

	Safety Data Sheet MSDS-MPK03-EN	Creation: January 2013 Date of review: Aug 2022 Version: 06
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: MucoPAP-F

Catalogue number: MPK03

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: cystic fibrosis newborn screening

1.3. Details of the supplier of the safety data sheet

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

Telephone: +33 (0)486 94 85 04 (Monday to Friday 9am – 5pm)

E-mail address: communication@dynabio.eu

1.4. Emergency telephone number

Land	Center	Phone number
Austria	Vergiftungsinformationszentrale	+43 1 406 43 43
Belgium	Belgisch Antigifcentrum / Centre antipoisons belge	+32 70 245 245
Chile	Emergencias químicas Santiago	+56 2 247 3600
	Emergencias toxicológica Santiago	+56 2 635 3800
	RITA Chile Recoleta	+56 2 2777 1994
Deutschland	Giftnotruf Berlin	+49 30 192 40
	Informationszentrale gegen Vergiftungen Bonn	+49 228 192 40
	Giftnotruf Erfurt	+49 361 730 730
	Vergiftungs-Informationen-Zentrale Freiburg	+49 761 192 40
	Giftinformationszentrum-Nord	+49 551 19240
	Giftinformationszentrum Rheinland-Pfalz/Hessen	+49 6131 192 40
	Giftnotruf München	+49 (0)89 192 40

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Greece	Κέντρο Δηλητηριάσεων	+30 21 07 79 37 77
The Netherlands	Anti gif informatiecentrum	+31 (0)88 755 8000
Hungary	Health toxicological information service	+36 80 20 11 99
Iceland	Eitrunarmiðstöð	+354 543 22 22
Italy	Niguarda Ca 'Granda Poison Center – Milano	+39 02 6610 1029
	Centro antiveleni – Firenze	+39 55 794 7819
	Centro antiveleni – Pavia	+39 382 24444
	Centro antiveleni – Sapienza Universita de Roma	+39 6 499 70 698
	Centro antiveleni – Universita Cattolica Roma	+39 06 3054 343
	Centro antiveleni – Bergamo	+39 800 883300
	Centro antiveleni – Foggia	+39 881 732 326
	Centro antiveleni – Turin	+39 011 663 76 37
Portugal	CIAV - Centro de Informação Antivenenos	800 250 250
Serbia	Национални центар за контролу тровања	+381 11 3608 440
Spain	Instituto de Toxicología y Ciencias Forenses - Barcelona	+34 933 17 40 61
	Instituto Nacional de Toxicología y Ciencias Forenses - Madrid	+34 91 562 0420
	Instituto Nacional de Toxicología y Ciencias Forenses - Sevilla	+34 954 37 12 33

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Is not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2. Label elements

Is not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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 bovine hemoglobin with which the standard range and controls are formulated. This kit also contains rabbit serum with which antibodies are formulated. The assay buffer, the biotinylated antibodies, the ranges and controls 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.

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.

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

Data not available

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 vapours, 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 not 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 - +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

Components with limit values that require monitoring at the workplace:

CAS Number	Name	Component	TWA
56-81-5	Glycerol (10%)	Streptavidin-europium	10 mg/m ³ (8 hours)

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
Standard hPAP Range/ Internal Controls	Paper	White with brown spots
Anti-hPAP Biotinylated antibodies	Solid	Brown
Assay Buffer	Liquid	Transparent
Streptavidin-Europium conjugate	Liquid	Transparent
Enhancement solution	Liquid	Transparent
Tween 20 (10%)	Liquid	Slightly yellow
PBS tablet	Solid	White
8 X 12 coated well plate	Plastic	Transparent

- | | |
|--|-------------------|
| (b) Odour | No data available |
| (c) Odour threshold | No data available |
| (d) pH | No data available |
| (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

No data available

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

No data available

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
(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

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vPvB - very Persistent, very Bioaccumulative

RTECS - Registry of Toxic Effects of Chemical Substances

TWA - Time weighted Average

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 Safety Data Sheet