	File Title: Product File	Document Title: Material Safety Data Sheet.	Date Issued 14.04.2018
	Item Title: TPHA	Item Code: 8.00.19.x.xxxx	Issue Level: 1.1


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Amendment Record

Issue Level	Date Issued	Summary of Amendment	Reviewed by
1.1	14.04.2018	General Review	Sondos Shalabi

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2. General Information.

Trade Names & Synonyms: TPHA Test Kit (Treponema Pallidum indirect Haemagglutination Test)

Chemical Family: In Vitro Diagnostics

Formula: not applicable.

Manufacturer: Atlas Medical.

Manufacturer's address: William James House
Cowley Road
Cambridge, CB4 0WX, UK.

Manufacturer's phone: ++44 (0) 1223 858 910

Manufacturer's Fax: ++44 (0) 1223 858 524

Email: info@atlas-site.com.uk

3. Composition, Information on Active Ingredients.


Composition: TPHA Test Cells
(Preserved coated avian erythrocytes: Contains <1% Sodium Azide
TPHA Control Cells
(Preserved avian erythrocytes: Contains <1% Sodium Azide
Diluent: Contains <1% Sodium Azide
Positive and Negative Control: Contain <1% Sodium Azide

Hazardous Components: SODIUM AZIDE: <1%

4. Hazard Information.

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.

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5. Fire & Explosion Hazard Data.

Extinguishing media: Not combustible. Suitable extinguishing media for the surrounding fire should be used.

Exposure hazards: None in small quantities

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, labeled 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 control and personal gear.

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

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Positive and Negative Controls: Colorless liquid
 Diluent: yellow/orange liquid
Odor: Odorless
pH: Test and Control Cells: pH6.6
 pH7.8 – 8.2
Solubility: Soluble/ suspension
Flammability: Not combustible

10. Stability and Reactivity Data.

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.

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. Waste disposal information.

Waste code number: 160506 Hazardous waste.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

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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.

17. 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.

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18. Disclaimer.

The information above is believed to be accurate represents the best information currently available to us.

However we make no warranty of merchantability or any other warranty expressed or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company be liable for any claims, losses or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

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