

MATERIAL SAFETY DATA SHEET

Section 1: IDENTIFICATION

Name: RPR – RAPID PLASMA REAGIN

Description: Reagent for the determination of RPR in human serum.

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Cat No. : SYPRPR1, SYPRPR2, SYPRPR3, SYPRR01, SYPRR02, SYPRR03, SYPRR04, SYPRR05

SECTION 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture

Directive 67/548/EEC & Directive 1999/45/EC Not classified as dangerous for supply/use.

Label elements According to Directive 67/548/EEC & Directive 1999/45/EC

Special labelling phrase: Safety data sheet available for professional user on request. Note: The preparation is exempt from the above labeling 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.

Other hazards: None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures

Description: In vitro diagnostic reagent test device.

Preparation: Liquid reagents, buffered saline with inactive animal proteins.

Dangerous components: Contains no hazardous substances in reportable quantities.

Sodium azide 0.98 g/L. is classified according to EEC directive 88/379 (the Chemicals Act and Hazardous Goods Regulations) as non-hazardous.

Kit controls contain rabbit antiserum

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General information. The following first aid measures are only relevant in the event of serious misuse, whereby the device is mishandled and there is exposure to the liquid reagent...

Inhalation: Supply fresh air; consult doctor in case of complaint.

Skin Contact: Wash skin with soap and water.

Eye Contact: Rinse cautiously with water for several minutes. Consult doctor in case of complaint.

Ingestion: Wash out mouth with water. Consult a doctor.

Most important symptoms and effects, both acute and delayed: None.

Indication of the immediate medical attention and special treatment needed: None.

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing media: Suitable Extinguishing Media CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Special hazards arising from the substance or mixture

In case of fire, the following can be released: Hazardous fumes and vapours.

Advice for fire-fighters Use fire-extinguishing methods suitable to surrounding conditions.

Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

Environmental precautions

Avoid release to the environment.

Methods and material for containment and cleaning up

Collect material and dispose of as waste according to Section 13

Reference to other sections 8, 13

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children. Specimens should be handled as potentially infectious materials.

Refer to Directive 2000/54/EC for information on handling biohazardous materials. Wash hands before breaks and after work. Clean work areas with hypochlorite or other disinfecting agent.

Conditions for safe storage, including any incompatibilities

Store in original container at 2 to 8°C.

Specific end use(s) Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters.

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

Exposure controls

Appropriate engineering controls Not relevant for this material.

Personal protection equipment

Eye/face protection Safety glasses recommended. (EN166) Hand protection Disposable gloves. (EN374). Material of gloves: Latex / natural rubber Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use. Body protection Laboratory coat. Respiratory protection Not normally required.

Environmental Exposure Controls No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance Liquid reagents in glass plastic or glass vials.

Colour: RPR, clear liquid with black particles.

Controls, clear to straw.

Odour No odour.

Odour Threshold (ppm)

Not applicable

pH (Value)

6.4 – 8.5

Melting Point (°C) / Freezing Point (°C)

Not determined

Boiling point/boiling range (°C):

Not determined

Flash Point (°C)

Not applicable

Evaporation rate (BA = 1)

Not applicable

Flammability (solid, gas)

Not determined

Explosive limit ranges	Not applicable
Vapour Pressure (mm Hg)	Not applicable
Vapour Density (Air=1)	Not applicable
Density (g/ml)	Not determined
Solubility (Water)	Not applicable
Solubility (Other)	Not applicable
Partition Coefficient (n-Octanol/water)	Not determined
Auto Ignition Temperature (°C)	Not applicable
Decomposition Temperature (°C)	Not determined
Viscosity (mPa.s)	Not determined
Explosive properties	Not explosive.
Oxidising properties	Not oxidising
Other information	Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity None known.

Chemical stability The product is stable in accordance with the recommended storage conditions. Possibility of hazardous reactions None known.

10.4 Conditions to avoid None

Incompatible materials. Sodium azide may cause explosive salts if built up in copper piping. Flush with water.

Hazardous Decomposition Product(s) None known.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Mixtures

Acute toxicity Based upon the available data, the classification criteria are not met.

Irritation Based upon the available data, the classification criteria are not met.

Corrosivity Based upon the available data, the classification criteria are not met.

Sensitisation Based upon the available data, the classification criteria are not met.

Repeated dose toxicity No data

Carcinogenicity Based upon the available data, the classification criteria are not met.

Mutagenicity No data

Toxicity for reproduction Based upon the available data, the classification criteria are not met.

STOT-single exposure Based upon the available data, the classification criteria are not met.

STOT-repeated exposure Based upon the available data, the classification criteria are not met.

Aspiration hazard Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact No significant harmful effects anticipated

Eye Contact No significant harmful effects anticipated

Ingestion No significant harmful effects anticipated

Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

Toxicity The product does not contain significant quantities of ingredients that are environmentally toxic.

Persistence and degradability. The product is unlikely to persist in the environment.

Bio-accumulative potential None anticipated.

Mobility in soil The product is predicted to have high mobility in soil.

Results of PBT and vPvB assessment Not applicable

Other adverse effects Not applicable

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Product: Used devices should be disposed of as potentially biohazardous material 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.

Packaging: Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled.

Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

UN number Not applicable

Proper Shipping Name Not applicable

Transport hazard class(es) Not classified as dangerous for transport.

Packing Group: Not applicable

Environmental hazards: Not applicable

Special precautions for user: Not applicable

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable

SECTION 15: REGULATORY INFORMATION

Safety, health & environmental regulations/legislation specific for the substance or mixture

In Vitro diagnostics medical devices directive 98/79/EC.

Chemical Safety Assessment Not applicable.

SECTION 16: OTHER INFORMATION

To the best of our knowledge, the information contained herein is accurate. However, Prestige Diagnostics does not assume any liabilities 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 described herein, we cannot guarantee that these are the only hazards that exist.