

SAFETY DATA SHEET

Febrile Antigen Test Reagents

1. PRODUCT AND COMPANY INFORMATION

Company name: **Lab21 Healthcare Ltd.,**
29, Dreadnought Trading Estate, Bridport, Dorset, DT6 5BU UK
Tel: +44 (0) 1308 421829 ;
Fax: +44 (0) 1308 421846 Web site: www.Lab21.com

Emergency contact: As above, during office hours.

Product name: **Febrile Antigen Test Reagents** (Stained bacterial suspensions for the identification of antibodies in human sera following infection with certain *Salmonellae*, *Rickettsiae* and *Brucella* pathogens)

Product code: **Test Kits:** FA/040, FA/042; 2/034, 2/040

Individual Febrile Antigens:

FA/002, FA/102 Salmonella Typhi H
FA/004, FA/104 Salmonella H Paratyphi A
FA/006, FA/106 Salmonella H Paratyphi B
FA/008, FA/108 Salmonella H Paratyphi C
FA/010, FA/110 Salmonella Typhi O
FA/011, FA/111 Salmonella Typhi Vi
FA/012, FA/112 Salmonella O Paratyphi A
FA/014, FA/114 Salmonella O Paratyphi B
FA/016, FA/116 Salmonella O Paratyphi C
FA/018, FA/118 Brucella abortus
FA/020, FA/120 Brucella melitensis
FA/022, FA/122 Proteus OX2
FA/024, FA/124 Proteus OX19
FA/022, FA/122 Proteus OXK
FA/030, FA/130 Positive Polyvalent Febrile Control
FA/032, FA/132 Negative Febrile Control
2/002 to 2/050 and other versions thereof.

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.

FORMALDEHYDE: Harmful by inhalation, in contact with skin and if swallowed.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Febrile Antigens: Formalin and Merthiolate
Febrile Positive Control: Sodium Azide

Hazardous Components: **SODIUM AZIDE:** Less than 0.1% w/w EINECS: 247-852-1 CAS: 26628-22-8
[T+] R28; [-] R32; [N] R50/53

THIOMERSAL (Merthiolate): Less than 0.1% w/v CAS: 54-64-8 [T+] R26/27/28; [Xn-] R33; [N] R50/53

FORMALDEHYDE: Less than 0.25% v/v CAS: 50-00-0 EINECS: 200-001-8 [T] Toxic, Cat 3 carcinogen (cause for concern but not enough information for satisfactory assessment)

Risk phrases used in section.3:

R26/27/ R28: Very toxic by inhalation and in contact with skin. Very toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R33: Danger of cumulative effects.
R43: May cause sensitization by skin contact.

SAFETY DATA SHEET

Febrile Antigen Test Reagents

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

4. FIRST AID MEASURES

Skin contact: May cause mild irritation at the site of contact. Wash skin with soap and water.
May cause skin sensitization.

Eye contact: May cause irritation and redness. Flush with water.

Ingestion: Avoid hand to mouth contact. If ingested wash out mouth with water, drink 1-2 glasses of water to dilute stomach contents.

5. FIRE-FIGHTING MEASURES

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 tissue, 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. Do not handle in confined areas.

Storage conditions: Store in cool (2° to 8°C) , well-ventilated area. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazardous ingredients:

FORMALIN: WEL (8 hr TWA): 2.55 mg/m³ WEL (15 min STEL): 2.5 mg/m³

Respiratory protection: Respiratory protection not required.

Hand protection: Nitrile gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Impermeable protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

State: Liquid

Colour: **Positive Control, Negative Control :** Colourless
Somatic O antigens, Proteus and Brucella: Blue colour
Flagellar H antigens: Red
Typhi Vi: Off white colour

Odour: Odourless

pH: pH6.8 – pH 7.4
Positive Control: pH 7.6 – 8.0

Solubility: Soluble

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. The components contain Sodium Azide. Sodium azide reacts with lead or copper plumbing to form potentially explosive azides. When disposing of such reagents flush with large volumes of water.

Hazardous decomposition products: In combustion may emit toxic fumes. Formalin: Some metallic oxides.
Hydrogen Bromide Nitrogen oxides.

SAFETY DATA SHEET

Febrile Antigen Test Reagents

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

THIOMERSAL:

IPR MUS LD50 54 mg/kg
IVN MUS LD50 45 mg/kg
ORL MUS LD50 91 mg/kg
ORL RAT LD50 75 mg/kg
SCU MUS LD50 66 mg/kg
SCU RAT LD50 98 mg/kg
UNR RAT LD50 40 mg/kg

FORMALIN:

ORL RAT LD50: 100 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:

Sodium Azide: No data available.

Merthiolate: Toxic to aquatic organisms. Toxic to soil organisms.

Formalin: No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

Waste code number: 18 01 07 Hazardous waste.

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

14. TRANSPORT INFORMATION

SODIUM AZIDE:

Shipping name: Not classified as dangerous in the meaning of transport regulations.

THIOMERSAL:**ADR / RID**

ADR Class 6.1

UN no:2024

Shipping name: MERCURY COMPOUND, LIQUID N.O.S

Labelling: 6.1 Classification Code: T4 Hazard ID: 66

IMDG / IMO

Class 6.1

UN no:2024

Marine Pollutant:PP

Shipping name: MERCURY COMPOUND, LIQUID N.O.S

Labelling: 6.1 EmS: F-A,S-A

IATA/ICAO

Class 6.1

UN no:2024

Packing instructions: 610(P&CA); 605(CAO)

Labelling: 6.1

FORMALIN: Not regulated

SAFETY DATA SHEET

Febrile Antigen Test Reagents

15. REGULATORY INFORMATION

FORMALIN:

Hazard symbols: Irritant.

Risk phrases: R43: May cause sensitization by skin contact.

EC classification: Xi- Irritant

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.

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.

Sources of information used in this data sheet:

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH): Article 31:- Requirements for safety data sheets, and Annex II:- Guide to the Compilation of Safety Data Sheets, OJ L 136/35 – L 136/36 and L 136/84 – L 136/92, 29.5.2007.

The Chemicals (Hazard Information & Packaging for Supply) Regulations [CHIP], United Kingdom Statutory Instrument 2002 No. 1689, based on the European Directives on Dangerous Substances (67/548/EEC) and Dangerous Preparations (1999/45/EC).

Approved Supply List (8th edition), information approved for the classification and labelling of substances and preparations dangerous for supply, United Kingdom Health & Safety Commission, 2005, based on Annex I to 67/548/EEC.

Commission Decision 2000/532/EC establishing a list of wastes pursuant to Article 1(a) of Directive 75/442/EEC on waste and Article 1(4) of Directive 91/689/EEC on hazardous waste.

CONSLEG: 2000D0532 – 01/01/2002, Office for Official Publications of the European Communities.

Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices, Annex I, Essential Requirements, OJ L 331/20, 7.12.98.

List of approved workplace exposure limits, Table 1 of EH40/2005, United Kingdom Health & Safety Commission.