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1. SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product Identifier

Trade Name:	RPR Kits
Reference No.:	NB012, NB013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use – In-vitro diagnostic reagent	For PROFESSIONAL use only

1.3. Details of the supplier of the Safety Data Sheet

Newmarket Biomedical Ltd.
Unit 1 Lanwades Business Park
Kentford, Suffolk
CB8 7PN UK

Tel: +44 (0)1638 552 340
email: regulatory@new-bio.com – (Competent Person) Europe & Middle East

1.4. Emergency Telephone Number

Emergency Tel No.:	+44 (0)1638 552 340

2. SECTION 2 HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification under CLP: Not classed as hazardous according to Regulation (EC) 1272/2008 (CLP) or EU Directive 67/548/EEC, Directive 1999/45/EC but contains hazardous ingredients	
Label elements	The labelling for these products is not classified as hazardous according to Regulation (EC)1272/2008 (CLP)
Contains preservative: Sodium Azide	

2.2. Other hazards

None anticipated

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3. SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substance – N/A

3.2. Mixtures

Description:	In vitro diagnostic reagent test device for human use only
Preparation:	Liquid reagents, buffered saline with inactive animal proteins
Dangerous Components:	Contains sodium azide as a preservative, but at concentrations below levels to influence the classification of the mixture.

Ingredient	CAS / EC	Reagent	CONC (w/w)	Symbol	Hazard Statements
Sodium azide	26628-22-8 247-852-1	RPR Antigen Positive Control Negative Control	0.098% 0.095% 0.097%		H300, H310, H330, H373, H400, H410, EUH032

Product	Component	Description
30018	RPR Antigen	Activated carbon particles coated with cardiolipin antigen suspended in a phosphate buffered saline solution containing 0.09% sodium azide.
30026	RPR Positive Control	Antiserum with antibodies to Treponema pallidum antigen in phosphate buffered saline, and 0.09% sodium azide as a preservative.
30027	RPR Negative Control	Serum with no detectable antibodies to Treponema pallidum in phosphate buffered saline, and 0.09% sodium azide as a preservative.

4. SECTION 4 FIRST AID MEASURES

4.1. 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:	Move to area of fresh air; consult doctor in case of discomfort.
Skin Contact:	Wash skin with soap and water.
Eye Contact:	Rinse cautiously with water for several minutes. Consult doctor in case of discomfort.
Ingestion:	Wash out mouth with water. Consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

NONE

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4.3. Indication of the immediate medical attention and special treatment needed

NONE

5. SECTION 5 FIRE FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media CO_2, or water spray. Fight larger fires with water spray or alcohol resistant foam. Product does not support combustion.

5.2. Special hazards arising from the substance or mixture

No known hazardous fumes and vapours as a result of combustion or heating.

5.3. Advice for Firefighters

Use fire-extinguishing methods suitable to surrounding conditions.

6. SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions; protective equipment and emergency procedures

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

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect material by using suitable spill kit or absorbing materials, such as sand or clay and dispose of as waste according to Section 13.

6.4. Reference to other sections

8; 13

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7. SECTION 7 HANDLING AND STORAGE

7.1. 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.

7.2. Conditions for safe storage, including any incompatibilities

No specific hazards. Store in original container at 2 – 8°C.

7.3. Specific end use(s)

Use as per Instructions for Use. This product is intended for laboratory use by professional users only.

8. SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. 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.

8.2. Exposure Controls

Appropriate engineering controls:	Not relevant for this material
Personal protective equipment:	
Eye / face protection:	Safety glasses recommended. (EN166)
Hand protection:	Disposable gloves. (EN374)
Material of gloves:	Latex / natural rubber / Nitrile
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

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9. SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Liquid reagents in glass vials
Colour:	RPR Antigen – black particle suspension in clear liquid Positive Control – clear to straw liquid Negative Control – clear to straw liquid
Odour:	No odour
Melting point (°C) / Freezing point (°C):	As for water
Boiling point (°C) / boiling range (°C):	As for water
Flammability (solid, gas):	Not applicable
Flammability limits:	Not applicable
Flash point (°C):	Water mixture
Auto Ignition Temperature (°C):	Not applicable
Decomposition Temperature (°C):	Not determined
pH (value):	6.8 – 7.3
Viscosity (mPa.s):	As for water
Solubility (water):	Miscible
Partition Coefficient (n-Octanol/water):	Not applicable
Vapour pressure:	As for water
Density (g/mL):	As for water
Vapour density:	Not applicable
Particle characteristics:	Not applicable
Other information:	No known danger

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10. 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:	The Sodium Azide in this mixture may react with acids to release very toxic gas (hydrogen azide).
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

11. SECTION 11 TOXICOLOGICAL INFORMATION

11.1. 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.
Carcinogenicity	Based upon the available data; the classification criteria are not met.
Mutagenicity	Based upon the available data; the classification criteria are not met.
Toxicity	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.

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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: Endocrine disrupting properties – Contains no components considered of concern.	

12. SECTION 12 ECOLOGICAL INFORMATION

Toxicity:	The product does not contain significant quantities of ingredients that are environmentally toxic.
Persistance and degradability:	The product is unlikely to persist in the environment. Organic components are either of biological origin or considered biodegradable.
Bio accumulative potential:	None of the components are known to be potentially accumulative in the environment.
Mobility in soil:	The product is predicted to have high mobility in soil.
PBT, PMT, vPvB, vMvP assessment:	Contains no components considered of concern
Endocrine disrupting properties:	Contains no components considered of concern
Other adverse effects:	None known

13. SECTION 13 DISPOSAL CONSIDERATIONS

13.1. 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.	

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14. 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

15. SECTION 15 REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization:	No ingredients listed
1272/2008/EC Classification, labelling and packaging regulation (CLP)	Non-hazardous – There is no labelling requirement
Biocidal Products Regulation (EU) 528/2012	Contains Sodium Azide as a preservative
IVD Regulation (EU) 2017/746	Product classified as diagnostic kits and reagents for human use only. Reactive Control contains human antiserum. Any human material included in this kit has been tested and found negative or non-reactive for HBsAg, HIV 1 Ag (or HIV PCR (NAT)), HIV 1/2 antibody, HCV antibody and HCV PCR (NAT) as required at the time of bleeding using FDA licensed test kits

15.2. Chemical safety assessment

Not applicable

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16. SECTION 16 OTHER INFORMATION

To the best of our knowledge, the information contained herein is accurate. However, Newmarket Biomedical 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.

References: Raw material safety data sheets

Relevant phrases from Section 3: REG 1272/2008	
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal in inhaled
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
EUH032	Contact with acid liberates very toxic gas

Acronyms / Abbreviations	
CLP	Classification, Labelling and Packaging
EC	European Commission
STOT	Specific Target Organ Toxicity
PBT	Persistent Bio accumulative Toxic
PMT	Persistent, Mobile, Toxic
vPvB	Very Persistent / Very Bio accumulative
vPvM	Very Persistent / Very Mobile
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
IVD	In-Vitro Diagnostic

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Department issuing SDS: Quality Assurance Department

Amy M Fairley
QA Manager
Newmarket Biomedical

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Australian Sponsor Information:

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