TECHNICAL DATA SHEET OCRYL® SELF POLYMERIZED ACRYLIC RESIN DPFTPT-069

1. GENERALITIES OF THE PRODUCT

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.

The Ocryl[®] self-polymerized acrylic resin is chemically activated by the addition of a tertiary amine to the liquid component, without require the use of thermal energy. It is used for the elaboration of orthodontic and orthopedic appliances.

2. INFORMATION ABOUT COMPOSITION

- Polymer components: Self-polymerized acrylic (Type II) Poly (methylmethacrylate).
 Pigments.
- Monomer components: Self-polymerized monomer (Type II). Methyl Methacrylate. Ethylene Glycol Dimethacrylate. Chemical initiator (Amine type).

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 of finished product. The most relevant physical properties are shown in the following chart:

Parameters	Requirements	Experimental results
Absorption.	Not higher than 32 µg/mm ³ .	22.26
Solubility.	Not higher than 8.0 µg/mm ³ .	3.65
Flexure Strength.	60 MPa minimum.	60.75
Flexural Modulus.	1500 MPa minimum.	2423.04
Residual Monomer Content.	4.5% maximum (in weight).	3.51

Creation date		Elaborated by:	Revised by:	
2011-07-12		Technical Analyst of Medical Devices	Prosthetic Solutions Analyst	
Class	Page	Approved by:	Update:	Version
E	1 Of 5	Technical Director of Medical Devices	2019-09-06	03
REFERENCE DOCUMENT: DPDDPR-019 UPDATE: 2017-12-02 VERSION: 00				



TECHNICAL DATA SHEET OCRYL® SELF POLYMERIZED ACRYLIC RESIN DPFTPT-069

Other physical properties as color, color stability, polishing capacity, translucency, and porosity meet with the accepted limits.

4. USES AND APPLICATIONS

The composition of O-cryl® self-polymerized acrylic resin (polymer and monomer) is intended for the elaboration of several orthodontic and orthopedic appliances; these acrylic bases in combination with other complements, help to correct the stethic, functionality, unsuitable habits and prevent the bad dental position.

The main characteristics are the following:

- The period of time required for the elaboration of the repairing of different acrylic structures of the orthodontic and orthopedic appliances is minimum, and it allows an optimum working time for its manipulation.
- Complements as retainers, springs and screws can be incorporated into the acrylic.
- It does not require heat treatment for its polymerization process.
- It allows an easy polishing to recover its gloss.
- Using the polymer-monomer ratio as it is indicated, the possible vertical and linear contractions of the acrylic structure can be 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 ISO Standard 9001 and ISO Standar 13485. Moreover, in its Quality Control Laboratory, New Stetic verifies the compliance of ISO Standard 20795 according to the quality requisites for the finished product, using specialized equipment.

Water absorption and solubility: The amount of water that can be absorbed by acrylic resins or the amount of weight that they can lose when are immersed in water. Acrylic is not soluble in saliva or in any other oral fluid.

Creation date		Elaborated by:	Revised by:	
20	11-07-12	Technical Analyst of Medical Devices	Prosthetic Solutions Analyst	
Class	Page	Approved by:	Update:	Version
E	2 Of 5	Technical Director of Medical Devices	2019-09-06	03
REFERENCE DOCUMENT: DPDDPR-019				
UPDATE: 2017-12-02				
VERSION: 00				

TECHNICAL DATA SHEET OCRYL® SELF POLYMERIZED ACRYLIC RESIN DPFTPT-069

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; additionally, 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 can remained during the prosthesis elaboration, must be minimum in order to guarantee the absence of irritations in oral tissues.

6. INSTRUCTIONS FOR USE

new stetic

The Ocryl® self-polymerized acrylic monomer must be used with the Ocryl® self-polymerized acrylic polymer, for the elaboration and repairing of orthodontic and orthopedic appliances bases.

6.1 Proportions

By volume: Two parts of Ocryl[®] self-polymerized Polymer + One part of Ocryl[®] self-polymerized Monomer.

6.2 Preparation of the mixture:

- The acrylic dough is prepared in an adequate container (a dappen dish or a glass, silicon, or porcelain container).
- The dosed polymer is poured into the monomer in the indicated ratios, and it is mixed in a cross-wise way continuously for about 30 seconds approximately, to avoid the air generation and ensure the polymer particles are fully incorporated in the mononer.
- Proceed to pour the dough in its fluid state over the model, in order to obtain a total covering of the retentions of the functional wires.
- The mixture is molded into the palate of the model, wetting in the mixture with the self polimerized acrylic liquid.

Creation date		Elaborated by:	Revised by:		
2011-07-12		Technical Analyst of Medical Devices	Prosthetic Solutions Analyst		
Class	Page	Approved by:	Update:	Version	
E	3 Of 5	Technical Director of Medical Devices	2019-09-06	03	
REFERE	REFERENCE DOCUMENT: DPDDPR-019				
UPDATE: 2017-12-02					
VERSION: 00					

TECHNICAL DATA SHEET OCRYL® SELF POLYMERIZED ACRYLIC RESIN DPFTPT-069

- The excesses are cut in order to mold the teeth necks and the limit of the acrylic support in the palate.
- Cover the acrylic model with a container, which can be with the container used for mixing the cast, while the exothermal reaction of the material is done.

6.3 Polymerization

new stetic

The Ocryl self-polymerized acrylic, polymerizes in a average time of 10 minutes. These intervals can vary according to the room temperature of the site.

6.4 Polishing

Polishing are made according to the current procedures and techniques in practice in dental laboratories.

7. COMMERCIAL PRESENTATIONS

O-cryl® Self-polymerized monomer:

Bottles per 55 ml, 110 ml, 250 ml, 500 ml, 1000 ml, 1 gallon, 200 L, 8 oz, 32 oz.

O-cryl® Self-polymerized polymer:

Bottles per 30 g, 40 g, 60 g, 125 g, 250 g, 500 g, 1000 g, 2,5 kg, 10 kg, 20 kg, 25 kg, 125 kg, 1 lb, 5 lb, 22 lb, 44 lb, 55 lb

O-cryl® Self-polymerized kit:

Bottle per 1000 g of acrylic powder + 500 ml of acrylic liquid. Bottle per 500 g of acrylic powder + 250 ml of acrylic liquid. Bottle per 250 g of acrylic powder + 110 ml of acrylic liquid. Bottle per 125 g of acrylic powder + 110 ml of acrylic liquid. Bottle per 60 g of acrylic powder + 55 ml of acrylic liquid. Bottle per 30 g of acrylic powder + 15 ml of acrylic liquid. 4 Bottles per 40 g (each one) of acrylic powder + 2 bottles per 55 ml (each one) of acrylic liquid.

Creation date		Elaborated by:	Revised by:	
20	11-07-12	Technical Analyst of Medical Devices	Prosthetic Solutions Analyst	
Class	Page	Approved by:	Update:	Version
E	4 Of 5	Technical Director of Medical Devices	2019-09-06	03
REFERENCE DOCUMENT: DPDDPR-019				
UPDATE: 2017-12-02				
VERSION: 00				

TECHNICAL DATA SHEET OCRYL® SELF POLYMERIZED ACRYLIC RESIN DPFTPT-069

8 Bottles per 40 g (each one) of acrylic powder + 2 bottles per 55 ml (each one) of acrylic liquid.

A sample free of commercial value of a bottle per 30 g of acrylic powder + 15 ml acrylic liquid.

8. EXPIRATION DATE

new stetic

O-cryl®, self-polymerized Polymer: Four (4) years. O-cryl®, self-polymerized acrylic Monomer: Two (2) years.

9. STORAGE AND PRESERVATION CONDITIONS

- Storage: Keep this product in a fresh and well-ventilated
- Keep it away from any flame or spark source.
- Do not smoke.
- Keep it away from heat and direct sunlight.
- Store it away from oxidants, acids, bases, and polymerization initiators.
- Do not store for long periods of time.

Creation date		Elaborated by:	Revised by:	
201	11-07-12	Technical Analyst of Medical Devices	Prosthetic Solutions Analyst	
Class	Page	Approved by:	Update:	Version
Е	5 Of 5	Technical Director of Medical Devices	2019-09-06	03
REFEREN	NCE DOCUMEN	IT: DPDDPR-019		
UPDATE:	2017-12-02			
VERSION	: 00			