FISIOGRAFT Powder

1. IDENTIFICATION OF THE PRODUCT AND MANUFACTURER

Identification of the material

Chemical Name	
Commercial Name / Synonym	FISIOGRAFT Powder Bio-resorbable material for use in implantology and periodontics

Identification of the manufacturer

Ghimas S.p.A.	Via Cimarosa, 85 40033 Casalecchio di Reno (BO) – ITALY Tel. +39 051 57.53.53
Emergency telephone number	Emergency Poison Control Center – Tel. 118

2. COMPOSITION AND INFORMATION ABOUT THE INGREDIENTS

Description: Mixture of copolymers in the ratio listed below for 379 mg of product (single dose)

Composition:	Quantity	CAS N:
Poly (D,L-lactic-*co*-glycolic) acid 50:50	110 mg.	26780-50-7
Dextrane	270 mg.	9004-54-0

Dangerous components: None

Product description:
- Invasive surgical medical device for submucous membrane and infraosseous contact utilized in dental and maxillo-facial surgery.
- FISIOGRAFT type POWDER is particularly suited for infraosseous one or two walled defects, for filling the cavity that remains after a cystectomy, for the regeneration of the alveolar crest which has been subjected to pathologic or traumatic processes.
- FISIOGRAFT type Powder retains its consistency even after it has been dampened with blood or other sterile solutions.

General instructions for use:
FISIOGRAFT type POWDER
- Open the package of FISIOGRAFT POWDER and empty the contents into the small sterile tray that is provided; mix with blood from the patient or sterile saline solution using a small spatula.
- Once a paste with the desired consistency has been obtained, it can be placed into the defect.
- To obtain a denser and more resistant filling material, FISIOGRAFT type POWDER may be combined with FISIOGRAFT type GEL

Precautionary measures:
WARNING: IT IS EXTREMELY IMPORTANT NOT TO OVERPACK OR OVERFILL THE DEFECT WITH MATERIAL. Care should be taken that the product does not come into direct contact with the vascular system.
- If edema should form at the implant site treat it with an appropriate pharmacological therapy. If this condition does not subside within 48 hours remove the material.
- If the packaging has been damaged or tampered with: DO NOT USE THE MATERIAL dispose of it as dangerous waste.

Contraindications:
There are no general contraindications for the use of FISIOGRAFT, except for individual intolerance in patients where a specific sensitivity to the components has been recorded. Nevertheless all the contraindications typical for oral and maxillo-facial surgery should be applied.

The use of FISIOGRAFT is not indicated in cases of:

- Acute or chronic infections at the implant site
- Patients being treated with i immune-suppressing drugs.
- In immune-suppressed patients

Side effects: - FISIOGRAFT may, in predisposed patients cause edema at the implant site

Shelf life: - 3 years when stored properly in a sealed package.

3. INFORMATION ON ENVIRONMENTAL IMPACT

None.

4. WHAT TO DO IN AN EMERGENCY

Immediately remove contaminated clothing.
- Contact with the eyes:
Rinse thoroughly with water for at least 15 minutes.
- Contact with the skin:
None
- If swallowed:
None
- If inhaled:
Does not apply

5. IN CASE OF FIRE

Extinguish with any normal fire extinguishing device (water, carbon dioxide, powder or foam).

6. ACCIDENTAL LEAKS AND SPILLAGE

Care should be taken when gathering the spilled material. Thoroughly wash the area and follow the standard procedure for disposal of chemical products.

7. INSTRUCTIONS FOR STORAGE

Conserve in the original packaging material, in a cool, dry, well ventilated and reasonably clean area in order to reduce the risk of contamination.

8. HANDLING INSTRUCTIONS

Personal protection:

The product should be handled in such a way as to minimize any risk of possible contamination due to bacteria. While working with the product sterile conditions must be maintained at all times.

9. CHEMICAL AND PHYSICAL PROPERTIES

Physical state:	Solid Powder
Color:	Ivory-white
Odor:	Odorless
Solubility in water:	Partially soluble
Solubility in the main organic solvents:	Acetone, Chloroform, Dichloromethane
pH:	-
Density (Water = 1):	-
Vapor Pressure:	-
Temperature at which material softens	- 82 – 83°C
Flash point:	-
Lower and upper flash point in air (% by volume)	-
Temperature of autocombustion:	-
Temperature of decomposition	-

10. STABILITY AND REACTIVITY

Incompatibility: Avoid contact with strong oxidizing agents

11. TOXICOLOGICAL INFORMATION

Vias of entry into the body: Contact - Inhalation – Ingestion

TOXICITY:
Poly(D,L-lactic-co-glycolic) acid
The product presents a very low risk of acute toxicity, there is no evidence of chronic systemic toxicity attributed to Poly (D,L-lactic-*co*-glycolic) acid. In some cases, when implanting FISIOGRAFT Powder, a localized subcutaneous hypersensibility may appear, this tends to disappear in approximately one week. Occasionally, this phenomenon of edema will manifest for a longer period of time (about seven days), usually without causing any negative effects to the final results.

- For the eyes: Can cause irritation.

SENSITIZING ACTION: The products can cause sensitizing reactions which tend to disappear within 10 days.

CARCINOGENIC ACTION: No experimental or epidemiological evidence is available for this material.

TERATOGENESIS: No evidence reporting this effect

12. INFORMATION ON ENVIRONMENTAL IMPACT

Observe the normal environmental regulations regarding handling and treating chemical products

13. DISPOSAL INFORMATION

Dispose of in accordance with the current regulations regarding the disposal of dangerous products.

14. INFORMATION REGARDING TRANSPORT

Transport by LAND and RAIL:	No particular precautions must be taken
Transport by SEA:	No particular precautions must be taken
Transport by AIR:	No particular precautions must be taken

15. LABELING CLASSIFICATION

Indication of danger:	None	
Danger symbol	None	
Risk codes:	None	
Other indications:	STERILE	Sterilization by gamma radiation. The product must. NEVER be re-sterilized.
Precautionary information:	S47/49	Conserve in the original packaging and at temperatures below 50°C.

Sterility is guaranteed only if the original packaging is intact and has not been tampered with or damaged

16. ADDITIONAL INFORMATION

None

The information contained in this technical data sheet is the result of information that was available at the time this was written. The manufacturer assumes no responsibility for damage to persons or things derived from an improper use of the product on the basis of the information provided in this document.

Prepared by: Date:	Verified by: Date:	Approved by: Date: