TECHNICAL DATA SHEET ACRYLIC POLYMER SELF POLYMERIZED NOVACRYL® DPFTPT-056

1. GENERAL PRODUCT INFORMATION

new stetic

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.

SELF-POLYMERIZED NOVACRYIL®: The composition of Self-polymerized (polymer and monomer) is the one that is used to repair provisional teeth, crowns and bridges, which is chemically activated by the addition of a tertiary amine to the liquid component. In this case, the use of thermal energy is not necessary.

2. INFORMATION ABOUT CHEMICAL COMPOSITION OF THIS PRODUCT

- 2.1. POLYMER COMPONENTS: Self-polymerized Acrylic (Type II) Poly (methylmethacrylate). Pigments.
- 2.2. MONOMER COMPONENTS: Self-polymerized Monomer (Type II). Methyl Methacrylate. Ethylene Glycol Dimethacrylate. Chemical initiator (Amine type).

3. PHYSICAL PROPERTIES

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

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

Creation date		Elaborated by:	Revised by:		
2011-01-14		Technical Analyst of Medical Devices	Technical Coordinator of Medical Device		
Class	Page	Approved by:	Update: Versio		
E	1 of 6	Technical Director of Medical Devices	2018-08-13	03	
REFERENCE DOCUMENT: DPDDPR-019					
VERSION: 00					

Telepho TECHNICAL DATA SHEET ACRYLIC POLYMER SELF POLYMERIZED NOVACRYL® DPFTPT-056

Parameters	Requirements	Experimental results	
Absorption	Not higher than 32 µg/mm ³	19.50	
Solubility	Not higher than 8.0 µg/mm ³	5	
Flexure Strength	60 MPa minimum	65.4	
Flexural Modulus	1500 MPa minimum	1700	
Residual Monomer Content	4.5% maximum (in weight)	1.45	

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

4. USAGE AND APPLICATIONS

The composition of Self-polymerized Novacryl®, (polymer and monomer) is the one that is used to repair provisional teeth, crowns and bridges.

The main characteristics of self-polymerized are the following:

- The period of time required for the repairing of different acrylic structures. This product allows an optimum working time for its manipulation.
- It does not require heat treatment for its polymerization process.
- It allows an easy polishing to recover its gloss.
- The polymer-monomer ratio is used as indicated, in order to avoid the possible vertical and linear contractions of the acrylic structure.

5. QUALITY ASSURANCE OF THIS 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 13485.

Moreover, in its Quality Control Laboratory, New Stetic verifies the fulfilling of ISO Standard 20795-1 Denture Base Polymers concerning the quality requisites for the finished product, using specialized equipment.

The most representative machines used for quality control are the following:

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

Creation date		Elaborated by:	Revised by:		
2011-01-14		Technical Analyst of Medical Devices	Technical Coordinator of Medical Device		
Class	Page	Approved by:	Update:	Version	
E	2 of 6	Technical Director of Medical Devices	2018-08-13	03	
REFERENCE DOCUMENT: DPDDPR-019					
/ERSION: 00					

TECHNICAL DATA SHEET ACRYLIC POLYMER SELF POLYMERIZED NOVACRYL® DPFTPT-056

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

new stetic

Self-polymerized acrylic Novacryl® Monomer must be mixed only with the Selfpolymerized Novacryl® Polymer for preparing the acrylic used in repair provisional teeth, crowns and bridges, according to the current procedures and techniques in practice in dental laboratories or dental practice.

Acrylic Mixture Ratios:

Weight ratio: Two parts of Self- polymerized Polymer + One part of Self-polymerized Monomer.

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

Creation date		Elaborated by:	Revised by:		
2011-01-14		Technical Analyst of Medical Devices	Technical Coordinator of Medical Devices		
Class	Page	Approved by:	Update:	Version	
E	3 of 6	Technical Director of Medical Devices	2018-08-13	03	
REFERENCE DOCUMENT: DPDDPR-019					

VERSION: 00

Telepho TECHNICAL DATA SHEET ACRYLIC POLYMER SELF POLYMERIZED NOVACRYL® DPFTPT-056

Put a lid on the co Cover the container to avoid the inclusion of air until the mixture reaches a thickness in a fluid phase. Finally, Immediately empty the mixture in the corresponding area.

Work Time:

This mixture allows a work time from 3 to 5 minutes approximately, at a room temperature of 23±2 °C.

Polymerized time:

This mixture has a self-polymerizing average time of 10 minutes approximately. These intervals can vary according to the room temperature of the site.

Polishing:

Anatomy and contour are perfect as necessary according to the technical conventional dental. Carefully place the bridge or Crown on the support teeth and establish proper occlusion.

7. COMMERCIAL PRESENTATIONS

NOVACRYL®, Self-polymerized Powder

- POLYETHYLENE BOTTLES: 30g bottle, 40g bottle; 60g bottle (Box per 200 bottles); 125g bottle (Box per 100 boxes); 250g bottle (Box per 40 bottles); 500g bottle (Box per 24 bottles); 1000g bottle (Box per 15 bottles), 2,5 kg. Wide variety of teeth shades.
- POLYETHYLENE DRUM of self- polymerized acrylic powder per 10, 20kg (unit), 25 kg (unit)
- METALLIC DRUM of self- polymerized acrylic powder per 125kg (unit)

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

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

KIT: Cardboard Box with a 250g bottle of powder acrylic and 110 ml of liquid acrylic.

Creation date		Elaborated by:	Revised by:		
2011-01-14		Technical Analyst of Medical Devices	Technical Coordinator of Medical Devices		
Class	Page	Approved by:	Update: Vers		
E	4 of 6	Technical Director of Medical Devices	2018-08-13	03	
REFERENCE DOCUMENT: DPDDPR-019					
VERSION: 00					

TECHNICAL DATA SHEET ACRYLIC POLYMER SELF POLYMERIZED NOVACRYL® DPFTPT-056

KIT: Cardboard Box with a 125g bottle of powder acrylic and 110 ml of liquid acrylic.

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

KIT: Cardboard Box with a 30g bottle of powder acrylic and 15 ml of liquid acrylic.

NOVACRYL® Self- polymerized Liquid

new stetic

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

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

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

KIT: Cardboard Box with a 250g bottle of powder acrylic and 110 ml of liquid acrylic.

KIT: Cardboard Box with a 125g bottle of powder acrylic and 110 ml of liquid acrylic.

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

KIT: Cardboard Box with a 30g bottle of powder acrylic and 15 ml of liquid acrylic



Creation date		Elaborated by:	Revised by:		
2011-01-14		Technical Analyst of Medical Devices	Technical Coordinator of Medical Device		
Class	Page	Approved by:	Update:	Version	
E	5 of 6	Technical Director of Medical Devices	2018-08-13	03	
REFERENCE DOCUMENT: DPDDPR-019					
VERSION: 00					

TECHNICAL DATA SHEET ACRYLIC POLYMER SELF POLYMERIZED NOVACRYL® DPFTPT-056

8. EXPIRATION DATE

new stetic

Novacryl®, self- polymerized powder: Four (4) years. Novacryl®, Opti-cryl® and self-polymerized acrylic Liquid: Two (2) years.

9. STORAGE AND CONSERVATION MEASURES

- Storage: 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.

Creation date		Elaborated by:	Revised by:		
2011-01-14		Technical Analyst of Medical Devices	Technical Coordinator of Medical Device		
Class	Page	Approved by:	Update: Versi		
E	6 of 6	Technical Director of Medical Devices	2018-08-13	03	
REFERENCE DOCUMENT: DPDDPR-019					
VERSION: 00					