

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 SELF-CURING ACRYLIC RESIN FOR TEMPORARY DPFTPT-013

### 1. GENERALITIES OF THE PRODUCT

Methacrylate polymers have become very popular in dentistry because they are easily processed using relatively simple techniques, and they offer the essential properties and features required for oral restoration.

Novacryl Flow® / Novacryl C® self-curing acrylic resin (polymer and monomer) is used for temporary repairs and restorations, crowns and bridges. This is chemically activated by adding a tertiary amine to the liquid component and do not require applying heat.

### 2. INFORMATION ABOUT COMPOSITION

• Polymer components (Type II):

Ethyl and methyl methacrylate copolymer. Polymethyl methacrylate. Fluorescent additive. Pigments.

Monomer components (Type II):

Methyl methacrylate. Ethylene glycol dimethacrylate. Amine type chemical initiator.

#### 3. PROPERTIES OF THE PRODUCT

The physical properties of the product are measured in the Quality Control Laboratory using specialized and calibrated equipment based on the ISO 20795-1 standard for finished product. The most relevant physical properties are shown in the following table.

Parameter	Requirement	Experiment Results
Absorption	Not greater than 32 µg/mm <sup>3</sup>	17.59
Solubility	Not greater than 8.0 µg/mm <sup>3</sup>	3.09
Flexural strength	Minimum 60 MPa	63.88
Flexural modulus	Minimum 1500 MPa	1611
Residual monomer	Maximum 4.5% by weight	3.19

Other properties are assessed qualitatively, such as: Color comparison, color stability, suitability for polishing, porosity, and they are all within the acceptance limits.

Creat	ion date	Elaborated by:	Revised by:	
2014-06-06 Technical Coordinator of Medical Devices Regulatory Affair		Regulatory Affairs A	Analyst	
Class	Page	Approved by:	Update:	Version
Е	1 of 3	Technical Director of Medical Devices	2023-08-28	03

**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 SELF-CURING ACRYLIC RESIN FOR TEMPORARY DPFTPT-013

#### 4. USES AND APPLICATIONS

The features of the Novacryl Flow® / Novacryl C® are:

- The preparation and repair of the various acrylic structures can be performed in a very short time, while allowing sufficient time for manipulation.
- The curing does not require thermal treatment for its polymerization.
- It can be easily polished to recover its shine.
- When used in the indicated proportions of polymer and monomer, vertical and linear contractions to the acrylic structure are avoided.

## 5. QUALITY ASSURANCE OF THE PRODUCT

The acrylic resins are manufactured with high-quality raw materials by means of a standardized manufacturing process which is certified under ISO 9001 and ISO 13485. Additionally, the Quality Control Laboratory verifies fulfillment of the requirements of ISO 20795-1 standard for finished products using specialized equipment.

**Water absorption and solubility:** Verify the amount of water absorbed by the acrylic resins or the amount of weight they lose when they are immersed in water. The acrylic is not soluble in saliva or any other mouth liquid.

**Porosity:** The processed acrylic is free from imperfections and porosity.

**Flexural strength and flexural modulus**: It measures the degree of deformation of the acrylic resins to resist the forces that take place during chewing; in addition, it measures the resist forces of the resin until the fracture that guarantees its good clinical performance.

**Translucency:** It must be possible to see an object on the opposite side of the test tube with acrylic.

**Residual monomer**: The amount of monomer left over during prosthesis construction must be minimal to ensure that no irritation occurs in mouth tissues.

#### 6. INSTRUCTIONS FOR USE

- Cover the supporting teeth and gingival tissues with a thin layer of vaseline, which helps lubricate and facilitates the removal of the temporary bridge. Mix according to the instructions, add the mix to the impression and position it in the patient's mouth.
- Before to begin the exothermic reaction, remove the impression from the mouth. Let the temporary bridge or crown polymerize in the impression. Do not allow it polymerize in the mouth directly, remove the bridge from the impression.

Creat	ion date	Elaborated by:	Revised by:	
2014-06-06 Technical Coordinator of Medical Devices Regulatory Affairs		Analyst		
Class	Page	Approved by:	Update:	Version
E	2 of 3	Technical Director of Medical Devices	2023-08-28	03

**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 SELF-CURING ACRYLIC RESIN FOR TEMPORARY DPFTPT-013

- Place carefully the bridge or crown on the supporting teeth and fit an appropriate occlusion.
   When the fit and occlusion are satisfactory, then cement the bridge or crown. After cementation, check the occlusion again.
- The anatomy and contour are refined as necessary. If you want to get a better characterization of the bridge or crown, apply Novacryl Flow® / Novacryl C® incisal to degrade the enamel simulation of the teeth.

#### 7. COMMERCIAL PRESENTATIONS

Polymer:

Bottle per 40, 60, 125, 250, 500 and 1000 g; 10, 20 and 125 kg.

Monomer:

Bottle per 55, 110, 250, 500 and 1000 ml.

• Kit presentations:

1000 g + 500 ml. 500 g + 250 ml. 60 g + 55 ml. 4 bottles per 40 g each + 2 bottles per 55 ml each. 8 bottles per 40 g each + 2 bottles per 55 ml each.

## 8. STORAGE AND PRESERVATION CONDITIONS

- Keep the product in a cool and well-ventilated area (room temperature), away from spark or fire sources, direct sunlight and heat.
- Do not smoke.
- Store away from oxidizing agents, acids, bases and polymerization initiators.
- Do not store at temperatures above 30 °C (86 °F).

Creat	ion date	Elaborated by:	Revised by:	
2014	1-06-06	Technical Coordinator of Medical Devices	Regulatory Affairs Analyst	
Class	Page	Approved by:	Update:	Version
E	3 of 3	Technical Director of Medical Devices	2023-08-28	03

REFERENCE DOCUMENT: DPDDPR-019

UPDATE: 2021-11-12 VERSION: 02