

PRESSING DENTAL SRL

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Product: **TSM Acetal Dental (for discs injection - CAD CAM technology)**

Int. Ref. SHEET 01/15

MATERIAL SAFETY DATA SHEET (MSDS)

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

Review No 3-

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 data of the substance or compound and of the manufacturing company

1.1 Product identification

Trade name: **TSM Acetal Dental**

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

No other information available

Use of the substance / preparation Discs in various shapes for CAD CAM technology and pressure-injection

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 (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

The compound does not meet the PBT / vPvB criteria in conformity with REACH, annex XIII

SECTION 3: Composition/Information on the ingredients

Chemical characterization: Acetal polymer, additives, colourants

3.1 Substances : Not applicable

3.2 Compounds

Components: Formaldehyde No CAS 50-00-0 No - EC. 200-001-8

Components	1272/2008/EC (CLP)	Hazard definitions
Formaldehyde	Acute toxicity orally – category 3	H301

	Acute dermal toxicity – category 3 Acute toxicity by inhalation – category 3 Corrosion/skin irritation - category 1B Skin sensitization – category 1 Carcinogenicity - category 2	H311 H331 H314 H317 H351
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Remarks: as for the complete text of declarations H and 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-extinguishing measures

5.1 Extinguishers
Suitable extinguishers:
Water, foam

5.2 Special hazards resulting from the substance or compound:
Hazardous products of combustion
Carbon monoxide
Carbon dioxide
Formaldehyde vapours

5.3 Recommendations for the fire brigade
Specific protection means: No particular measures are required considering the little amount of product used.
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

5.5 Additional information: Potential hazard (explosion of dust)

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 precautions: 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. Do not smoke, potential danger (explosion of dust)

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: Strong acids, oxidizing agents, Polyvinyl chloride
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

EC threshold limit values for exposure: provisional threshold (OEK): 0.37 mg/m³

National limits of exposure: Breathable dust—TWA 3 mg/m³—Total Dust 10 mg/m³

DNELs This product is a compound, so it is not directly subject to REACH registration requirements.

PNECs This product is a compound, so it is not directly subject to REACH registration requirements.

8.2 Controls of exposure

General information: Do not breathe the 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 protective 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 case of pressure-injection or drilling, pay attention to the melted product. By way of precaution, always use gloves that resist chemical products and heat.

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

Protective mask:

In case of mechanical manufacturing:

In case of dust use respiratory protection.

Filtering apparatus recommended for temporary use: Filter P1

SECTION 9: Physical and chemical properties

9.1 Information on 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: 225 °C

Boiling temperature/range: Not defined.

Flammability point: Not applicable.

Flammability (solid, gaseous): Not defined.

Lighting temperature: 320°C

Decomposition temperature: 240°C.

Danger of explosion: Not explosive.

Flammability Limits: Not applicable.

Vapour tension: Not determined.

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 storing conditions.

- **Thermal decomposition / conditions to avoid:**
The product does not decompose if used according to the norms.
Thermal decomposition may occur above 240°C
- **10.3 Possibility of hazardous reactions:**
Polyvinyl chloride, incompatibility with strong acids and oxidizing agents.
- **10.4 Conditions to avoid**
Flame. Avoid temperatures exceeding 238°C /460°F
- **10.5 Incompatible materials:**
Polyvinyl chloride, strong acids, oxidizing agents
- **10.6 Hazardous products of decomposition: (melted product)**
Formaldehyde, Formic acid, Trioxane, Paraformaldehyde, but none of them in normal storing 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 with the exception of dust
Sensitization: No sensitizing effects are known.
Further toxicological data: No other information available.

SECTION 12: Ecological information

- 12.1 Toxicity**
- 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 Waste treatment methods**
 - **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. Continues on page No
- **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**
Hazard class for water (WGK): Not polluting for water **WGK registration No:** 766
WGK source: Classification according to the administrative Rule on noxious substances for water
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 (CSA) required.

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 / prevention statements

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 235 Keep in a cool place

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 410 Protect from sunrays

P 403+P235 Keep in a cool and ventilated place

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.

Hazard Phrases

H332	Noxious if inhaled
H317	It can cause a skin allergic reaction
H314	It causes serious burns to the skin and the eyes (in case of contact with melted polymer)
H320	It causes eye irritation
H335	It may irritate the airways

Formaldehyde	Acute toxicity orally - category 3	H301
	Acute dermal toxicity - category 3	H311
	Acute toxicity by inhalation - category 3	H331
	Corrosion/skin irritation - category 1B	H314
	Skin sensitization - category 1	H317
	Carcinogenicity - category 2	H351

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)