SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: PancrePAP

Catalogue number: PPK01

REACH Number: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

CAS number: -

CE number: -

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use: immunoenzymatic kit for human PAP assay - For research use only

1.3. Details of the supplier of the material safety data sheet

Company: DYNABIO S.A.
Luminy Biotech Entreprises
163, avenue de Luminy - Case 922
13288 Marseille Cedex 9
FRANCE

Telephone: +33 4 86 94 85 04 (Monday to Friday 9 am – 5 pm)

E-mail address: communication@dynabio.eu

1.4. Emergency telephone number

Land	Center	Phone number
USA	Indiana Poison Center – Indianapolis California Poison Control System: - Sacramento Division - San Diego Division - Fresno/Madera Division - San Francisco Division	+1 317 962 2335 +1 800 222 1222

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Components	CAS number	Hazard statement
Range / Internal Control	/	Is not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
Anti-hPAP biotinylated antibodies		
Dilution buffer		
Avidin-peroxidase conjugate		
Chromogenic substrate		
Tween 20		
PBS tablet		
6 x 16 coated well plate		
Sulfuric acid 5%	7664-93-9	H290 - may be corrosive to metals

2.2. Label elements

Components	Pictogram	Hazard statement
Range / Internal Control	/	Is not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
Anti-hPAP biotinylated antibodies		
Dilution buffer		
Avidin-peroxidase conjugate		
Chromogenic substrate		
Tween 20		
PBS tablet		
6 x 16 coated well plate		
Sulfuric acid 5%		H290 - may be corrosive to metals

2.3. Other hazards

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Biological hazard

This kit contains rabbit serum with which antibodies are formulated. The biotinylated antibodies, the avidin-peroxidase, the dilution buffer, the ranges and control as well as the plates contain bovine serum albumin.

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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

No components need to be disclosed according to the applicable regulations except the acid solution.

Components	Concentration	CAS number	Hazard classes and categories	ATE, LCS Factor and/or M Factor
Sulfuric acid	5%	7664-93-9	Met. Corr. 1 - H290 Skin Corr. 1A - H314	Skin Irrit. 2; H315: 5 % ≤ C < 15 % Eye Irrit. 2; H319: 5 % ≤ C < 15 %

As a reminder:
H290 - may be corrosive to metals
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice

See a doctor. Show this safety data sheet to the doctor in attendance.

Inhalation

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

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.

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.

Ingestion

If swallowed, wash out mouth with water provided person is conscious. Call a physician or poison control. DO NOT induce vomiting. Give nothing to eat or drink.

4.2. Most important symptoms and effects, both acute and delayed

No other important information available

4.3. Indication of any immediate medical attention and special treatment needed

Data not available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2. Special hazards arising from the substance or mixture

In case of fire, risk of release of sulfur oxides, carbon monoxide, carbon dioxide.

5.3. Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment (see section 8). Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

6.2. Environmental precautions

Do not let product enter drains.

6.3. Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes. Wash hands after handling all materials. Do not drink, eat, smoke, or apply make-up. Do no pipette with the mouth. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature +2°C - +8 °C

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

It does not contain substances with occupational exposure limit values.

8.2. Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Use equipment for eye protection (Safety glasses with side-shields) tested and approved under appropriate government standards such as NIOSH (US) or EN 166.

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN374 derived from it.

Body Protection

Impervious clothing, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

(a) Appearance

Components	Physical state	Color
Range / Internal Control	Solid	White
Anti-hPAP biotinylated antibodies	Solid	Brown
Dilution buffer	Liquid	Slightly yellow
Avidin-peroxidase conjugate	Solid	Pearly white
Chromogenic substrate (TMB)	Liquid	Very light yellow
Sulfuric acid 5%	Liquid	Transparent
Tween 20 (10%)	Liquid	Yellow
PBS tablet	Solid	White
6 x 16 coated well plate	Plastic	Transparent

(b) Odour — No data available
(c) Odour threshold — No data available
(d) pH

Components	pH
Range / Internal Control	No data available
Anti-hPAP biotinylated antibodies	
Dilution buffer	
Avidin-peroxidase conjugate	
Chromogenic substrate (TMB)	
Tween 20 (10%)	
PBS tablet	
6 x 16 coated well plate	
Sulfuric acid 5%	< 1 (20°C)

(e) Melting point/freezing point — No data available
(f) Initial boiling point and boiling range — No data available
(g) Flash point — Not applicable
(h) Evaporation rate — No data available
(i) Flammability (solid, gas) — No data available
(j) Upper/lower flammability or explosive limits — No data available
(k) Vapour pressure — No data available
(l) Vapour density — No data available
(m) Relative density — No data available
(n) Solubility — Soluble in water
(o) Partition coefficient: n-octanol/water — No data available
(p) Auto-ignition temperature — No data available
(q) Decomposition temperature — No data available
(r) Viscosity — No data available
(s) Explosive properties — No data available
(t) Oxidizing properties — No data available

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Sulfuric acid can be corrosive to metals.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

Metals.

10.6. Hazardous decomposition products

If involved in a fire, poisonous gas may be produced by the packaging material.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

(a) acute toxicity	No data available for components except sulfuric acid. Acute oral toxicity: LD50 > 2140 mg/kg - Rat - (Merck KGaA) Acute inhalation toxicity: LC50 = 375 mg/m^3 - Rat - (IUCLID)
(b) skin corrosion/irritation	No data available
(c) serious eye damage/irritation	No data available
(d) respiratory or skin sensitization	No data available
(e) germ cell mutagenicity	No data available
(f) carcinogenicity	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
(g) reproductive toxicity	No data available
(h) Specific target organ toxicity-single exposure	No data available
(i) Specific target organ toxicity-repeated exposure	No data available

(j) aspiration hazard	No data available
(k) Additional Information	RTECS: Not available To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1. Toxicity

Do not empty into drains.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

The product is water soluble, and may spread in water systems. Will likely be mobile in the environment due to its water solubility. Highly mobile in soils.

12.5. Results of PBT and vPvB assessment

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Must not be released to the environment.
Dispose of in accordance with local regulations and directive on waste and hazardous waste.
Contaminated packaging: dispose of as unused product.

SECTION 14: Transport information

14.1. UN number

ADR/RID: - IMDG: - IATA: -

14.2. UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3. Transport hazard classes

ADR/RID: - IMDG: - IATA: -

14.4. Packing group

ADR/RID: - IMDG: - IATA: -

14.5. Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6. Special precautions for user

No data available

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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

15.2. Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Document
Creation Date March 2000
Revision Date May 2022
Revision Summary
March 2019 - Version 2: Improved document readability
May 2022 - Version 3: Formatting according to regulation CE n°1907/2006
August 2022 - version 4: change of contacts: email addresses and website address (section 1.3)

Legend
ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road
CAS - Chemical Abstracts Service
CE / EC – Communauté Européenne or European Community
IARC - International Agency for Research on Cancer

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association
IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code
NIOSH - National Institute for Occupational Safety and Health
PBT - Persistent, Bioaccumulative, Toxic
vPvB - very Persistent, very Bioaccumulative
RTECS - Registry of Toxic Effects of Chemical Substances
UE / EU – Union Européenne or European Union

Further 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 only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Dynabio S.A. shall not be held liable for any damage resulting from handling or from contact with the above product.

End of Material Safety Data Sheet