



SAFETY DATA SHEET

MEDENTAL PIT AND FISSURE SELF-CURE

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1. **Product Identifier:**
Product Name: PIT AND FISSURE SEALANT SELF-CURE
Trade Name: MEDENTAL
- 1.2. **Relevant identified uses of the substances or mixture and uses advised against**
Identified uses: It is intended to be applied on the pits and fissures of occlusal surfaces susceptible to developing caries.
Uses Not Recommended: Only for intended use.
Chemical Family: Self-curing methacrylate-based dental sealant resin
- 1.3. **Details of the supplier of the Safety Data Sheet**
Manufacturer: Conamco S.A. de C.V. dba MEDENTAL
José Maria Bustillos 28-Bis 1st. y 2nd. Floor
Col. Algarín
Deleg. Cuahutémoc, C.P. 06880
Ciudad de México, México.
- 1.4. **Emergency telephone number:**
Contact Person: Ma. de los Ángeles Pérez V.
email: atencionaclientes@conamcosacv.com.mx
Phone Number: 5555190508 and 5555303080
Opening hours: From Monday to Friday from 8:00am to 5:00pm.
Manufacturer: Conamco S.A. de C.V. dba MEDENTAL

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Device class/Rule: IIa
Application Standard: EU 2017/245MDR, Annex II and III

Physical hazards:

H412 Harmful to aquatic life with long lasting effects.
H410 Very toxic to aquatic life with long lasting effects.
H400 Very toxic to aquatic life.

Health hazards:

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H302 Harmful if swallowed
H318 Causes serious eye damage
H241 Heating may cause a fire or explosion.

Environmental hazards:

EUH 401 To avoid risks to human health and the environment, comply with the instructions for use.

2.2. Label elements:

Pictogram: GHS07: Skin reaction; Eye irritation, allergic skin reaction



Precautionary statements:

P103 Read carefully and follow all instructions
P260 Do not breathe dust/fume/gas/mist/vapours/spray



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P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P302+P352 If on skin: Wash with plenty of water.

P304+P340 If inhaled: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 If in Eyes: Rinse Cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: get medical advice/attention.

P501 Dispose of contents/ container in accordance with local regulations.

P280 Wear protective gloves/protective clothing/eye protection/face protection

P233 Keep container tightly closed

P314 Get medical advice/attention if you feel unwell

P330 Ask for patient to rinse his mouth immediately after treatment.

P102 Keep away the reach of children

P210 Keep away from heat or sparks

P410+P403 Protect from sunlight. Store in a well-ventilated place.

P411 Stores at temperatures between (0-25°C, 32-77°F).

Contains/Presentations:

Bottle Catalyst 3ml

Bottle Base 3ml

Bottle Base Opaque 3ml

Etch Syringe 2ml

Supplementary precautionary statements:

Fragile

Non-Sterile

No requires refrigeration

Only for professional dental use

Room temperature before use

Not requires cold chain to transport

Do not use after date of expiry

2.3. Other hazards:

Not identified

SECTION 3: Composition/Information on Ingredients

3.2. Mixtures

INGREDIENTS	%	CAS.NO.	EC No.	CLASSIFICATION
SEALANT BASE:				
Part 1				
B.H.T (Butyl Hydroxy Toluene)	<1%	128-37-0	204-881-4	H410
HEMA (2-Hidroxyethylmetacrylate)	<5%	868-77-9	212-782-2	H315; H319; H317
Triedma 100 ppm B.H.T (Triethylene Glycol Dimetacrylate)	45-55	109-16-0	203-652-6	H317
DHEPT (N, N-Bis(2-Hidroxyethyl)-p-Toluidine)	<5	3077-12-1	221-359-1	H302; H318; H317; H412
Part 2				
BIS-GMA (Bisphenol A Glycidil Methacrilate)	35-45	1565-94-2	216-367-7	----
SEALANT BASE (OPAQUE):				
Part 1				
B.H.T (Butyl Hydroxy Toluene)	<0.5	128-37-0	204-881-4	H410
HEMA (2-Hidroxyethylmetacrylate)	<5	868-77-9	212-782-2	H315; H319; H317
Triedma 100 ppm B.H.T (Triethylene Glycol Dimetacrylate)				



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DHEPT (N, N-Bis(2-Hidroxyethyl)-p-Toluidine) Part 2	45-55 <5	109-16-0 3077-12-1	203-652-6 221-359-1	H317 H302; H318; H317; H412
Aerosil 972 (Colloidal Silicium dioxide)				
Titanium Dioxide P25	<5	68611-44-9	271-893-4	----
BIS-GMA (Bisphenol A Glycidyl Methacrylate)	<5	13463-67-7	643-044-1	----
SEALANT CATALYST: Part 1	35-45	1565-94-2	216-367-7	----
B.H.T (Butyl Hydroxy Toluene)				
HEMA (2-Hidroxyethylmetacrylate)	<0.5	128-37-0	204-881-4	H410
Triedma 100 ppm B.H.T (Triethylen Glycol Dimethacrylate)	<5	868-77-9	212-782-2	H315; H319; H317
Uvinul MC-80 (methoxycinnamate de ethylhexyl)	50-60	109-16-0	203-652-6	H317
Peroxyde de Benzoyl Part 2	<0.5 <5	5466-77-3 94-36-0	226-775-7 202-327-6	---- H241; H319; H317; H400; H410
BIS-GMA (Bisphenol A Glycidyl Methacrylate)	35-45	1565-94-2	216-367-7	----

*In alignment with CLP Annex (Source: ECHA)

SECTION 4: First aid measures

4.1. Description of first aid measures

General Information:

Inhalation: In case of inhalation, clean your nose with water and seek medical assistance.

Ingestion: If accidentally swallowing induces vomit immediately and get medical attention.

Skin Contact: In case of contact with skin wash the area with soap and water.

Eye Contact: In case of contact with the eye, wash immediately with abundant water for at least 15 minutes and if the irritation persists consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

Skin Contact: Allergic rash

Eye Contact: Irritation (red eye)

Ingestion: Stomachache

Inhalation: Irritation, sensitivity

4.3. Indication of any immediate medical attention and special treatment needed.

Notes for the doctor: No specific recommendations

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media: Extinguish with the following media: Foam. Carbon dioxide or dry powder.

5.2. Special hazards arising from the substance or mixture

Specific hazards: Irritating gases or vapours

Hazardous combustion products: No known hazardous decomposition products.

5.3. Advice for firefighters

Protective actions during firefighting: Avoid breathing fire gases or vapours. Special protective equipment for firefighters: Wear a chemical protective suit.

SECTION 6: Accidental Release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions; Wear protective clothing as described in Section 8 of this safety data sheet.



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6.2. Environmental precautions:

- Do not discard in the drainage.
- Separate the components from the packaging before discarding them for recyclability.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up:

- P210 Eliminate all sources of ignition.
- P210 No smoking, sparks, flames or other sources of ignition near spillage.
- P340 Provide adequate ventilation.

6.4. Reference to other sections for waste disposal: see section 13.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Usage precautions: Not classified as dangerous good for transport.

7.2. Conditions for safe storage, including any incompatibilities:

Storage precautions:

- P402 Store in a cool, dark place
- P411 Stores at temperatures between (0-25°C, 32-77°F).
- P210 Keep away from heat, direct sunlight, sparks and open flames.
- P403 Use in a well-ventilated place.

7.3. Specific end use(s): The identified uses for this product are detailed in Section 1.2.

- Room temperature before use
- Not requires cold chain to transport

SECTION 8: Exposure Controls/Personal Protection

8.1. Exposure controls: Appropriate engineering controls provide adequate general and local exhaust ventilation.

P280 Eye/face protection the following protection should be worn: Chemical splash goggles.

P280 Hand protection: Wear protective gloves.

P280 Other skin and body protection: Wear appropriate clothing to prevent any possibility of skin contact.

P270 Hygiene measures: Do not smoke in work areas.

P264 Wash hands at the end of each work shift and before eating, smoking and using the toilet.

P352 Wash promptly with soap and water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin.

P270 When using do not eat, drink or smoke.

P340 Respiratory protection: No specific recommendations. Respiratory protection must be used if the airborne contamination exceeds the recommended occupational exposure limit.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties:

Appearance: Viscous Liquid

Colour: White to Pale Yellow

Odour: Slight Odor to Acrylate

Odour threshold: Not available.

pH: Not available

Melting point: Not available.

Initial boiling point and range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Evaporation factor: Not available.



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Upper/lower flammability or explosive limits: Not available

Other flammability: None

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility(ies): Not available.

Partition coefficient: Not available.

Auto-ignition temperature: Not available.

Decomposition Temperature: Not available.

Viscosity: Not available.

Explosive properties: None.

Oxidizing properties: None.

9.2. Other information

Other information: Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity: Not available

10.2. Chemical stability

The product is stable

10.3. Possibility of hazardous reactions

Not available

10.4. Conditions to avoid

Keep away from heat, sunlight and direct light intense

10.5. Incompatible materials

Strong Acids and oxidizing agents

10.6. Hazardous decomposition products

Monoxide and carbon dioxide, low molecular weight hydrocarbons

SECTION 11: Toxicological information

11.1 Information on the hazard classes defined in the EC Regulation 1272/2008:

Acute toxicity - Ingestion

Calculation method: Not classified.

Acute toxicity - Skin Contact

Calculation method: Not classified. No data.

Acute toxicity - Inhalation

Calculation method: Not classified. No data.

Skin corrosion/irritation

Calculation method: Not classified. Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Calculation method: Not classified. Based on available data, the classification criteria are not met.

Skin sensitization

Calculation method: May cause an allergic skin reaction.

Respiratory sensitization

Calculation method: Not classified.

Germ cell mutagenicity

Calculation method: Not classified.

Carcinogenicity

Calculation method: Not classified.



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Reproductive toxicity

Calculation method: Not classified.

Lactation

Calculation method: Not classified.

STOT - single exposure

Calculation method: Not classified.

STOT - repeated exposure

Calculation method: Not classified.

Aspiration hazard: Not classified.

Calculation method: Not applicable.

Endocrine disrupting properties: Not known.

11.2 Other information

Route(s) of entry Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2.

SECTION 12: Ecological information

Environmental Risk: WGK1

12.1 Toxicity:

Toxicity - Aquatic invertebrates: Not classified.

Toxicity - Fish: Not classified.

Toxicity - Algae: Not classified.

Toxicity - Sediment Compartment: Not classified.

Toxicity - Terrestrial Compartment: Not classified.

12.2 Persistence and degradability: Not known.

12.3 Bio accumulative potential: Not known.

12.4 Mobility in soil: Not known.

12.5 Results of PBT and vPvB assessment: This product does not contain any substances classified as PBT or vPvB.

12.6 Endocrine disrupting properties: Not known.

12.7 Other adverse effects: Not know

Primary Package: PP5

Secondary Package: PAP21

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/ regional/ national/ international regulations.

Must not be disposed of together with household garbage. Dispose of a suitable refuse site. Do not allow to enter drains, sewers or watercourses. Empty containers may retain some product residues and hence be potentially hazardous.

13.2 Additional Information

New, clean nitrile gloves should be worn.

1. Removal of excess. Fresh (before complete setting): Remove with a probe or spatula. Recommends cleaning immediately. Setting: Using cement chisels, curettes or metal excavators with controlled movements, pass waxed dental floss in interproximal areas, pulling downwards to avoid fracturing restorations.

2. Removal under restorations or crowns: It is not possible to remove it without removing the restoration; in these cases, the crown must be sectioned with a carbide/diamon bur and the tooth cleaned manually or with ultrasound.

*In both cases, it is recommended to protect soft tissues, work with good lighting, and use a magnifying glass to identify cement residues.

3. Dispose of with solid waste in accordance with the regulations of each country.



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SECTION 14: Transport information

General: The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID)

14.1. UN number: Not applicable.

14.2. UN proper shipping name: Not applicable.

14.3. Transport hazard class(es): Not applicable.

14.4. Packing group: Not applicable.

14.5. Environmental hazards: Environmentally hazardous substance/marine pollutant: None

14.6. Special precautions for user: Not Applicable

14.7. Maritime bulk transport according to OMI Instruments: Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

Regulation (EU) 2020/878; Regulation EU 2025/40 (PPWR)

15.2. Chemical safety assessment:

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to: Regulation (EU) 2020/878.

Ensure operatives are trained to minimize exposure: Only trained personnel should use this material.

Revision: 02 to complies Regulation (EU) 2020/878

Revision date: 30/JAN//2026

Version: 01

Replaces: Version 00

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