Fax: (574) 551 31 34

TECHNICAL DATA SHEET HIGH IMPACT HEAT-CURING ACRYLIC RESIN DPFTPT-011

1 GENERALITIES OF THE PRODUCT

One of its principal applications is for total or removable prosthesis to rehabilitate the masticatory, phonetic, and esthetic functions.

Prosthesis is composed of artificial teeth placed on an acrylic base as a support to keep the contact with the oral tissue. Denture bases can be made using heat-curing acrylics that require thermal energy to polymerize using a thermostatic water bath. These resins present advantages such as dimensional stability, handling features, color and biocompatibility with the oral tissues.

High impact acrylic is a product that presents an upgrade in the mechanical properties of the denture bases, particularly the resistance to high impact, due to the development of the formulation which incorporates several monomers to produce a copolymer. This product can be processed under the same techniques as the conventional acrylic, keeping the standard quality characteristics according to ISO 20795-1.

Impact resistance is the energy required to fracture a material under the impact force. The impact is related to the reaction of the stationary object to the collision against a moving object. An impact can be a blow from an external object, or the falling of the prosthesis when it is hit to a hard surface.

2 INFORMATION ABOUT COMPOSITION

- Polymer components: High impact heat-curing acrylic:
- Copolymer with polymethyl-methacrylate.
- Pigments.
- Polyester (If veined references are needed)
- Additives.
- Heat-curing monomer components (Type I):
- Methyl methacrylate.
- Ethylene glycol dimethacrylate.

3 PROPERTIES OF THE PRODUCT

The physical properties of the polymers are measured in the Quality Control laboratory, through the use of specialized and calibrated equipment, based on the ISO 20795 standard for finished product. The most relevant physical properties are shown in the following table.

Parameter	Requirement	Experimental Results (Average)
Maximum stress intensity factor	1,9 MPa m ^{1/2} minimum	2,6
Total fracture work	900 J/m ² minimum	1088

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Parameter	Requirement	Experimental Results (Average)
Absorption	It must not exceed not exceed 32 µg / mm ³	25.36
Solubility	It must not exceed not exceed 1,6 µg / mm ³	0,21
Flexural strength	65 MPa minimum	68.68
Flexural modulus	2000 MPa minimum	2133.62
Residual monomer	2,2% in weight	0.86

Other properties are qualitatively evaluated such as: color, color stability, polishing capacity, translucency, porosity and are within the acceptance limits.

4 USE AND APPLICATIONS

The compositions of High Impact Heat-curing Acrylic Resins (polymer and monomer) Veracril®, Opticryl®, GoodFit® and Super-C are indicated for the preparation of total and partial dentures and removable prostheses. Their characteristics are:

- High Impact Heat-curing Acrylics have the ability to be molded into complex shapes with the application of heat and pressure.
- Provides the essential capabilities and features necessary to use them in the oral cavity.
- Easy to manipulate.
- Show enough translucencies to impart the natural appearance of the oral tissues replaced.
- They do not show color changes or pigmentation over time neither being subjected under body temperatures.
- It is recommended for patients with mental disorders that require dental rehabilitation.

5 QUALITY ASSURANCE OF THE PRODUCT

Acrylic resins are manufactured with high quality raw materials and through a process production standardized and certified under ISO 9001 and ISO 13485. In addition, in the laboratory of Quality Control verifies compliance with the requirements of ISO 20795-1 for finished product, through specialized teams.

 Water absorption and solubility: Check the amount of water absorbed by acrylic resins or the amount of weight they lose when submerged in water. Acrylic is insoluble in saliva or in any other oral fluid.

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- Porosity: The processed acrylic presents a surface free of imperfections and porosities.
- Flexural strength and flexural modulus: It measures the degree of deformation of resins acrylics to be able to withstand the occlusal forces exerted at the time of use, additionally it measures the force that a resin supports until fracturing, which guarantees its good clinical performance.
- **Translucency:** An object on the opposite side of the acrylic specimen should be visible.
- Residual monomer: The monomer content that may remain during the elaboration of the prosthesis must be minimal to guarantee the absence of irritations in the oral tissues.
- Impact resistance: Measures the energy required to fracture the acrylic resin under force impact. The impact is related to the reaction of a stationary object to the collision against a moving object. An impact can be a blow from an external object, or the falling of the prosthesis when it is hit to a hard surface.

INSTRUCTIONS FOR USE 6

High Impact Heat Acrylic Resin Veracril®, Opticryl®, GoodFit® and Super-C®:

- High Impact Heat-curing Acrylic Veracril®, GoodFit® and Super-C® must be used with the heat-curing Monomer Veracril® and polymerized to heat.
- High Impact heat-curing Acrylic Opticryl® must be used with the heat-curing Monomer Opticryl® and polymerized to heat.
- **6.1 Proportions:** The mixing ratio is:
 - By weight: Two parts of polymer and one part of monomer (heat-curing).
 - By volume: Three parts of polymer and one part of monomer (heat-curing).
- **6.2 Mixture preparation:** Prepare the mixture in a suitable container (Dappen dish, glass container, porcelain or silicone container). Pour the monomer into the container and then pour the polymer in the indicated proportions. Mix for approximately 30 seconds to make sure that the polymer particles are completely incorporated with the monomer. Cover the container to avoid air inclusion until the mixture reaches the plastic stage (when the mixture does not stick to the spatula or to the container's walls). Finally, proceed to pack the dental flask.
- **6.3 Pressing:** Pack the material in the dental flask previously elaborated and places a polyethylene sheet between the resin and the impression model. Press slowly with 1500 psi, remove the press, open up the dental flask to remove the polyethylene sheet and proceed to cut off the surplus with the help of a spatula, close the dental flask again and apply pressure of 2000 psi to ensure a vertical dimension without alterations.
- **6.4 Working time:** The mixture allows a working time of approximately 10 minutes considering room temperature.

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6.5 *Polymerization* thermostat bath: Follow the steps of the chart below.

Steps	Temperature (°C)	Time (min)	Means
1	73	90	Water
2	100	30	Water
3	23	30	Air
4	23	15	Water

6.6 Polishing: Polishing is performed according to the techniques and procedures of the dental laboratory.

7 COMMERCIAL PRESENTATIONS

Heat-curing High Impact Veracril®, Opticryl®, Good Fit ® and Super-C® (only for export) in colors: VR1 Veined and B Veined (in Colombia) and Original (in Colombia and Export). MEXICO: Opticryl brand - Original color.

Package:

Individual presentations:

- HDPE plastic pots: 30 g, 40 g, 60 g, 125 g, 250 g, 500 g, 1000 g, 2.5kg y 10kg (for USA 1 lb, 5 lb, 22 lb, 44 lb y 55lb)
- HDPE plastic drum (20kg y 25kg).
- Plastic bag of polyethylene (20kg y 25kg) in cardboard box reinforced with double walls.
- Metallic drum (125kg).

Kits presentations:

- 1000 g + 500 ml
- 500 g + 250 ml
- 250 g + 110 ml
- 125 g + 110 ml
- 60 g + 55 ml
- 30 g + 15 ml
- MSVC (30 g + 15 ml)

Packing: Cardboard boxes on pallets protected with plastic films.

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8 **EXPIRATION DATE**

The lifetime of Veracril®, Opticryl®, GoodFit® and Super-C® High Impact Heat-curing Acrylic Resin is four (4) years.

9 STORAGE AND PRESERVATION CONDITIONS

- Keep the product in a cool and well-ventilated place.
- Keep it away from all flames or sources of spark.
- Keep it away from heat and direct sunlight.
- Do not smoke.
- Store away from oxidants, acids, bases and polymerization initiators.
- Do not store for long periods of time beyond its expiration date.

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