



## Safety Data Sheet

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

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

#### 1.1 Product identifier

Trade name: **PK7400 TP HA Controls**

Reference No. B11187

#### 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](mailto: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.



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### 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
B11187	REACTIVE CONTROL	Each tube contains liquid human serum with antibodies to <i>Treponema pallidum</i> antigen in phosphate buffered saline, and 0.09% sodium azide as a preservative.
B11187	NONREACTIVE CONTROL	Each tube contains normal rabbit serum with no detectable antibodies to <i>Treponema pallidum</i> 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.



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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 CO<sub>2</sub>, 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

### SECTION 7: HANDLING AND STORAGE



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### 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



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Appearance		Colour	
REACTIVE CONTROL	Liquid reagents in glass vials	REACTIVE CONTROL	Clear to straw liquid
NONREACTIVE CONTROL		NONREACTIVE 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 7.1 – 7.3
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



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### SECTION 10: STABILITY AND REACTIVITY

10.1 <u>Reactivity:</u>	None known.
10.2 <u>Chemical stability:</u>	The product is stable in accordance with the recommended storage conditions.
10.3 <u>Possibility of hazardous reactions:</u>	The Sodium Azide in this mixture may react with acids to release very toxic gas (hydrogen azide).
10.4 <u>Conditions to avoid:</u>	None
10.5 <u>Incompatible materials:</u>	Sodium azide may cause explosive salts if built up in copper piping. Flush with water.
10.6 <u>Hazardous Decomposition Product(s):</u>	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



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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 <u>Toxicity:</u> significant ingredients that are environmentally toxic.	The product does not contain quantities of
12.2 <u>Persistence and degradability:</u>	The product is unlikely to persist in the environment. Organic components are either of biological origin or considered biodegradable.
12.3 <u>Bio-accumulative potential:</u>	None of the components are known to be potentially accumulative in the environment.
12.4 <u>Mobility in soil:</u>	The product is predicted to have high mobility in soil.
12.5 <u>Results of PBT and vPvB assessment:</u>	None of the components are known to be potentially PBT / vPvB



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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.





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### SECTION 14: TRANSPORT INFORMATION

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: N/A

### SECTION 15: REGULATORY INFORMATION

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

#### US Federal and State Regulations

##### SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8 Sodium Azide 1.0% de minimis concentration

##### CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 26628-22-8 Sodium Azide

CAS # 7558-79-4 Sodium Phosphate, Dibasic

##### California Proposition 65

No ingredients listed.

##### Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

CAS # 7558-79-4 Sodium Phosphate, Dibasic

##### New Jersey Dept. of Health Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

##### Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

CAS # 7558-79-4 Sodium Phosphate, Dibasic

##### REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.



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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.

### **Canada**

This product is exempt from WHMIS label and SDS requirements.

15.2 Chemical Safety Assessment: Not applicable.

## **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



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### **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 2022