
IDENTIFICATION OF MANUFACTURER

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MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE PRODUCT

1.1 Product name: MucoPAP-F

1.2 Catalog number: MucoPAP-F TRF kit – MPK03

1.3 Date of issue: February 2017

1.4 Description of product:

The MucoPAP-F kit is a sandwich time resolved fluoro-immunoassay (TRF-IA) allowing the quantitative determination of human Pancreatitis-Associated Protein (PAP) in blood specimens dried on filter paper. It is intended to be used in cystic fibrosis newborn screening.

2. COMPOSITION OF THE PRODUCT

2.1 Appearance

Test kit consisting of 96-well microtitration plate, buffers, PAP standards and controls, europium-streptavidin complex and fluorescence enhancement solution.

2.2 Biological material

This kit contains bovine hemoglobin with which the standard range and controls are formulated. This kit also contains rabbit serum with which antibodies are formulated.

Serum of animal origin could be infectious and must be considered as a potential biohazard. No known test method can offer assurance that products derived from animals will not be infectious.

2.3 Chemical material

1. Dimethyl Sulfoxide (DMSO): CAS# 67-68-5
2. Thimerosal (buffers): CAS# 54-64-8
3. EDTA (buffers): CAS# 6381-92-6

3. HAZARDS IDENTIFICATION

This product is not classified as hazardous.

The reagents of the kits do not contain hazardous chemicals in reportable quantities.

Some components contain small amounts (less than 0.02%) of thimerosal (CAS# 54-64-8).

3.1 Toxicology/health effects of reagents

Occasional exposure to the reagents is not expected to produce adverse human health effects following prudent workplace practices. Contact with skin or eyes may produce irritation or burns. Wash with plenty of water and seek medical advice if irritation develops.

If swallowed, wash mouth with water and seek medical advice.

3.2 Information on other reagents

The physical, chemical and toxicological properties of all kit components have not been fully investigated. It is recommended that all laboratory personnel follow standard laboratory safety procedures when handling this product. Safety procedures should include wearing OSHA approved safety glasses, gloves, and protective clothing. Direct physical contact with all components in this product should be avoided. All recommended precautions for the handling of blood derivatives should be observed.

4. EXPOSURE CONTROL MEASURES/PERSONAL PROTECTION

4.1 Personal Protective Equipment: Barrier gloves, eye and mouth protection, laboratory coat are required as laboratory conditions indicate.

4.2 Ventilation: No special ventilation is necessary, however, a biosafety cabinet, as recommended in the CDC/NIH manual, may be necessary.

5. FIRST AID MEASURES

5.1 Route of Entry: Inhalation, ingestion and skin contact.

5.2 Emergency and First Aid Procedures:

Ingestion

If swallowed, wash out mouth with water provided person is conscious. Call a physician or poison control.

Skin Contact

Flush with copious amounts of water and wash with soap and water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician if irritation or discomfort develops.

Inhalation

Remove victim to fresh air. If breathing becomes difficult, give oxygen. If breathing stops, administer artificial respiration. Call a physician.

Eye Contact

Flush with copious amounts of water for at least 15 minutes. Check for and remove contact lenses. Assure adequate flushing by separating the eyelids. Call a physician. If medical attention is required, provide product label and/or MSDS.

6. ACCIDENTAL RELEASE MEASURES

Ventilate area. Shut off all sources of ignition. Wear appropriate protective gear. Wipe or pick-up materials, place in dealer container, dispose of in accordance with federal, state, and local regulations. Wash spill site thoroughly with soap and water after material pickup is complete.

7. HANDLING AND STORAGE

This kit should be stored as recommended on the product label. All components should be kept in tightly closed containers. Refer to the Storage section of the kit insert for further information. This kit should only be handled and used by qualified, trained professionals.

8. PRECAUTIONS FOR SAFE HANDLING

8.1 General: Read the package insert.

8.2 Steps to Be Taken in Case Material is Spilled: If solution spills, wash spill site thoroughly with soap and water after material pickup is complete.

8.3 Waste Disposal Method: Wipe or pick-up materials, dispose of in accordance with federal, state, and local regulations. Wash spill site thoroughly with soap and water after material pickup is complete.

9. FIRE AND EXPLOSION HAZARD DATA

9.1 Condition: No fire or explosion hazards. Packaging material will burn in a fire.

9.2 Extinguishing Media: Use standard fire fighting procedures depending on the source of the surrounding fire.

10. REACTIVITY DATA

10.1 Incompatibilities: No known incompatibilities.

10.2 Hazardous Polymerization: Will not occur.

10.3 Conditions to Avoid: This product is stable. If involved in a fire, poisonous gas may be produced by the packaging material.

10.4 Hazardous Decomposition or Byproducts: This product is stable. If involved in a fire, poisonous gas may be produced by the packaging materials.

10.5 Stability and reactivity: This product is stable until the expiration date indicated on the label under the specified storage conditions. There are no known reactivities with these components. Refer to the kit insert for further information.

11. ECOLOGICAL INFORMATION

None available.

12. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used as a guide only. Dynabio S.A. shall not be held liable for any damage resulting from handling or contact with the above product. The burden of safe use of these materials rests solely with the user.