

**MATERIAL SAFETY DATA SHEET – ETHOSS®**

Issued by: QA&amp;RA

Ver.: 03

Effect. Date: 19-05-22

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**SECTION 1: IDENTIFICATION****Product Name:** EthOss®**Product Use:** Synthetic Bone Grafting Material**Manufacturer:** Medbone – Medical Devices Lda.**Address:**

Centro Empresarial Lusoworld II  
Rua Pé de Mouro, Nº 26, Linhó  
2710-335 Sintra, Portugal

**Tel.:** (+351) 210 938 956**Fax:** (+351) 211 946 681**SECTION 2: HAZARDS IDENTIFICATION****Hazard Classification:** Non-hazardous substance, Non-Dangerous goods.**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

65% Beta-Tricalcium Phosphate + 35% Calcium Sulfate

Compound	Synonyms	Formula	CAS Number
Beta-Tricalcium Phosphate	Tricalcium diphosphate	$\beta\text{-Ca}_3(\text{PO}_4)_2$	7758-87-4
Calcium Sulphate Dihydrate	Gypsum	$\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$	10101-41-4
Calcium Sulphate Hemihydrate	Gypsum hemihydrate	$\text{CaSO}_4 \cdot \frac{1}{2}\text{H}_2\text{O}$	10034-76-1

**SECTION 4: FIRST AID MEASURES****In case of eye contact:** No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.**In case of skin contact:** No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.**In case of Ingestion:** Rinse mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.**In case of Inhalation:** No special measures required. If inhaled, breathe fresh air. Get medical attention if symptoms occur.**SECTION 5: FIRE FIGHTING MEASURES**

All fire-extinguishers are suitable.

**SECTION 6: ACCIDENTAL RELEASE MEASURES****Personal precautions:** No special measures required.**Environmental precautions:** No special measures required.**Methods for cleaning up:** Pick-up with customary cleaning equipment and dispose of with domestic or organic waste.

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**SECTION 7: HANDLING AND STORAGE****Handling:** Avoid inhalation. Avoid contact with eyes, skin, and clothing.**Storage:** Store in a dry place away from excessive heat and direct sun light.**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

Appropriate clothes and footwear. Wear protective gloves. No other special measures are required for small quantities under normal and intended conditions of product use.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES****Appearance:** White powder with granules with dimensions ranging from 0.1 to 0.5 mm.**Color:** White / Ivory**Odor:** Odorless**pH:** NA**Melting Point:** 1600°C**Initial boiling point:** NA**Flash point:** NA**Evaporation point:** NA**Flammability:** NA**Lower and upper explosive (flammable) limits:** NA**Vapor pressure:** NA**Relative density:** NA**Vapor density:** NA**Water solubility:** Insoluble**Partition coefficient:** NA**Self-ignition temperature:** NA**Decomposition temperature:** NA**Viscosity:** NA**SECTION 10: STABILITY AND REACTIVITY**

The preparation is stable at the handling and storage conditions recommended per section 7 of the safety data sheet.

**SECTION 11: TOXICOLOGICAL INFORMATION****Acute toxicity:** Quantitative data on the acute toxicity of this product are not available.**Sensitization:** No data available.**Chronic exposure:** No data available.



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**Signs and symptoms of exposure:** No data available.

**Potential health effects:**

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.

**Skin:** May be harmful if absorbed through skin. May cause irritation to skin.

**Eyes:** May cause eye irritation.

**Ingestion:** May be harmful if swallowed.

### SECTION 12: ECOLOGICAL INFORMATION

Quantitative data on the ecological effects of this product are not available, however, no ecological problems are to be expected when product is handled and used with due care and attention. Avoid contamination of drains, waters and soil.

### SECTION 13: DISPOSAL CONSIDERATIONS

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company. Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

### SECTION 14: TRANSPORT INFORMATION

Not dangerous goods for road, sea, and air transport.

### SECTION 15: REGULATORY INFORMATION

Regulated as a class III medical device according to Medical Devices Directive (MDD) 93/42/EEC.

### SECTION 16: OTHER INFORMATION

This document has been compiled by Medbone Medical Devices Ltd. and serves as the manufacturer's Material Safety Data Sheet (MSDS). The information contained herein is believed to be accurate but does not purport to be all inclusive and shall be used only as a guide. The information contained 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. Final determination of suitability of any material is the sole responsibility of the user. Medbone shall not be held liable for any damage resulting from handling or from contact with the above product.

**CAUTION:** This MSDS comes in addition to the instructions for use (IFU) but it does not replace it. Use of the product for any other purpose than the one indicated in the instructions for use is at user's own risks.