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**IDENTIFICATION OF MANUFACTURER**

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**DYNABIO S.A.**

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**MATERIAL SAFETY DATA SHEET**

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**1. IDENTIFICATION OF THE PRODUCT**

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**1.1 Product name:** MucoPAPII

**1.2 Catalog number:** MucoPAPII ELISA kit – MPK02

**1.3 Date of issue:** February 2017

**1.4 Description of product:**

The MucoPAPII kit is a sandwich enzyme-linked immunoassay (ELISA) 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.

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**2. COMPOSITION OF THE PRODUCT**

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**2.1 Appearance**

Test kit consisting of 96-well microtitration plate, buffers, PAP standards and controls, substrate solution and stop 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. 3,3',5,5' tetramethylbenzidine (substrate solution); CAS# 54827-17-7.
3. Thimerosal (buffers): CAS# 54-64-8
4. Sulfuric acid (stop solution); Content: 2 N; CAS# 7664-93-9.

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### 3. HAZARDS IDENTIFICATION

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This product is not classified as hazardous. However, caution should be taken when handling acidic stop solution which may cause irritation or burns.

Other 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 Characteristics of the stop solution

Stop solution has the following characteristics:

Boiling Point: 338°C

Specific Gravity: 1.84

Solubility: Complete

pH: 1.0

Vapor Pressure: <0.3

#### 3.2. Toxicology/health effects of stop solution

Occasional exposure to this product 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. The stop solution is a poison and cause severe burns. The oral LD50 (rat) for sulfuric acid is 2140 mg/kg.

#### 3.3 Information on other reagents

3,3',5,5'- tetramethylbenzidine may cause skin and eye irritation.

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.

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### 4. EXPOSURE CONTROL MEASURES/PERSONAL PROTECTION

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**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.

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### 5. FIRST AID MEASURES

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**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.

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**6. ACCIDENTAL RELEASE MEASURES**

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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.

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**7. HANDLING AND STORAGE**

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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.

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**8. PRECAUTIONS FOR SAFE HANDLING**

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**8.1 General:** Read the package insert.

**8.2 Steps to Be Taken in Case Material is Spilled:** If stop solution spills, neutralize with soda ash, lime, or a commercially available acid neutralizer.

**8.3 Waste Disposal Method:** Place material in a sealed container and dispose of as medical waste in accordance with applicable environmental regulations. For blood derived material, dispose of as biological material.

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**9. FIRE AND EXPLOSION HAZARD DATA**

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**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.

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## 10. REACTIVITY DATA

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**10.1 Incompatibilities:** The stop solution is incompatible with strong oxidizing agents, alkalis, metals, strong reducing agents and many other reactive substances.

**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 and the stop solution may release oxides of sulfur.

**10.4 Hazardous Decomposition or Byproducts:** This product is stable. If involved in a fire, poisonous gas may be produced by the packaging materials. The stop solution will produce oxides of sulfur and hydrogen.

**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.

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## 11. ECOLOGICAL INFORMATION

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None available.

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## 12. OTHER INFORMATION

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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.