TECHNICAL DATA SHEET ACRYLIC HEAT POLYMERIZED DPFTPT-068

1. GENERALITIES OF THE PRODUCT

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Polymers of methacrylate have become very popular in dentistry because of their easily processing capacity with relatively simple techniques. They have proved to provide the essential properties and the necessary characteristics to be used in oral restorations.

One of their main applications is for total and removable prosthesis, and metallic structures like cap dental, bolts dental that re-establish the patient's chewing, phonetic and aesthetic functions.

These prosthesis are made of artificial teeth that are placed on an acrylic base that constitutes a support to maintain contact with oral tissues. Denture bases and provisional teeth can be made of heatpolymerized acrylic that needs thermal energy to polymerize under the influence of a thermostatic water bath. These resins have some advantages such as dimensional stability, easily handling features, color, and compatibility with oral tissues.

2. INFORMATION ABOUT COMPOSITION

Polymer components: Heat-polymerized Acrylic (Type I). Poly (methylmethacrylate). Pigments. Polyester (If a veined reference is required).

Monomer components: Heat-polymerized Monomer (Type I). Methyl Methacrylate. Ethylene Glycol Dimethacrylate.

3. PROPERTIES OF THE PRODUCT

Physical properties of polymers are measured in New Stetic's Quality Control Laboratory by means of well-gauged high specialized equipment, according to ISO Standard 20795-1.

The most relevant physical properties of Heat-polymerized polymers are showed in the following chart:

| Parameters | Requirements | Experimental results |
|--------------------------|--|----------------------|
| Absorption | Not higher than 32 µg/mm ³ | 20.71 |
| Solubility | Not higher than 1.6 µg/mm ³ | 0.50 |
| Flexure strength | 65 MPa minimum | 74.39 |
| Flexural modulus | 2000 MPa minimum | 2248 |
| Residual monomer content | 2.2% maximum (in weight) | 1.00 |

Other physical properties like color, polishing capacity, translucency, and porosity are evaluated qualitatively. These properties are inside accepted limits.

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4. USES AND APPLICATIONS

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Heat-polymerized Veracril®, Opti-cril®. The composition of Heat-polymerized (polymer and monomer) is the one that is used for the making of total or partial denture bases, removable prosthesis, aesthetic plates, templates (guides for implant placement) and bruxism plates.

The main characteristics of these heat-polymerized acrylic are the following:

- Heat-polymerized acrylics can be molded in complex forms by applying heat and pressure. These two aspects are specifically required for dental use resins.
- They have the essential capacities and the necessary properties to be used in the oral cavity.
- They are easy to manipulate.
- They have enough translucency to give the natural appearance of replaced tissues.
- They do not change their color or their pigmentation through time, even if they are subjected to body temperature.

5. QUALITY ASSURANCE OF THE PRODUCT

Acrylic resins are made from the highest quality raw materials through a completely standardized production process which conforms to both ISO Standard 9001 and ISO Standar 13485.

Moreover, in its Quality Control Laboratory, New Stetic verifies the fulfilling of ISO Standard 20795-1 concerning the quality requisites for the finished product, using specialized equipment. The most representative are:

Water absorption and solubility: The amount of water that can be absorbed by acrylic resins or the amount of weight that they lose when submerged in water is accurately tested. Acrylic is not soluble in saliva or in any other oral fluid.

*Porosity:*The surface of processed acrylics is free from imperfections and porosity.

Flexural Strength and Flexural Modulus : The degree of distortion suffered by acrylic resins under the occlusion forces that are applied during the use is verified in an Instron Testing Machine. The force supported by a resin until its fracture is also measured. This aspect ensures the good clinical performance of resins.

Translucency: An object placed at the opposite side of the test tube containing acrylic resin must be visible.

Residual Monomer Content: The amount of monomer that remains after the making of a prosthesis must be minimum in order to avoid possible irritations of oral tissues.

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6. INSTRUCTIONS FOR USE

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Heat-polymerized acrylic: Veracril®, Opti-cril® Heat-polymerized Monomer must be mixed only with the Heat-polymerized Polymer. Polymerization occurs by using a heat- polymerized method.

6.1 Conventional technique

Acrylic Mixture Ratios: Weight ratio: Two parts of Heat-polymerized Polymer + One part of Heat- polymerized Monomer.

Volume ratio: Three parts of Heat-polymerized Polymer + One part of Heat-polymerized Monomer.

Preparation of Acrylic Dough:

- The acrylic dough is prepared in an adequate container (a dappen dish or a glass, silicon, or porcelain container).
- The polymer is poured over the monomer in the indicated ratios. The mixing is continually made crosswise during 30 seconds approximately in order to ensure the complete incorporation of polymer and monomer particles.
- Put a lid on the container for avoiding the entrance of air until the acrylic dough reaches its plastic phase (i.e. when the mixture does not adhere to the spatula or to the walls of container).
- Finally, proceed to make the packaging of the flask.

Pressing

- The heat-curing material is packaged in the flask, with a polyethylene sheet between the heatcuring resin and the impression model.
- Apply a slow pressure of 1500 psi. Take out material from the press. Open the flask to remove the polyethylene sheet and cut out the acrylic excess with a spatula. Close the flask again and apply a definite 2000 psi pressure to the flask, in order to ensure a non-altered vertical dimension.

Polymerization: Follow the steps described in the chart below.

| STEP | TEMPERATURE (°C) | TIME (min) | MEDIUM |
|------|------------------|------------|--------|
| 1 | 73 | 90 | water |
| 2 | 100 | 30 | water |
| 3 | 23 | 30 | Air |
| 4 | 23 | 15 | water |

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Work Time: This mixture allows a work time of 10 minutes approximately, taking into account the room temperature of the site.

6.2 Microwave Technique

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The indicated microwave polymerization oven must have the following characteristics:

- Any oven having a minimum power of 900 watts and a maximum power of 1350 watts.
- Programmable power with increases of 10 percent.
- It must have a programmable chronometer in minutes and Turntable.

The flask for microwavable acrylic must have the following characteristics:

- It must not be made of metal.
- Must be recommended by the manufacturer for use in microwave.

Acrylic Mixture Ratios:

- Weight ratio:

Two parts of Heat-polymerized Polymer OPTI-CRYL® + One part of Heat-polymerized OPTI-CRYL® Monomer.

- Volume ratio: Three parts of Heat-polymerized Polymer OPTI-CRYL® + One part of Heat-polymerized OPTI-CRYL® Monomer.

Wax elimination: Eliminate the wax with the traditional system or using the Microwave oven. To eliminate any wax excess with the microwave oven, place cotton moistened with water on the wax; tighten the flask and place it in the oven for one (1) minutes at maximum power.

Remove the flask, extract the cotton and check that there is no wax left on the surfaces. If necessary, finish the wax elimination with hot water and a detergent using the conventional method. Apply a thin coat of separator on the stone surfaces with the hot flask avoiding any excess.

Preparation of Acrylic Dough:

- Use the measures of OPTI-CRYL® (powder) and one measure of OPTI-CRYL®, (liquid) monomer, measured by volume.

- Pour the monomer in a glass or porcelain container and add the polymer; mix with a spatula for 30 seconds in a transversal way to avoid any air inclusion.

- Cover the container until the mix achieves its fibrous or filamentous state (approximately 3 minutes).

Pressing

- Place the mix in plastic state into the flask.

- Cover the mix with a polyethylene film and close the flask.

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- Press slowly at 1500 psi maximum.

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- Unload the press, open the flask, and remove the polyethylene fil, removing any acrylic excess with a spatula.

- Again, close the flask and apply a final pressure of 2000 psi maximum and place the locking screw of the flask.

NOTES:

- It is not necessary to reach a pressure of 1500 and 2000 psi. If the flask adjusted completely at a lower pressure, then do not apply more load.
- If your lab does not have a press with gauge, close the flask with enough pressure to allow the evacuation of excess acrylic material, avoid excessive forces that can damage the flask. This closure can be performed by 2 or 3 times until no residues of acrylic observe.

Polymerization in microwave oven:

Place the muffle in the oven, with screws facing down. Set the time to 4 minutes power level according to the following table and press start.

| MAXIMUM POWER OVEN (WATTS) | POWER (%) |
|----------------------------|-----------|
| 900 -1100 | 100 |
| 1100 -1250 | 90 |
| 1250-1350 | 80 |

NOTE: Remove the flask from the oven and let it rest at room temperature before opening. Avoid cooling the hot flask in cold water.

7. COMMERCIAL PRESENTATIONS

Veracril®, Heat- polymerized Powder:

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- POLYETHYLENE BOTTLES: 30 g bottle, 40 g bottle; 60 g bottle (Box per 200 bottles); 125 g bottle (Box per 100 boxes); 250 g bottle (Box per 40 bottles); 500 g bottle (Box per 50 bottles); 1000 g bottle (Box per 15 bottles); 2,5 kg. Wide variety of veined and smooth pink shades.
- POLYETHYLENE DRUM of heat- polymerized acrylic powder per 10 kg, 20kg, 25 kg (unit).
- POLYETHYLENE BAG of heat polymerized acrylic powder per 20 kg, box double wall reinforced (unit).
- METALLIC DRUM of heat-polymerized acrylic powder per 125 kg (unit).

KIT: Cardboard Box with a 1000 g bottle of powder acrylic and 500 ml of liquid acrylic (12 KIT). KT: Cardboard Box with a 500 g bottle of powder acrylic and 250 ml of liquid acrylic (24 KIT). KIT: Cardboard Box with a 250 g bottle of powder acrylic and 110 ml of liquid acrylic.

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KIT: Cardboard Box with a 125 g bottle of powder acrylic and 110 ml of liquid acrylic. KIT: Cardboard Box with a 60 g bottle of powder acrylic and 55 ml of liquid acrylic (36 KIT). KIT: Cardboard Box with a 30 g bottle of powder acrylic and 15 ml of liquid acrylic.

Veracril®, Heat- polymerized Liquid:

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- AMBER GLASS BOTTLES: 15 ml, 30 ml, 55 ml bottle (Box per 150 bottles); 110 ml bottle (Box per 100 bottles); 250 ml bottle (Box per 50 bottles); 500 ml bottle (Box per 25 bottles); 1000 ml bottle (Box per 12 bottles).
- METALLIC DRUM of heat polymerized acrylic liquid per 200 L (unit).
- POLYETHYLENE DRUM of heat polymerized acrylic liquid per 1 gallon (Box per 4 unit).

KIT: Cardboard Box with a 1000 g bottle of powder acrylic and 500 ml of liquid acrylic (12 KIT). KT: Cardboard Box with a 500 g bottle of powder acrylic and 250 ml of liquid acrylic (24 KIT). KIT: Cardboard Box with a 250 g bottle of powder acrylic and 110 ml of liquid acrylic. KIT: Cardboard Box with a 125 g bottle of powder acrylic and 110 ml of liquid acrylic. KIT: Cardboard Box with a 60 g bottle of powder acrylic and 55 ml of liquid acrylic (36 KIT). KIT: Cardboard Box with a 30 g bottle of powder acrylic and 15 ml of liquid acrylic

8. EXPIRATION DATE

Veracril®, Opti-cryl® heat - polymerized powder: Four (4) years. Veracril®, Opti-cryl® heat - polymerized acrylic liquid: Two (2) years.

9. STORAGE AND CONSERVATION MEASURES

- Keep this product in a cool and well-ventilated place (air in or around such place).
- Keep it away from any flame or spark source. Do not smoke.
- Keep it away from heat and direct sunlight.
- Avoid contact with oxidants, acids, bases, and polymer initiators.
- Do not store for long periods of time after the expiration date.

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