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.

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

1.1 Product identifier

Trade name: **TPHA Reagent (TPHA Positive Control – Diluted)**

Reference No. 30014

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

Identified use(s) 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
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) 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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance : not applicable

3.2 Mixtures

Description: In vitro diagnostic reagent test device.

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

Dangerous components: Contains sodium azide as 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	Positive Control	0.073 – 0.096%		H300, H310, H330, H373, H400, H410, EUH032

Product	Component	Description
30014	POSITIVE CONTROL	Antiserum with antibodies to *Treponema pallidum* antigen 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: 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.

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_2, 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

No specific hazards following combustion or heating.

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 and dispose of as waste according to Section 13

6.4 Reference to other sections 8, 13

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 to 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.

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 normally required.

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

Appearance: Liquid reagents in plastic bottles or glass vials.

Colour : Test cells, clear liquid with tan particles.

Control cells, clear liquid with tan particles.

Sample diluent, yellow liquid

Controls, clear to straw liquid

Odour	No odour
Melting Point (°C) / Freezing Point (°C)	As for water
Boiling point/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)	7.0 – 7.4
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

9.2 Other information — No known danger

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

11.1.1 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 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: No hazards expected

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.
12.3 Bio accumulative potential:	None anticipated.
12.4 Mobility in soil:	The product is predicted to have high mobility in soil.
12.5 PBT, PMT, vPvB, vMvP assessment:	Contains no components considered of concern
12.6 Endocrine disrupting properties	Contains no components considered of concern
12.7 Other adverse effects:	Not applicable

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

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 & 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.

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 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

Department issuing SDS: Quality Assurance Department

Revision date: 4 September 2024. Minor formatting updates. No technical changes.