

PRESSING DENTAL SRL

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Product: **F.J.P. Compound** (Resin for pressure-injection)

Int. Ref. **SHEET 01/15**

MATERIAL SAFETY DATA SHEET (MSDS)

In accordance with Regulation (EC) No 1907/2006
16/07/2015

Review N° 2-

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 identification

· **Trade name:** **F.J.P compound** (resin for dental prostheses in various colourings)

· **1.2 Relevant uses of the substance or compound identified and advised against**

No other information available

· **Use of the substance / Preparation** Compound in granules or discs

· **1.3 Information on the supplier of the safety data sheet**

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 telephone number:**

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

Monday-Friday Office hours 9-17.30

SECTION 2: Identification of hazards

2.1 Classification of the substance or compound

Classification in accordance with Regulation EC No 1272/2008

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**

High temperature: Thermal decomposition in toxic and corrosive products

Avoid breathing dusts from the milling and grinding process.

Results of the PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable

SECTION 3: Composition/Information on the ingredients

3 Chemical characterization: Vinylidene polysulphide, polyamide, polyethylene, additives, pigments

3.1 Substances: Not applicable

3.2 Compounds: Compounds of polymers, additives, colourants.

No hazardous component to be mentioned according to Regulations (EC) No. 1907/2006 and (EC) No 453/2010

The product is not considered hazardous in normal use conditions and if used for the intended purposes. It does not contain hazardous substances (SVHC) with concentrations exceeding 0.1%

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:** In case of melted polymer (vapours from thermal decomposition of the product): take the person involved to the open air and monitor his/her conditions.

In case of 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.

In case of melted polymer, 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.

Protection of rescuers: Products from thermal decomposition: in case of insufficient ventilation, use breathing equipment

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.

Unsuitable extinguishers: Abundant water jet

· **5.2 Special hazards resulting from the substance or compound:**

Hydrofluoric acid, carbon monoxide

· **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. Do not breathe dusts

· **6.2 Environmental precautions:** Do not abandon the product in the environment, do not let it penetrate the plumbing system.

· **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: Titan dioxide, silica (glass fibres), boron oxide, strong bases

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 FFP1/FFP2

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: 160-170°C

Boiling temperature/range: Not defined.

Flammability point: Not applicable.

Flammability (solid, gaseous): No data available.

Lighting temperature:

Decomposition temperature: >350°C.

Self-lighting: Not self-inflammable product.

Danger of explosion: Product is not applicable

Flammability Limits:

Lower: Not defined.

Upper: Not defined.

Vapour tension: Not applicable.

Density at 20 °C: ca. 1000 kg/cm³

Relative density: Not defined.

Vapour density: Not applicable.

Evaporation rate: Not applicable.

Solubility in/Mixability with water: Insoluble.

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.

Do not overheat the product above the melting temperature indicated in the instructions for use.

Keep the product away from heat sources or other causes of fire

10.3 Incompatible materials: Titanium dioxide, silica, strong bases, boron oxide. Risk of violent reactions with high temperatures

10.4 Possibility of hazardous reactions

Decomposition temperature: > 350°C toxic and corrosive products – Hydrofluoric acid, carbon oxides

10.5 Conditions to avoid:

10.5 Incompatible materials: Titanium dioxide, silica, strong bases, boron oxide – risk of violent reactions (decomposition)

10.6 Hazardous products of decomposition: None in normal storage and use conditions, with no prejudice for previous indications.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on toxicological effects

- **Acute toxicity:** If used properly and for intended uses no toxicological effects are known, the product is biologically inert.
 - **Inhalation:** Inhalation of vapours due to thermal decomposition of the product:
 - The inhalation of fumes resulting from decomposition by heating > 350°C may cause flu-like symptoms with fever and muscle pains.
 - **Hydrofluoric acid:** with significant concentrations of vapours: severely irritant for the airways. Risk of lung oedema. Delayed effects are possible. On rats: CL50/10 min 3,847 mg/l
 - **Ingestion:** A little noxious by ingestion
 - **At skin level:** A little noxious in case of contact with the skin
 - **Local effects (Corrosion /irritation/serious ocular lesions:**
 - **Contact with the skin:** A little or not at all irritant for the skin (caution: if handled when hot, it can cause serious burns). The products of decomposition may be irritant at high temperature
 - **Contact with the eyes:** A little or not at all irritant for the eyes
 - The products of decomposition may be irritant at high temperature
 - Respiratory and dermal sensitization:
 - No data available
 - **Contact with the skin:** No data available
 - **CMR effects:** No particular concern for man
 - Specific toxicity for target organs:
 - **Inhalation:** At high temperature, the products of thermal decomposition may be irritant for the airways
 - **Sensitization:** No sensitizing effects are known.
- Other information:
- According to our experience and the literature we were provided, the product does not cause any noxious effects if used and handled based on regulations.
- **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

<p>14.1 UN number: not classified as hazardous in accordance with (EC) No 1272/2008, directive 67/548/EC ADR: Not regulated AND: Not regulated ICAO/IATA: Not regulated</p> <p>14.2 UN shipping name ADR, ADN, IMDG, IATA: not applicable</p> <p>14.3 Classes of hazard connected to carriage ADR, ADN, IMDG, IATA: Class is not applicable</p> <p>14.4 Packaging group ADR, IMDG, IATA: not applicable</p> <p>14.5 Dangers for the environment: Marine pollutant: No</p> <p>14.6 Special precautions for users: Not applicable.</p> <p>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).</p>

SECTION 15: Information on regulation

<p>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.</p> <p>15.2 Assessment of chemical safety: The product is not considered hazardous in normal use conditions and if used for the intended purposes. It does not contain hazardous substances (SVHC)with concentrations exceeding 0.1%</p>

SECTION 16: Other information

<p>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.</p> <p>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 234+P410 Keep in a cool place and protect from sunrays</p> <p>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</p> <p>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.</p>

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.

<p>• 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)</p>
