This SDS is not mandated and is provided for information use only. All components are considered non-hazardous or below thresholds of concern

---

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

1.1 Product identifier

Trade name: **PK TPHA 2000**

Reference No. NB004

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

Identified use(s): In vitro diagnostic reagents. 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
Tel: +44 (0)1638 552 340
E-Mail (competent person) Europe & Middle East: regulatory@new-bio.com

1.4 Emergency telephone number

Emergency Phone No. +44 (0)1638 552 340

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)

2.2 Label elements

Not classified as hazardous according to Regulation (EC) 1272/2008 (CLP).

2.3 Other hazards: None anticipated.

This SDS is not mandated and is provided for information use only. All components are considered non-hazardous or below thresholds of concern

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 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 under the CLP.

According to the Biocidal Products Regulation (EU) 528/2012, the following are used as preservatives.

Ingredient	CAS No.	Conc. (w/v)	Symbol	Hazard Statements
Sodium azide	026628-22-8	0.09%		H300, H310, H330, H373, H400, H410 EUH032

The Hazard Classification listed refers to the chemical at a pure concentration.

Product	Component	Description
NB004	REAGENT	Avian erythrocytes coated with antigens of *T. pallidum* and suspended in a saline solution containing 0.09% sodium azide
NB004	SAMPLE DILUENT	Saline solution containing absorbents and 0.09% sodium azide
NB004	POSITIVE CONTROL	Liquid human serum with antibodies to Treponema pallidum antigen in phosphate buffered saline, and 0.09% sodium azide as a preservative.
NB004	NEGATIVE CONTROL	Normal rabbit serum with no detectable antibodies to Treponema pallidum in phosphate buffered saline, and 0.09% sodium azide as a preservative.

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: 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.

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

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

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media CO2, powder 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

In case of fire, the following can be released: No known hazardous fumes and vapours.

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

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

This SDS is not mandated and is provided for information use only. All components are considered non-hazardous or below thresholds of concern

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

Store in original container at 2 to 8°C to maintain product integrity.

No known hazards if stored under ambient conditions

7.3 Specific end use(s): Use as per instructions for use. This product is intended for laboratory use by professional users only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters..

8.1.1 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

8.2.1 Appropriate engineering controls. Not relevant for this material.

8.2.2 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 required during normal use as directed.

8.2.3 Environmental Exposure Controls. No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

This SDS is not mandated and is provided for information use only. All components are considered non-hazardous or below thresholds of concern

Appearance		Colour	
REAGENT	Liquid reagents in plastic bottles	REAGENT	Clear liquid with tan particles
SAMPLE DILUENT		SAMPLE DILUENT	Orange liquid
POSITIVE CONTROL	Liquid reagents in glass vials	POSITIVE CONTROL	Clear to straw liquid
NEGATIVE CONTROL		NEGATIVE CONTROL	Clear to straw liquid

The following properties are common for the water based products covered by this SDS

Odour	No odour
Odour Threshold (ppm)	Not applicable
pH (Value)	Range 6.2 – 7.4
Melting Point (°C) / Freezing Point (°C)	Approximately 0°C
Boiling point/boiling range (°C):	Approximately 100°C
Flash Point (°C)	Not flammable
Evaporation rate (BA = 1)	As for water
Flammability (solid, gas)	Not applicable
Explosive limit ranges	Not applicable
Vapour Pressure (mm Hg)	As for water
Vapour Density (Air=1)	Not applicable
Density (g/ml)	Approximately 1 g/ml
Solubility (Water)	Miscible
Solubility (Other)	Not applicable
Partition Coefficient (n-Octanol/water)	Not applicable
Auto Ignition Temperature (°C)	Not applicable
Decomposition Temperature (°C)	Not applicable
Viscosity (mPa.s)	As for water
Explosive properties	Not explosive
Oxidising properties	Not oxidising

9.2 Other information Not available

This SDS is not mandated and is provided for information use only. All components are considered non-hazardous or below thresholds of concern

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity None known.

10.2 Chemical stability The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions The Sodium Azide in this mixture may react with acids to release very toxic gas (hydrogen azide).

10.4 Conditions to avoid. None

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

10.6 Hazardous Decomposition Product(s) None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 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

11.2 Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

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

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

Organic components are either of biological origin or considered biodegradable

12.3 Bioaccumulative potential None of the components are known to be potentially accumulative in the environment.

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

12.5 Results of PBT and vPvB assessment None of the components are known to be potentially PBT / vPvB

12.6 Other adverse effects None known

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.

SECTION 14: TRANSPORT INFORMATION

This SDS is not mandated and is provided for information use only. All components are considered non-hazardous or below thresholds of concern

14.1 UN number Not applicable

14.2 Proper Shipping Name Not applicable

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

14.4 Packing Group: Not applicable

14.5 Environmental hazards: Not applicable

14.6 Special precautions for user: Not applicable

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

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 Directive 98/79/EC

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.

This SDS is not mandated and is provided for information use only. All components are considered non-hazardous or below thresholds of concern

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 if inhaled
H373 may cause damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
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
vPvB – Very Persistent / Very Bio accumulative
REACH – Registration, Evaluation, Authorisation and Restriction of Chemical Substances
IVD – In Vitro Diagnostic

Department issuing SDS: Quality Assurance Department

Revision date: Dec 2023