

Section 1: IDENTIFICATION

Name: Febrile Antigens

Description: Stained and killed bacterial suspensions for the detection of antibodies in human sera following infection with certain Salmonella, Rickettsiae and Brucella pathogens

Manufacturer: **Prestige Diagnostics UK Ltd.,
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CAT NO	DESCRIPTION	PACK SIZE
FEBBAB1	Brucella abortus – Stained antigen suspension	10x5ml
FEBBME1	Brucella melitensis – Stained antigen suspension	10x5ml
FEBO191	Proteus OX19 – Stained antigen suspension	10x5ml
FEBOX21	Proteus OX2 – Stained antigen suspension	10x5ml
FEBOXK1	Proteus OXK – Stained antigen suspension	10x5ml
FEBAGK1	Febrile Antigen Kit – Stained Salmonella antigens without controls	8x5ml
FEBAGK2	Febrile Antigen Kit – Stained Salmonella antigens with controls	8x5ml / 2x1ml
FEBPAH1	Salmonella paratyphi A-H – Stained antigen suspension	10x5ml
FEBPAO1	Salmonella paratyphi A-O – Stained antigen suspension	10x5ml
FEBPBH1	Salmonella paratyphi B-H – Stained antigen suspension	10x5ml
FEBPBO1	Salmonella paratyphi B-O – Stained antigen suspension	10x5ml
FEBPCH1	Salmonella paratyphi C-H – Stained antigen suspension	10x5ml
FEBPCO1	Salmonella paratyphi C-O – Stained antigen suspension	10x5ml
FEBSTH1	Salmonella typhi H – Stained antigen suspension	10x5ml
FEBSTO1	Salmonella typhi O – Stained antigen suspension	10x5ml

Section 2: CHEMICAL COMPOSITION

Some components consist of preparations and are therefore not listed in CAS

Reagent:	Component:	CAS No.
	NaN ₃	26628-22-8
	Thiomersal	54-64-8
	Formaldehyde	

Section 3: HAZARDS IDENTIFICATION

Potential Biohazard:

The components of the product are formulated with constituents from animal serum, human serum and potentially infectious components. The human sera are tested by a licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product. All bovine products and goat sera originate from countries where BSE has not been reported.

Chemical Hazard:

Some components are formulated with NaN₃. In its concentrated form NaN₃ is fatal if swallowed, in contact with skin or if inhaled. May cause damage to organs (the brain) through prolonged or repeated exposure by ingestion. Some components are formulated with Thiomersal. In its concentrated form Thiomersal is fatal if swallowed, in contact with skin or if inhaled. May cause damage to organs through prolonged or repeated exposure. Some components are formulated with Formaldehyde. In its concentrated form Formaldehyde may cause cancer and is harmful if swallowed. May cause an allergic skin reaction in contact with skin. Suspected of causing genetic defects. Very toxic to aquatic life. Handle with the precautions listed in Sections 4, 5, 7 and 8. Avoid contact with eyes, skin, inhalation and ingestion. The following Hazard statements apply to the neat form of the chemical although the components are used in diluted form in the preparation of the device.

Hazard and Precaution Statements

H300 + H310 + H330 – Fatal if swallowed, in contact with skin or if inhaled.

H302 – Harmful if swallowed.

H317 – May cause an allergic skin reaction.

H341 – Suspected of causing genetic defects.

H350 – May cause cancer.

H373 – May cause damage to organs (brain) through prolonged or repeated exposure if swallowed.

H410 – Very toxic to aquatic life with long lasting effects.

P102 – Keep out of reach of children.

P201 – Obtain special instructions before use.

P262 – Do not get in eyes, on skin, or on clothing.

P273 – Avoid release into the environment.

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P301 + P310 + P330 – IF SWALLOWED: Immediately call a doctor or medical facility. Rinse the mouth.

P302 + P352 + P310 – IF ON SKIN: Wash with plenty of water. Immediately call a doctor or medical facility.

P304 + P340 + P310 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.

P308 + P313 – IF exposed or concerned: Get medical advice/ attention.

P391 – Collect spillage.

P405 – Store locked up.

P501 – Dispose of contents/container to an approved waste disposal plant.

Section 4: FIRST AID MEASURES

May cause mild irritation at the site of contact with skin. In the event of skin contact immediately wash skin with copious amounts of water. Cover skin with an emollient. Remove contaminated clothing and wash garments before reuse.

May cause irritation and redness in contact with eyes. In the event of eye contact, immediately flush eyes with copious amounts of water for at least 15 minutes. Call a physician.

If inhaled, remove to fresh air. If breathing is difficult, give oxygen.

Avoid hand to mouth contact during reagent use. If swallowed, wash out mouth with water provided person is conscious, then drink two glasses of water to dilute the stomach contents. Call a physician.

Section 5: FIRE FIGHTING MEASURES

Water spray, carbon dioxide, dry chemical powder, alcohol-resistant foam or appropriate form.

Section 6: ACCIDENTAL RELEASE MEASURES

Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete. Wear Personal Protective Equipment including laboratory coat, safety glasses and latex or nitrile gloves. After a spillage, can be washed off with plenty of water. Mop up spillages into absorbent tissue, sand or absorbent granules. Transfer to a closable container for appropriate disposal. Special measures to limit damage are not necessary

Section 7: HANDLING AND STORAGE

Handling – For In Vitro diagnostic use only. Read the Instructions For Use. Avoid the formation of aerosols of the reagent. Avoid direct contact with the substance.

Storage – Store in tightly closed containers at 2 – 8°C.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Wear chemical resistant gloves, safety eyeglasses, other protective clothing.

Safety shower, eye bath, sterile eye wash.

Mechanical exhaust required.

Do not breathe dust.

Avoid contact with eyes, skin and clothing.

Avoid prolonged or repeated exposures.

Wash thoroughly after handling

Keep tightly closed

Store all components dry, refrigerated at 2 - 8°C.

Formaldehyde solution:

Workplace Exposure Limit (8 hr TWA): 2.55 mg/m³

Workplace Exposure Limit (15 min STEL): 2.5 mg/m³

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odour: Red / Blue Liquid, odourless, pH 6.8-7.4

Section 10: STABILITY AND REACTIVITY

Reactivity – Contact with acids liberates very toxic gas. Tends to polymerise. Explosible with air in a vaporous/gaseous state when heated.

Chemical stability – Stable. Stabiliser: Methanol.

Possibility of hazardous reactions – Violent reactions possible with: Acids, nitrogen oxides, hydrogen peroxide, Oxidizing agents, performic acid, polymerisation initiators, Alkali metals, The generally known reaction partners of water.

Conditions to avoid – An explosion occurred when a mixture of sodium azide, methylene chloride, dimethyl sulfoxide, and sulfuric acid were being concentrated on a rotary evaporator. Strong heating (decomposition). Exposure to moisture. Heating.

Incompatible materials – Strong oxidizing agents, Strong acids, Strong bases, Various metals, Various alloys, Various plastics, Magnesium, Zinc alloys

Hazardous combustion products – Carbon oxides, Sulphur oxides, Sodium oxides, Mercury/mercury oxides

Hazardous decomposition products – No data available

Section 11: TOXICOLOGICAL INFORMATION

Sodium Azide:

LD50 oral, mouse: 27 mg/kg

LD50 oral rat: 27 mg/kg

LD50 skin rat: 50 mg/kg

Thiomersal:

LD50 IVN mouse: 54 mg/kg

LD50 oral mouse: 91 mg/kg

LD50 oral rat: 75 mg/kg

Formaldehyde solution:

LD50 oral rat: 100 mg/kg

Section 12: ECOLOGICAL INFORMATION

The product contains substances known to be hazardous to the environment. Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment. The product contains substances not degradable in waste water treatment plants.

Section 13: DISPOSAL CONSIDERATIONS

Waste-handling code: 18 01 07 Hazardous waste.
Accordance with local regulations should be observed.

Section 14: TRANSPORT INFORMATION

Is not affected by the current rules for transport of hazardous goods (GGVS/ADR, GGVE/RID, IMDG, IATA/ICAO)

Section 15: REGULATORY INFORMATION

European information: This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

Section 16: OTHER INFORMATION

The components of the reagents have tested negative for antibodies to HIV and HCV and to HBsAg but since no test method can offer complete assurance that these or other infectious agents are absent, the components of the kit should be handled as infectious biological material. The above mentioned information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Prestige Diagnostics UK Ltd shall not be held liable for any damage resulting from handling or from contact with the above product.