

Material Safety Data Sheet

1. IDENTIFICATION OF SUBSTANCE AND COMPANY

Product information: DENTAL CUSTOM-MADE SEMIFINISHED STRUCTURES BY CAD/CAM TECHNOLOGY

Manufacturer/Supplier: PHIBO CAD/CAM, SL

Legal Address: Gato Pérez 3-9 08181 Sentmenat, Barcelona, Spain (EU)

2. COMPOSITION

Usage as: dental prostheses

User: qualified staff (e.g. dental lab technicians, dentists)

Depending on the type of restoration used, the following materials may be used for the manufacture of CAD/CAM structures: chrome-cobalt, titanium, zirconium, dental splints, e.max[®] (e.max is intended for single tooth restorations only) and PMMA (PMMA is intended for temporary restorations only). These materials are indicated for its use in the manufacture of dental restorations according to internal specifications. The chemical compositions of each material according to international specifications are described in the tables below.

These materials are biocompatible according to specifications ISO 10993-01 and ISO 7405. The biocompatibility guarantees that the product does not cause adverse or harmful effects on the human body.

CHROME COBALT

Element	Mass %
Cobalt (Co)*	56 - 66 %
Chrome (Cr)*	24 - 30 %
Molibden (Mo)*	4 - 7 %
Tungsten (W)*	0.2 - 6 %
Silicium (Si)*	< 1 %
Iron (Fe)*	< 1 %
Manganese (Mn)*	< 1 %
Niquel (Ni)	< 0.5 %
Carbon (C)	< 0.5 %
Possible traces: Al, S, P, Ti, B	< 0.1 %

TITANIUM

Element	Mass %
Nitrogen (N)	0,05 %
Carbon (C)	0,08 %
Hydrogen (H)	0,015 %
Iron (Fe)	0,25 %
Oxygen (O)	0,13 %
Aluminum (Al)	5.5 – 6.5 %
Vanadium (V)	3.5 – 4.5 %
Titanium (Ti)	The rest

ZIRCONIUM

Single Color:

Element	Mass %
Yttria-stabilised zirconium oxide: ZrO ₂ + Hf ₂ O ₃ + Y ₂ O ₃	> 99.9 %

Multilayer:

Element	Mass %
Yttria-stabilised zirconium oxide: ZrO ₂ + HfO ₂	> 90 %
Y ₂ O ₃	< 10 %

PMMA

Element	Mass %
Acrylic Copolymer based on Polymethyl Methacrylate (PMMA)	> 99.9 %

E-MAX

Element	Mass %
Nano-fluorapatite	> 99.9 %

DENTAL SPLINTS

Element	Mass %
Methacrylic Oligomers	> 90 %
Pigments	< 1 %

3. HAZARD IDENTIFICATION

By appropriate appliance and regarding the recommendations of the work hygiene it is improbable that dental restorations exhibits a health risk. In specific cases allergic reaction may occur. NFPA ratings for USA (scale 0-4):

Health = 0

Fire = 0

Reactivity = 0

4. FIRST AID MEASURES

If swallowed a doctor should be consulted.

5. FIRE FIGHTING MEASURES

The material is flammable and not oxidizing.

Toxic reaction products may occur by high temperatures.

All extinguishing agents are suitable. Favourable are sodium chloride, dry sand.

6. ACCIDENTAL RELEASE MEASURES

No personal precautions.

7. HANDLING AND STORAGE

Given the custom-made characteristics of the product, which is intended for a specific patient and it is not meant as an off-the-shelf product, no specific storage conditions are required to ensure preservation of the product.

By appropriate application no special measures for handling or storage are necessary for abutments, accessories and instruments used for the elaboration or adjustment of CAD/CAM structures.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Hand protection: if applicable use protective gloves (e.g. by known allergies against one or more alloy components).

Hygiene measures: the usual safety precautions for working with medical devices should be taken account of. During handling of CAD/CAM structures and prosthodontic procedure, do not eat, drink or smoke. Wash face and hands before and at end of work as clinical practice to prevent biological contamination.

9. PHYSICO-CHEMICAL PROPERTIES

Form: CAD/CAM structures are packed in a cardboard box labelled with traceability of the file sent by the customer electronically to be manufactured by Phibo.

Colour: silver (chrome-cobalt, titanium), white-yellowish (zirconium, PMMA), purple (e-max, it turns colour after heat treatment), blue Dental splints

Odour: odourless

Inflammable: yes

Oxidizing properties: no

10. STABILITY AND REACTIVITY

No dangerous reactions are foreseen in normal laboratory and clinical practice.

11. TOXICOLOGICAL INFORMATION

No dangerous reactions are known to occur with correct handling and storage.

12. ECOLOGICAL INFORMATION

Normally chemical substances, which accumulate as residual material, are special refuses. The removal is defined by legal waste management laws and corresponding regulations. In case of doubt contact the public authorities.

Prevent penetration into soil, water and drainage systems.

13. DISPOSAL CONSIDERATIONS

Residual material and used packaging must be disposed according to local authority regulations.

14. TRANSPORT INFORMATION

Dental alloys are no hazardous materials in the sense of transport regulations for land (RID/ADR), marine/in-land waterways (ADN/IMDG-Code) or air transport (ICAO-TI/IATA/DGR).

15. REGULATION

Semi-finished custom-made CAD/CAM structures for dental use are exempt of CE marking. Finished custom-made CAD/CAM structures for dental use are class CE IIa according to EU Medical Device Regulation (MDR).

Accessories used for design or scanning or elaboration of CAD/CAM structures are not considered to be medical devices either, except for those products that are intended to be used in the patient (for further info see MSDS PDS Material Safety Data Sheet Implant systems).

16. VIGILANCE

The described product is to be used exclusively for the intended use as described in the instructions for use. Any other use is considered as an off-label use and it is therefore not contemplated within the product guarantee plan.

CAD-CAM screwed structures are intended to be used with dental implants. Dental restorations with metal materials are not affected by magnetic fields in magnetic resonances (RMN), nevertheless it is advised to inform the technician since it may reduce the Quality of the image in areas near the mouth. For safe RMN, the following conditions are recommended to be followed: static magnetic field 1.5 and 3.0 Tesla only, gradient magnetic field of max 4000/cm (40T/m), specific absorption of full body 2 W/kg (normal level) or 4 W/kg (first level). Under described conditions, a maximum rise of 4.1° C is expected after 15 minutes of continued scanning.

The information provided in this Material Safety Data Sheet (MSDS) is correct to the best of our knowledge, information and belief at the date of its publication. They describe the product in respect of safety recommendations. The given information does not cause a legal relationship, it is designed only as guidance and is not to be considered a quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified so.

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