



TECHNICAL DATA SHEET
VERACRIL®, OPTI-CRYL® HEAT-CURING ACRYLIC
DPFTPT-068

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.

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 heat-polymerized 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 (type I):
Polymethyl methacrylate
Pigments
Polyester fibers (if a veined reference is required)
- Monomer components (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	22.64
Solubility	Not higher than 1.6 µg/mm ³	0.48
Flexure strength	65 MPa minimum	73.29
Flexural modulus	2000 MPa minimum	2277
Residual monomer content	2.2% maximum (in weight)	0.71

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

Creation date		Elaborated by:		Revised by:	
2010-01-19		Stability Analyst of Medical Devices		Technical Coordinator of Medical Devices	
Class	Page	Approved by:		Update:	Version
E	1 of 4	Technical Director of Medical Devices		2022-08-21	08



TECHNICAL DATA SHEET
VERACRIL®, OPTI-CRYL® HEAT-CURING ACRYLIC
DPFTPT-068

4. USE AND APPLICATIONS

The Veracril® - Opti-cryl acrylic resin is the one that is used for the making of total or partial denture bases, removable prosthesis, aesthetic plates, guides for implant placement, bruxism plates and characterization of prosthesis. The main characteristics of these heat-polymerized acrylic are the following:

- These acrylic resins 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.
- By using the indicated polymer to monomer ratio, vertical contraction and linear shrinkage of the acrylic structure are avoided.

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.

6. INSTRUCTIONS FOR USE

- The acrylic dough is prepared in an adequate container (a dappen dish or a glass, silicon, or porcelain container).

Creation date		Elaborated by:		Revised by:	
2010-01-19		Stability Analyst of Medical Devices		Technical Coordinator of Medical Devices	
Class	Page	Approved by:		Update:	Version
E	2 of 4	Technical Director of Medical Devices		2022-08-21	08



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
VERACRIL®, OPTI-CRYL® HEAT-CURING ACRYLIC
DPFTPT-068

- 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 (when the mixture does not adhere to the spatula or to the walls of container).
- Finally, proceed to make the packaging of the flask and press.

The dental professional is directly responsible for the diagnosis and treatment generated to the patient for the proper use of the product. The dental laboratory is directly responsible for the correct use of the product to prepare the denture bases for the different types of rehabilitation. See more information in the instructions for use of the product.

7. COMMERCIAL PRESENTATIONS

Polymer:

30, 40, 60, 125, 250, 500 and 1000 g; 2.5, 10, 20, 25 and 125 kg; 1, 5, 22, 44 and 55 lb.

Monomer:

15, 30, 55, 110, 250, 500 and 1000 ml; 1 gallon, 200 l; 8 and 32 oz.

Kits:

1000 g + 500 ml
500 g + 250 ml
250 g + 110 ml
125 g + 110 ml
60 g + 55 ml
30 g + 15 ml
4 bottles per 40 g each + 2 bottles per 55 ml each
8 bottles per 40 each + 2 bottles per 55 ml each

Characterization kit:

8 bottles per 40 g each

8. STORAGE AND PRESERVATION CONDITIONS

- Keep the product in a cool and well-ventilated place, away from any flame or spark source, heat and direct sunlight.
- Do not smoke.

Creation date		Elaborated by:		Revised by:	
2010-01-19		Stability Analyst of Medical Devices		Technical Coordinator of Medical Devices	
Class	Page	Approved by:		Update:	Version
E	3 of 4	Technical Director of Medical Devices		2022-08-21	08

REFERENCE DOCUMENT: DPDDPR-019
UPDATE: 2021-11-12
VERSION: 02



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
VERACRIL®, OPTI-CRYL® HEAT-CURING ACRYLIC
DPFTPT-068

- Avoid contact with oxidants, acids, bases, and polymer initiators.
- Do not store at temperatures above 30 °C (86 °F).

Creation date		Elaborated by:	Revised by:	
2010-01-19		Stability Analyst of Medical Devices	Technical Coordinator of Medical Devices	
Class	Page	Approved by:	Update:	Version
E	4 of 4	Technical Director of Medical Devices	2022-08-21	08

REFERENCE DOCUMENT: DPDDPR-019
UPDATE: 2021-11-12
VERSION: 02