

MATERIAL DATA SHEET

Product: Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen

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Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen are medical devices regulated according EC-Guidelines. It is not possible to apply the Material Safety Data Sheet (MSDS) questions for medical devices. The Material Data Sheet informs shortly about material properties. For detailed information please read the package insert of Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen or contact us.

1. IDENTIFICATION OF PRODUCT & MANUFACTURER

Products	Geistlich Bio-Oss® Granules Geistlich Bio-Oss® Block Geistlich Bio-Oss Pen® Geistlich Bio-Oss® Collagen
Manufacturer	Name: Geistlich Pharma AG
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2. COMPOSITION & PHYSICOCHEMICAL PROPERTIES

Geistlich Bio-Oss® is a bone substitution material, consisting of the inorganic matrix of bovine bone. It contains calcium and phosphorous, analogous to human bone. It possesses a wide-meshed system of interconnecting macro- and micropores. Due to its natural origin the porosity and crystal size are very similar to human bone.

Geistlich Bio-Oss® Collagen is made of Geistlich Bio-Oss® Spongiosa Granules with 10% collagen of porcine origin.

3. POSSIBLE HAZARDS

Health hazards

Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen are used in dental practices. The product should be handled as described in the package insert.

Possible adverse reactions are mentioned in the package insert. No risks of Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen for the dentist and assistants are known.

Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen should not be used in patients with a known allergy against collagen and in presence of infected wounds.

4. MEASURES IN CASE OF UNINTENDED DISPOSAL

none (natural material, degradable)

5. HEALTH EFFECTS & BIOCOMPATIBILITY

Health effects

Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen are used as bone substitute material for bone grafting in dental implantology and periodontology as well as in oral and maxillofacial surgery. Due to the wide interconnecting pore system and the natural crystalline structure Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen, the formation and ingrowth of new bone at the implantation site is encouraged.

Biocompatibility

Biocompatibility for Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen was assessed according to the international standard ISO 10993-1. Long-term experience with Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen show an excellent biocompatibility of the mineral bone material.

However, due to the presence of collagen (Geistlich Bio-Oss® Collagen) an inflammatory reaction is possible in rare cases.

6. STORAGE & HANDLING

Handling	The products should be handled as described in the package insert. The principles of sterile handling must be observed.
Storage	Expiry date: indicated on each package Do not use after expiry date.
Storage conditions	Storage at room temperature (15-25° C) under dry conditions.
Additional information	The contents of the vial or the blister are designed for single use only. Discard any unused material. Resterilization is not possible.
Packaging	Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen are delivered in a double sterile packaging. The product is sterile unless packaging has been opened or damaged. If the sterile packaging has been damaged, the product must not be used.
Transport	Recommended storage conditions should also be followed during transport.

7. DISPOSAL

Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen are degradable materials. The manufacturing process and sterilization minimize risks of contamination with pathogens. Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen can be disposed as ordinary waste.

8. INFORMATIONS ACCORDING TO REGULATIONS

EEC Regulations	93/42/EEC
EEC labeling	CE-Mark
FDA	510(k) Notification

The manufacturing of Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen is subjected to a quality control system based on international standards (ISO 9001:2008 / ISO 13485:2003/AC:2007), and is checked regularly by independent experts and authorities.

9. FURTHER INFORMATIONS

Please read the package insert for further information or contact us directly.