1 GENERAL PRODUCT INFORMATION

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.

Acrylic resins are also used in repairs the oral restorations total or partial denture bases, removable prosthesis, aesthetic plates, templates (guides for implant placement), bruxism plates and individual impression trays. Dental repairs can be made with Self-polymerized 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.
   Polyester (If a veined reference is required).

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 for Denture Base Polymers.

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

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Requirements</th>
<th>Experimental results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absorption</td>
<td>Not higher than 32 µg/mm³</td>
<td>19.50</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not higher than 8.0 µg/mm³</td>
<td>3.00</td>
</tr>
<tr>
<td>Flexural Strength</td>
<td>60 MPa minimum</td>
<td>62.00</td>
</tr>
<tr>
<td>Flexural Modulus</td>
<td>1500 MPa minimum</td>
<td>1780</td>
</tr>
<tr>
<td>Residual Monomer Content</td>
<td>4.5% maximum (in weight)</td>
<td>3.16</td>
</tr>
</tbody>
</table>

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

### 4 USAGE AND APPLICATIONS

Self-polymerized Veracril®, Opti-cryl®: The composition of Self-polymerized (polymer and monomer) is the one that is used to repair total or partial denture bases, removable prosthesis, aesthetic plates, templates (guides for implant placement), bruxism plates and individual impression trays.

The main characteristics of self-polymerized are the following:

- The period of time required for the repairing of different acrylic structures and the making of orthodontic and orthopedic appliances is minimum. This product allows an optimum working time for its manipulation.
- High resistance to fractures.
- 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 for 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 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 Intron 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

Self-polymerized acrylic Veracril®, Opti-cril®, Self-polymerized Monomer must be mixed only with the Self-polymerized Polymer for preparing the acrylic used in reparations of total, partial dental prosthesis.

**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. Put a lid on the container for avoiding the entrance of air until the acrylic dough reaches its filamentous phase (when the mixture comes in contact with a spatula, filaments can be seen). Finally, proceed to make the reparation of prosthesis.

**Work Time:**
This mixture allows a work time from 3 to 5 minutes approximately, at a room temperature of 23±2 ºC.

**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:**
Polishing of prosthesis will be made according to the current procedures and techniques in practice in dental laboratories.
COMMERCIAL PRESENTATIONS

Veracril®, Opti-cryl®, Self-polymerized Powder:

Polyethylene bottles: 30g bottle, 40g bottle; 60g bottle (Box per 196 bottles); 125g bottle (Box per 100 boxes); 250g bottle (Box per 30 bottles); 500g bottle (Box per 24 bottles); 1000g Bottle (Box per 15 bottles). Wide variety of veined and smooth pink shades.

Polyethylene drum of self-polymerized acrylic powder per 10 and 20kg (unit).

20 kg - Polyethylene bag, box double wall reinforced of heat-polymerized acrylic powder (unit).

Metallic drum of self-polymerized acrylic powder per 125kg (unit).

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

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

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

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

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

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

Veracril®, Opti-cryl®, Self-polymerized Liquid:

Mmber glass bottles: 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 (4 unit).

KIT: Cardboard Box with a 1000g bottle of self-polymerized acrylic powder and 500 ml of self-polymerized acrylic liquid (12 KIT).
8 EXPIRATION DATE

Veracril®, Opti-cryl® self-polymerized Powder: Four (4) years.
Veracril®, Opti-cryl® 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.