Address: Cra. 53 N° 50-09 Guarne (Antioquia) COLOMBIA. Telephones: (57-60-4) 550 00 00 - 403 87 60 Fax: (57-60-4) 551 31 34 infocolombia@newstetic.com

TECHNICAL DATA SHEET HEAT-CURING ACRYLIC RESIN NOVACRYL® DPFTPT-070

1 GENERALITIES OF THE PRODUCT

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.

Novacryl® is a heat-curing moldable resin used for the fabrication of provisional restorations as crowns and bridges, offering a wide variety of colors that are adapted to the physiognomy of each patient.

The product needs thermal energy to polymerize under the influence of a thermostatic water bath. This resin has advantages such as dimensional stability, easily handling features, color, and compatibility with oral tissues.

2 INFORMATION ABOUT COMPOSITION

2.1 Components of polymer (type I):

Polymethyl methacrylate. Pigments. Fluorescent additive.

2.2 Components of monomer (type I):

Methyl methacrylate. Ethylene glycol dimethacrylate.

3 PROPERTIES OF THE PRODUCT

Physical properties are measured in quality control laboratory by means of specialized equipment according to ISO standard 20795-1 for Denture Base Polymers. The most relevant physical properties are showed in the following chart.

Parameter	Requirement	Average experimental results
Water absorption	32 µg/mm ³ maximum	25.36
Solubility in water	1.6 µg/mm ³ maximum	0.21
Flexural strength	65 MPa minimum	68.68
Flexural modulus	2000 MPa minimum	2133.62
Residual monomer	2.2% (w/w) maximum	0.86

Other physical properties like color, packing plasticity, 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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Novacryl® is used for the fabrication of provisional restorations as crowns and bridges, offering a wide variety of colors that are adapted to the physiognomy of each patient. The main characteristics which allow these are the following:

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

5 QUALITY ASSURANCE OF THE PRODUCT

The product is made of high quality raw materials through a completely standardized production process which conforms to standard ISO 13485.

Moreover, in the quality control laboratory the requirements of ISO Standard 20795-1 are checked for the finished product using specialized equipment. The most representative tests are listed below:

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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First, the dentist makes an impression of the patient's oral cavity. The technologist, in the dental rehabilitation laboratory, fabricates the provisional teeth according to the patient's dental model. The technologist prepares the acrylic mass with a combination of acrylic resin polymer and monomer, then it is packaged and pressed, the mixture is polymerized according to the specific technique, and finally polished to a shiny surface. For more information refer to the instruction for use.

7 COMMERCIAL PRESENTATIONS

Polymer:

- Polyethylene bottles: 30, 40 and 60 g (box per 196 bottles); 125 g (box per 100 bottles); 250 g (box per 30 bottles); 500 g (box per 24 bottles); 1000 g (box per 15 bottles); and 2.5 kg. Wide variety of veined and smooth pink shades.
- Polyethylene drum: 10, 20 and 25 kg.
- Metallic drum: 125 kg.

Monomer:

- Amber glass bottles: 15, 30 and 55 ml (box per 150 bottles); 110 ml (box per 100 bottles); 250 ml (box per 50 bottles); 500 ml (box per 25 bottles); and 1000 ml (box per 12 bottles).
- Metallic drum per 200 L.
- Polyethylene drum per 1 gallon (4 unit).

Kits:

- Cardboard box with 1000 g of powder acrylic and 500 ml of liquid acrylic (12 kit).
- Cardboard box with 500 g of powder acrylic and 250 ml of liquid acrylic (24 Kit).
- Cardboard box with 250 g of powder acrylic and 110 ml of liquid acrylic.
- Cardboard box with 125 g of powder acrylic and 110 ml of liquid acrylic.
- Cardboard box with 60 g of powder acrylic and 55 ml of liquid acrylic (36 Kit).
- Cardboard box with 30 g of powder acrylic and 15 ml of liquid acrylic.

8 STORAGE AND PRESERVATION CONDITIONS

- Keep the product at a temperature not exceeding 30 °C.
- Keep it away from any flame or spark source, heat and direct sunlight.
- Do not smoke.
- Avoid contact with oxidants, acids, bases, and polymer initiators.

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