

FISIOGRAFT SPOGE

1. NAME OF SUBSTANCE / PREPARATION AND COMPANY

Identification of the material

Commercial Name / Synonym FISIOGRAFT SPONGE

Identification of the manufacturer

Ghimas S.p.A.
Via Cimarosa, 85, 40033 Casalecchio di Reno (BO) – ITALY

Technical information:

Mail: laboratorio@ghimas.it

Emergency telephone number

Centro antiveleno Az. Ospedalira "Niguarda – Cà Granda" – Milano tel. +390266101029

2. POSSIBLE HAZARDS

Dangerous components: None of the component used are listed as dangerous

3. COMPOSITION / INFORMATION ON CONSTITUENTS

Description: Mixture of polylactic-co-glycolic polymers and dextran

4. FIRST AID MEASURES

Immediately remove contaminated clothing.

- Contact with the eyes:

Rinse thoroughly with abundant amount of water for at least 15 minutes.

- Contact with the skin:

Rinse thoroughly with abundant amount of soap and water.

- If swallowed:

Rinse the mouth with water if the subject is conscious. Consult with a physician.

- If inhaled:

If inhaled move the person to a well ventilated area. In If they are having trouble breathing call a physician.

5. ACTIONS IN CASE OF FIRE

Extinguish with nebulized water, carbon dioxide, powder or appropriate foam.

6. ACTIONS IN CASE OF UNINTENTIONAL RELEASE

Collect the product and dispose according the national regulation

7. HANDLING AND STORAGE

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

8. MAXIMUM EXPOSURE LIMITS AND PERSONAL PROTECTION EQUIPMENT

Personal protection:

- Use protective gloves and adequate face mask. Handling of the material should be limited as much as possible to reduce the risk of microbial contamination.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Solid
Color:	White/pink
Odor:	Odorless
Solubility in water:	Relatively insoluble
Solubility in the main organic solvents:	-
pH:	-
Density (Water = 1):	-
Vapor Pressure:	-
Temperature at which material softens	-
Flash point:	-
Lower and upper flash point in air (% by volume)	-
Temperature of autocombustion:	-
Temperature of decomposition	-

10. STABILITY AND REACTIVITY

Dangerous decomposition by-products:	None if used as prescribed
Incompatibility	None if used as prescribed

11. TOXICOLOGICAL INFORMATION

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

TOXICITY:

Poly(D,L-lactic-co-glycolic) acid

There is no evidence of chronic systemic toxicity attributed to Poly (D,L-lactic-co-glycolic) acid. However In some cases, when FISIOGRAFT sponge is implanted, localized subcutaneous hypersensitivity may appear, this tends to disappear in approximately ten days.

Occasionally, this phenomenon of edema will manifest for a longer period of time (about one additional week), usually without causing any negative effects to the final results.

The metabolic effects of Poly (D,L-lactic-co-glycolic) acid on bone growth have not yet been evaluated.

CORROSIVE IRRITANT ACTION:

- For the skin and the respiratory via:
no evidence is available for the product

- For the eyes:
no evidence is available for the product

SENSITIZING ACTION:

The products can cause sensitizing reactions that tend to disappear within ten days.

CARCINOGENIC ACTION:

No experimental or epidemiological evidence is available for this material.

MUTAGENESIS:

No experimental evidence is available for this material

TERATOGENESIS:

No evidence reporting this effect

12. ECOLOGICAL INFORMATION

Observe the normal environmental regulations regarding handling and treating chemical products. Do not disperse in the environment.

13. INFORMATION ON DISPOSAL

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

14. TRANSPORT REGULATION

The product is not classified as dangerous goods

15. REGULATORY INFORMATION

Indication of danger:	None	
Danger symbol	None	
Risk codes:	None	
Other indications:	STERILE	Sterilized by gamma radiation. The product must NEVER be re-sterilized.

16. OTHER INFORMATIONS

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.