

SAFETY DATA SHEET

TPHA Test Kit

1. PRODUCT AND COMPANY INFORMATION

Company name: **Lab21 Healthcare Ltd.,**
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Product name: **TPHA Test Kit (Treponema Pallidum indirect Haemagglutination Test)**

Product code: **Test Kit:** TPHA/010, TPHA/012, TPHA/100, 2/830, 2/836 and versions thereof;
TPHA/101 Positive Control
TPHA/102 Test Cells
TPHA/103 Control Cells
TPHA/104 Diluent
TPHA/105 Negative Control

2. HAZARD IDENTIFICATION

Main hazards: These products are for in vitro diagnostic use only. Specimen material may contain pathogenic organisms. Handle with the appropriate precautions, according to good laboratory practices.
Product contains no hazardous constituents or the concentrations of all chemical constituents are below the regulatory threshold described in Article 31 Requirements for Safety Data Sheets.
All reagents contain less than 0.1% w/w sodium azide (NaN₃) as preservative.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: TPHA Test Cells
(Preserved coated avian erythrocytes: Contains <0.1% Sodium Azide
TPHA Control Cells
(Preserved avian erythrocytes: Contains <0.1% Sodium Azide
Diluent: Contains <0.1% Sodium Azide
Positive and Negative Control: Contain <0.1% Sodium Azide

Hazardous Components: **SODIUM AZIDE:** <1% w/w EINECS: 247-852-1 CAS: 26628-22-8
[T+] R28; [-] R32; [N] R50/53

4. FIRST AID MEASURES

Skin contact: May cause mild irritation at the site of contact. Wash skin with soap and water.
Eye contact: May cause irritation and redness. Flush with water.
Ingestion: Avoid hand to mouth contact.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Not combustible. Suitable extinguishing media for the surrounding fire should be used.
Exposure hazards: None in small quantities

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6. ACCIDENTAL RELEASE MEASURES

- Personal precautions:** Wear appropriate protective clothing. Refer to section 8 of MSDS for personal protection details.
- Environmental precautions:** Properly disinfect any spills. Do not discharge into drains or rivers. Contain large spillages using bunding.
- Clean-up procedures:** Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

7. HANDLING AND STORAGE

- Handling requirements:** For in vitro diagnostic use only. Read the instructions for use. Avoid the formation of aerosols. Avoid direct contact with the substance
- Storage conditions:** Store in cool, well-ventilated area. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazardous ingredients:

- SODIUM AZIDE:** WEL (8 hr TWA): 0.1 mg/m³ WEL (15 min STEL): 0.3 mg/m³
- Respiratory protection:** Respiratory protection not required.
- Hand protection:** Protective disposable gloves.
- Eye protection:** Safety glasses. Ensure eye bath is to hand.
- Skin protection:** Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

- State:** Liquid
- Colour:** Test and Control Cells: Brown/red suspension
Positive and Negative Controls: Colourless liquid
Diluent: yellow/orange liquid
- Odour:** Odourless
- pH:** Test and Control Cells: pH6.6
pH7.8 – 8.2
- Solubility:** Soluble/ suspension
- Flammability:** Not combustible

10. STABILITY AND REACTIVITY

- Stability:** Stable under normal storage and handling conditions. Do not use after expiry date.
- Materials to avoid:** Strong oxidising agents. Strong acids.
- Hazardous decomposition products:** In combustion may emit toxic fumes.

11. TOXICOLOGICAL INFORMATION

- Hazardous ingredients:** **SODIUM AZIDE:**
ORL MUS LD50 27 mg/kg
ORL RAT LD50 27 mg/kg
SKN RAT LD50 50 mg/kg
- Routes of exposure:** Refer to section 4 of SDS for routes of exposure and corresponding symptoms.

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12. ECOLOGICAL INFORMATION

Mobility: Readily absorbed into soil.
Persistence and degradability: No data available.
Bio-accumulative potential: No data available.
Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Waste code number: 160506 Hazardous waste.
NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

14. TRANSPORT INFORMATION

SODIUM AZIDE:
ADR / RID
UN no: - Not applicable.
Shipping name: Not classified as dangerous in the meaning of transport regulations.
IMDG / IMO
UN no: - Marine pollutant: NO
IATA / ICAO
UN no: - Not applicable.

15. REGULATORY INFORMATION

SODIUM AZIDE:
Hazard symbols: Harmful.
Risk phrases: R22: Harmful if swallowed.
R32: Contact with acids liberates very toxic gas.
EC classification: Xn- Harmful
Safety phrases: S29/35: Do not empty into drains; dispose of this material and its container in a safe way.
S36/37/39: Wear suitable protective clothing, gloves and eye / face protection.
S46: If swallowed, seek medical advice immediately and show this container or label.

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions that complete these regulations. Refer to all applicable national, international and local regulations or provisions.

16. OTHER INFORMATION

Warning: Because no test method can offer complete assurance that HIV, HCV, HbsAg or other infectious agents are absent, the components of this kit should be handled accordingly.

UK Legislation: Health and Safety at Work Act, 1974, and relevant statutory provisions.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.