitoneal: Not Known
L 50 Skin: Not Known
LC50 Inhalation: Not Known
Toxicologic Information: Not thoroughly investigated.

Section 12: ECOLOGICAL INFORMATION

Water Hazard class: Data not yet available

Section 13: DISPOSAL CONSIDERATIONS

Treat material as you would human body fluids. Disposal should therefore include autoclaving at 121oC for 20 minutes prior to appropriate disposal with regard to local regulations. Alternatively, decontamination using a 0.1% sodium hypochlorite is acceptable. Perform this type of decontamination in a fume hood

Section 14: TRANSPORT INFORMATION

Data Not yet available

Section 15: REGULATORY INFORMATION

This product contains no hazardous chemicals in reportable quantities according to CHIP 3. Hazard Symbol: None
Warnings: Material is of human origin, exercise due care.
Precautions: See section 2.

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.