

Safety data sheet

according to 1907/2006/EC, Article 31

Product to be used exclusively by qualified operators (dental technicians).

It is our obligation to provide exhaustive information on the product and the risks related to it, even in case it is certified medical device. The information in this sheet refers to raw materials used for industrial production, as a consequence, considerable amounts of materials are processed and handled.

It is true that in this specific case concerning our medical devices, the amounts of material we process to manufacture a prosthesis always refer to grams. Nonetheless, for your personal safety we recommend you abide by all precautions indicated: indeed, relative risks such as thermal decomposition, contact with melted polymer or breathing of dusts are to be taken seriously, despite the little amount used.

It is an obligation of users to clean the medical device several times with hot water (around 42°C) and toothpaste, before disinfecting and sending it to the professional who ordered it.

SECTION 1:

Identification of the substance or compound and of the manufacturing company

1.1 Product identifier:

- Commercial product name: anaxCAM The Real Composite (discs and blocks in various colourings)
- Article number: 30000001- 30000083

1.2 Relevant identified uses of the substance or mixture and uses advised against

No other information available

Use of the substance / preparation Discs in various shapes for CAD/CAM technology

1.3 Information on the supplier of the safety data sheet

Details of the supplier of the safety data:

Manufacturer/Supplier:

Pressing Dental Srl

Via Onesto Scavino,4; 47891 Falciano Repubblica di San Marino,

Tel: from Italy 0549 909948 From other countries **378 909948

Tel: from Italy 0549 909958 From other countries **378 909958

Information supplied by:

Quality Assurance Manager (RAQ)

Email: info@pressing-dental.com

1.4 Emergency number: Tel: from Italy 0549 909948 From other countries **378 909948 Monday-Friday from 9.00 a.m. to 5.30 p.m.

Section 2:

Identification of hazards

2.1 Classification of the substance or compound

Classification in accordance with Regulation EC No 1272/2008 (CLP)

Non-hazardous substance or preparation in conformity with Regulation No 1272/2008 (CLP)

2.2 Elements of the label:

- Not required

2.3 Other hazards: Avoid breathing dust from the polishing and grinding process.

Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable.

Section 3:

Composition /Information on ingredients:

3.1 Chemical characterization:

PMMA-based copolymer, additives, colourants

3.1 Substances

Not applicable

3.2 Compounds

PMMA-based copolymer, additives, colourants

The product is not considered hazardous in normal use conditions and if used for the intended purposes

Remarks: as for the complete text of declarations P, see paragraph 16

Section 4: First aid measures:

4.1 Description of first-aid measures

· **Inhalation:** Dust from the finishing process: take the person involved to a ventilated place, in case of problems, consult a doctor.

· **Contact with the skin:** In general, the product is not irritant for the skin.

In case of contact with the melted polymer, cool the skin quickly with cold water, do not remove the solidified product from the skin. Consult a doctor.

· **Contact with the eyes:** Dust from the finishing process: wash with running water for several minutes, keeping the eyelids well open. If pain persists, consult a doctor.

· **Ingestion:** Dust from the finishing process:

Rinse the mouth and drink a lot of water, do not induce vomiting, consult a doctor.

4.2 Main symptoms and effects, both acute and delayed: No other information available.

4.3 Indication on the possible need to consult a doctor immediately and to carry out special treatments

No other information available.

Section 5: Fire fighting measures:

5.1 Extinguishers

Suitable extinguishers:

CO₂, powder or nebulized water. Extinguish large fires with nebulized water or with alcohol-resistant foam.

5.2 Special hazards resulting from the substance or compound:

Carbon monoxide

Carbon dioxide

5.3 Recommendations for the fire brigade

In case of fire brigade intervention: wear a breathing apparatus and protective garments

5.4 Environmental precautions

Curb and collect the water used to extinguish fire

Section 6: Measures in case of accidental release

6.1 Personal precautions, protection devices and procedures in case of emergency:

Remove all combustion sources. Avoid dust formation. Do not breathe dusts

6.2 Environmental protection

No particular measures are required.

6.3 Methods and materials for containment and remediation

Collect with mechanical means.

6.4 Reference to other sections:

For information on safe handling, see Chapter 7.

For information on protective equipment for personal use, see Chapter 8.

For information on disposal, see Chapter 13.

Section 7: Handling and storing:

7.1 Precautions for safe handling

Only properly trained staff should handle this product.

For exclusive use by dentists and dental technicians.

Hygiene measures: Do not eat, drink or smoke while using the product. Once work is finished, clean the skin carefully and use a protective cream. Do not inhale the dusts during the manufacturing phases.

Warnings for a safe use: Ensure proper ventilation and the recovery of dusts

Indications in case of fire and explosion: Keep away from flames or sparks

7.2 Conditions for safe storing, including possible incompatibilities and storage:

Requirements for warehouses and containers: Keep away from heat sources and direct light.

Keep in a dry place.

Incompatible products: No other information available

Technical measures/storage methods: No particular precautions are required

Further indications related to storage conditions:

Protect from heat and direct sunrays.

7.3 Specific final uses : No other information available.

Section 8: Control of exposure/individual protection

Further indications on the structure of technical installations: No further data, see point 7.

8.1 Control parameters

The product does not contain significant amounts of substances whose threshold values must be kept under control in working environments.

8.2 Controls of exposure

General information: Do not breathe dusts, avoid contact with the skin and with the eyes

Hygiene measures: Do not eat, drink or smoke while using the product. Once work is finished, clean the skin carefully and use a skin cream. Do not inhale dust particles during the manufacturing phases.

Respiratory protection: If handling large amounts of product, wear an anti-dust mask

Eye protection: Protective glasses

Hand protection: In general, in case of mechanical or thermal manufacturing process, wear protective gloves.

After using gloves, use detergent and some healing cream for the skin.

Wash the hands before work breaks and/or once the work is finished.

Protective mask:

In case of mechanical manufacturing:

In case of dust, take respiratory protection measures.

Filtering apparatus recommended for temporary use: Filter P1

Section 9: Physical and chemical properties:

9.1 Information on the basic physical and chemical properties

General indications

· Appearance:	
· Form:	Solid
· Colour:	In conformity with the name of the product
· Odour:	Odourless
· Olfactory threshold:	Not defined
· pH values:	Not applicable
· Change of state:	
Melting point/range:	150 °C
Boiling temperature/range:	Not defined
· Flammability point:	Not applicable.
· Flammability (solid, gaseous):	Not defined
· Lighting temperature:	
· Decomposition temperature:	Not defined
· Self-lighting:	Not self-inflammable product
· Danger of explosion:	Not explosive
· Flammability Limits:	
Lower:	Not defined
Upper:	Not defined
· Vapour tension:	Not applicable
· Density at 20 °C:	1.3 g/cm ³
· Relative density:	Not defined
· Vapour density:	Not applicable
· Evaporation rate:	Not applicable

· Solubility in/Mixability with water:	Insoluble
· Distribution coefficient (n-Octanol/water)	Not defined
· Viscosity:	
· Dynamic viscosity:	Not applicable
· Kinematic viscosity	Not applicable
· Solvent level:	
· Solid content:	100 %

· 9.2 Other information

No other information available.

Section 10: Stability and Reactivity:

10.1 Reactivity

No other information available.

10.2 Chemical stability

Stable in normal handling and storage conditions.

· Thermal decomposition / conditions to avoid:

The product does not decompose if used according to the norms.

In case of local heating above 150°C, a slow decomposition is possible.

10.3 Possibility of hazardous reactions:

No hazardous reactions are known.

10.4 Conditions to avoid:

acetone

10.5 Incompatible materials:

No other information available.

10.6 Hazardous products of decomposition:

None in normal storage and use conditions.

Section 11: Toxicological information:

11.1 Information on toxicological effects

· Acute toxicity:

· Primary irritability:

on the skin:

It has no irritant effects

on the eyes:

Not irritant

· Sensitization:

No sensitizing effects are known

· Further toxicological data:

No other information available

Section 12: Ecological information:

12.1 Toxicity

· Aquatic toxicity: No other information available.

12.2 Persistence and degradability

No other information available.

12.3 Bioaccumulation potential

No other information available.

12.4 Mobility in the soil

No other information available.

· Further indications concerning the environment

· Further indications: Generally not dangerous

12.5 Results of PBT and vPvB assessments

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

12.6 Other adverse effects

No other information available.

Section 13: Considerations on disposal

13.1 Methods for waste treatment

- **Advice:** Transport to an approved dumping site or to an incinerator, complying with the conditions approved by local authorities.
- **European Waste Catalogue**
20 01 39 plastic
- **Unclean packaging:**
- **Advice:** Disposal in conformity with administrative provisions.

Section 14: Information on carriage

14.1 UN Number

ADR, ADN, ICAO/IATA: Not regulated

14.2 UN shipping name

ADR, ADN, IMDG, IATA: Not applicable

14.3 Classes of hazard connected to carriage

ADR, ADN, IMDG, IATA: Class is not applicable

14.4 Packaging group

ADR, IMDG, IATA: Not applicable

14.5 Dangers for the environment:

Marine pollutant: No

14.6 Special precautions for users: Not applicable

14.7 Carriage of materials in bulk according to annex II of MARPOL 73/78 and the IBC code:

Not applicable.

Carriage/further indications:

Not classified as hazardous goods according to transportation regulation (ADR, IMDG, IATA).

UN „Model Regulation“

Section 15: Information on regulation

15.1 Rules and legislation on health, safety and environment, specific for the substance or compound

National provisions:

Further provisions, restrictions, and prohibitive decrees

This product is a medical device according to directive No 93/42/EC.

15.2 Assessment of chemical safety:

No assessment of chemical safety has been made.

**Section 16:
Other information:****Generic recommendations**

P 101 In case you need to contact a doctor, have at your disposal the container, the instructions for use or the label.

Precautionary Statements /prevention

P202 Do not handle the product before reading and understanding all the warnings

P210 Keep away from heat sources/sparks/open flames/heated surfaces/Do not smoke

P 260 Avoid breathing dusts/fumes/gases/fog/vapours/aerosols

P 270 Do not eat, drink or smoke while using the product

P 281 Use the individual protection device as required

P 403+P235 Store in a cool, well-ventilated place

P410 Keep in a cool place and protect from sunrays

Precautionary Statements/Reaction

P312 In case of discomfort contact a poison centre or a doctor

P301+P312 In case of ingestion and discomfort: contact a poison centre or a doctor

P332+P313 In case of skin irritation: consult a doctor

P337 +P313 If the eye irritation persists, contact a doctor

Precautionary Statements and advice on conservation

P410+P412 Protect from sunrays, do not expose to temperatures exceeding 50°C /122 F

EUH 401 – To avoid risks for human health and the environment, follow the instructions for use.

Note: Product intended only for the manufacturing of dental prostheses, it must be used only by qualified professionals (dental technicians) who have attended a training course at premises recognized by Pressing Dental. Before use, it is mandatory to read the instructions for use contained in every package, further support can be obtained by reading the technical sheets for manufacturing. The data reported here are based on our current knowledge, however, they are no guarantee for the product features and quality, and they do not justify any juridical-contractual relation.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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