



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

## SAFETY DATA SHEET 3D RESIN PORTUX TRY-IN DPDDFS-114

### 1 IDENTIFICATION OF THE SUBSTANCE/BLEND AND THE COMPANY

#### 1.1 Product Identification:

TRADE NAME	CATALOG NUMBER	UDI-DI
3D Resin Portux Try-In 1000 g	0028045 CE	7701126900597XS
3D Resin Portux Try-In 500 g	0028444 CE	7701126900580X9
3D Resin Portux Try-In 250 g	0028732 CE	7701126900641X4

- Chemical name: Not applicable.
- Generic name: 3D resin for printing for temporary try-in dentures.
- Synonyms: Stereolithography resin, DLP resin, LCD resin.
- EC Number: Not applicable.
- CAS Number: Not applicable.

#### 1.2 Recommended use and restrictions of product: Product for printing of trial dental structures and prostheses in partially or totally edentulous patients. This product should not be used for purposes other than those indicated.

#### 1.3 SDS supplier details:

- Manufacturer/supplier: New Stetic S.A.
- Address: Carrera 53 No. 50 – 09, km 22 Autopista Medellín-Bogotá.
- Country phone code / postal code / place: 57 / 054050 / Guarne-Antioquia-Colombia.
- Telephone number: 57-604-4038760.
- Telefax: 57-604-5513134.
- Fax: 57-604-5513134.
- Electronic mail of competent person responsible for SDS: Research Analyst, aossa@newstetic.com
- National contact: Technical Director of Medical Devices, dosorio@newstetic.com.

#### 1.4 Emergency number: In case of emergency, contact the following numbers.

- Colombia: Safety and Health at Workplace Coordinator, tel. (57 60 4) 403 87 60, ext. 1304 (business hours). E-mail: lagomez@newstetic.com.
- Spain: Info@ranelaghcapital.com (business hours).

Creation Date		Elaborated by:	Revised by:	
2024-06-13		Research Analyst	Documentary Analyst of Medical Devices Director of Research and Technological Management Technical Coordinator of Medical Devices	
Class	Page	Approved by:	Update:	Version
E	1 of 7	Technical Director of Medical Devices	2024-10-22	01

REFERENCE DOCUMENT: DPDDPR-003  
UPDATE: 2023-11-29  
VERSION: 07

## SAFETY DATA SHEET

### 3D RESIN PORTUX TRY-IN



### DPDDFS-114

## 2 IDENTIFICATION OF HAZARDS

2.1 Classification according to EC Regulation No. 1272/2008 (CLP):

Health	Environmental	Physical
Corrosion / Skin irritation / Category 2	Acute toxicity Category 1	Non-harmful
Serious eye damage / Eye irritation / Category 2	Chronic toxicity Category 1	
Skin sensitization / Category 1		
Toxic for reproduction / Category 2		

2.2 Labeling:

Symbol	Signal word	Hazard indication
	Attention	H317: May cause an allergic skin reaction. H319: Causes serious eye irritation.
	Attention	H400: "Very toxic to aquatic life. H410: "Very toxic to aquatic life with long lasting effects.

Precautionary statements:



P261: Avoid breathing dust/fume/gas/mist/vapors/spray.  
P273: Avoid release to the environment.  
P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352: IF ON SKIN: Wash with plenty of water.  
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364: Take off contaminated clothing and wash it before reuse.

- 2.3 Precautionary indications: None.  
2.4 Appearance in case of emergency: None.  
2.5 Potential adverse health effects: This product has no negative health implications under normal conditions of use, handling, and storage.  
2.6 NFPA Classification: Not applicable.  
2.7 OSHA regulatory status: non-dangerous.

Creation Date		Elaborated by:	Revised by:	
2024-06-13		Research Analyst	Documentary Analyst of Medical Devices Director of Research and Technological Management Technical Coordinator of Medical Devices	
Class	Page	Approved by:	Update:	Version
E	2 of 7	Technical Director of Medical Devices	2024-10-22	01

## SAFETY DATA SHEET 3D RESIN PORTUX TRY-IN DPDDFS-114

### 3 INFORMATION ABOUT COMPOSITION

HAZARDOUS COMPONENTS				
Common name	Concentration	CAS Number	Hazard symbols	CE Number
Methacrylate monomers and oligomers	> 95%	41637-38-1 72869-86-4 629-11-8		609-946-4 276-957-5 211-074-0
Diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide	< 5%	75980-60-8	 Cat. 1B: H360	278-355-8

### 4 FIRST AID MEASURES

#### 4.1 Emergency procedures and first aid in case of:

- Inhaling: Move to a well-ventilated area. Seek medical attention immediately if irritation and prolonged discomfort occur.
- Eye contact: Rinse immediately with plenty of water for at least 10 minutes. If discomfort persists, consult an ophthalmologist immediately.
- Skin contact: Wash with plenty of water and soap. If irritation or inflammation occurs, see a doctor immediately.  
Wash the mouth and drink plenty of water. Do not induce vomiting and seek medical attention immediately.

#### 4.2 Most important symptoms/effects (acute and/or delayed):

- Inhalation: High vapor concentrations may cause respiratory tract irritation.
- Eye contact: Direct eye contact may cause irritation and discomfort, with burning and itching sensations.
- Skin contact: Prolonged exposure may cause irritation, inflammation, itching, or dryness.
- Ingestion: Information not available.

Creation Date		Elaborated by:	Revised by:	
2024-06-13		Research Analyst	Documentary Analyst of Medical Devices Director of Research and Technological Management Technical Coordinator of Medical Devices	
Class	Page	Approved by:	Update:	Version
E	3 of 7	Technical Director of Medical Devices	2024-10-22	01



## SAFETY DATA SHEET 3D RESIN PORTUX TRY-IN DPDDFS-114

- 4.3 Antidote: Not applicable.  
4.4 Information for doctors: Not applicable.

### 5 FIREFIGHTING MEASURES

- 5.1 Flammability properties: Non-flammable product.  
5.2 Suitable extinction of fire: Have CO<sub>2</sub> or extinguishing powder available. Combat larger fires with alcohol-resistant foam or water-resistant foam.  
5.3 Unsuitable extinction of fire: Water may be ineffective.  
5.4 Instructions for fire extinguishing: Standard procedures for fires Class A.  
5.5 Firefighters' protection: The combustion of the product may release toxic vapors. Closed containers that contain the product may rupture violently.  
5.6 Protective equipment and firefighters' protection: Normal firefighting clothing, that is to say, firefighting kit (BS EN 469), gloves (BS EN 659), and boots (specification HO A29 and A30) in combination with a positive pressure compressed air breathing apparatus with open circuit (BS EN 137).

### 6 ACCIDENTAL RELEASE MEASURES

- 6.1 Techniques, procedures, and materials and protective equipment in case of:
- Large spill: Use a plastic spatula or broom to move the spilled liquid towards a container. Clean the residue with alcohol and absorbent cloths.
  - Small spill: Collect manually using absorbent paper. Dispose of the contaminated paper in accordance with internal chemical waste regulations. Protective glasses and gloves should be worn during this action.
- 6.2 Environmental precautions: The product must not penetrate the sewage system or be in contact with surface or groundwater.
- 6.3 Further considerations: Contaminated disposable material used for cleaning spills must be disposed of in accordance with established provisions.

### 7 HANDLING AND STORAGE

- 7.1 Handling: Precautions should be taken for safe handling before manipulating the product; refer to all other sections of this material safety data sheet. Avoid product leaks into the environment. Do not eat, drink, or smoke during handling.
- 7.2 Storage: Store the sealed product before and after use in a cool, dry place away from direct light exposure at room temperature (< 30°C / 86°F). Keep the product away from potential sources of ignition. Avoid consuming and storing food and beverages near the product.

Creation Date		Elaborated by:	Revised by:	
2024-06-13		Research Analyst	Documentary Analyst of Medical Devices Director of Research and Technological Management Technical Coordinator of Medical Devices	
Class	Page	Approved by:	Update:	Version
E	4 of 7	Technical Director of Medical Devices	2024-10-22	01



## SAFETY DATA SHEET 3D RESIN PORTUX TRY-IN DPDDFS-114

### 8 EXPOSURE CONTROLS AND PERSONAL PROTECTION

- 8.1 Conditions to control the exposure: Do not consume food, beverages, or smoke while handling the product.
- 8.2 Engineering controls: There should be proper ventilation or air extraction conditions in the area where the product is handled to prevent prolonged exposure to vapors. Avoid areas with porous walls and floors.
- 8.3 Personal protective equipment: Wear protective clothing such as gloves, laboratory coat, and safety goggles when handling the product. If there is limited ventilation in the work area, use a mask with a respiratory protection filter.
- 8.4 Exposure parameters: Emissions generated by the manufacturing process, including those generated by ventilation equipment, must be verified to ensure compliance with environmental standards.

### 9 PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: Translucent viscous liquid.
- Color: slightly blue.
- Odor: Acrylic odor.
- Odor threshold: Not available.
- Physical state: Liquid.
- pH: Not available.
- Freezing or melting point: Not available.
- Evaporation rate: Not available.
- Initial boiling point and boiling range: Not available.
- Flash point: > 100 °C (> 212 °F).
- Flammability (solid, gas): Not available.
- Upper/lower flammability or explosive limits: Not available.
- Vapor pressure: Not available.
- Vapor density: Not available.
- Specific gravity or relative density: Not available.
- Solubility in water: Insoluble.
- Octanol/water partition coefficient: Not available.
- Auto-ignition temperature: Not available.
- Decomposition temperature: Not available.
- Heat value: Not available.
- Particle size: Not available.
- Volatile organic compound content: Not available.
- Softening point: Not available.
- Pour point: Not available.
- Viscosity: 350 - 450 cP.

Creation Date		Elaborated by:	Revised by:	
2024-06-13		Research Analyst	Documentary Analyst of Medical Devices Director of Research and Technological Management Technical Coordinator of Medical Devices	
Class	Page	Approved by:	Update:	Version
E	5 of 7	Technical Director of Medical Devices	2024-10-22	01



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

## SAFETY DATA SHEET 3D RESIN PORTUX TRY-IN DPDDFS-114

- Apparent density (bulk density): 1.1 g/cm<sup>3</sup>.
- Volatility percentage: Not available.
- Saturated vapor concentration: Not available.
- Molecular weight: Not available.
- Molecular formula: Not available.
- Other information: Not available.

### 10 STABILITY AND REACTIVITY

- 10.1 Chemical stability: The product is stable under normal conditions of use and storage.
- 10.2 Possibility of hazardous reactions: The product reacts in the presence of strong oxidizing agents, alkaline materials, and strong acids.
- 10.3 Conditions to avoid: Exposure to UV or sunlight. Keep the product in its original, properly sealed container, away from any direct light exposure.
- 10.4 Incompatibility with other materials: Strong acids, strong bases, organic peroxides, and hydroperoxides.
- 10.5 Dangerous breaking down products: Information not available.
- 10.6 Hazardous polymerization: Not available.

### 11 TOXICOLOGICAL INFORMATION

- 11.1 Possible routes of exposure: Possible routes of exposure: respiratory, dermal, and digestive.
- 11.2 Acute toxicity: Acute toxicity: Data not available.
- 11.3 Chronic toxicity: Chronic toxicity: Data not available.
- 11.4 Additional information: Other information: Not available.

### 12 ECOLOGICAL INFORMATION

- 12.1 Eco-toxicity: Sufficient data to support this item is not available. However, disposing of large quantities of the product in liquid form into water sources may be harmful to the ecosystem.
- 12.2 Persistence and degradability: Information not available.
- 12.3 Potential of bioaccumulation: Information not available.
- 12.4 Mobility on soil: Information not available.
- 12.5 Other adverse effects: Information not available.

Creation Date		Elaborated by:	Revised by:	
2024-06-13		Research Analyst	Documentary Analyst of Medical Devices Director of Research and Technological Management Technical Coordinator of Medical Devices	
Class	Page	Approved by:	Update:	Version
E	6 of 7	Technical Director of Medical Devices	2024-10-22	01

REFERENCE DOCUMENT: DPDDPR-003  
UPDATE: 2023-11-29  
VERSION: 07





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

## SAFETY DATA SHEET 3D RESIN PORTUX TRY-IN DPDDFS-114

### 13 DISPOSAL CONSIDERATIONS

Do not dispose of the product in water sources or sewage systems. This product should not be disposed of in soils or sub surfaces. Disposal should be carried out through an authorized waste management company, following national and local regulations.

Solid waste may be suitable for disposal in an authorized landfill and should be recovered or disposed of in accordance with national waste management standards.

WARNING: Local laws, regulations, and restrictions may change or be reinterpreted, and may differ from national ones, therefore, considerations for material disposal and packaging may vary from those stated in this document.

### 14 TRANSPORT INFORMATION

- 14.1 Hazardous material: Non-hazardous.
- 14.2 Class of risk: None.
- 14.3 UN Number: UN3082.
- 14.4 IATA Classification: Not Applicable
- 14.5 Packaging group: None.
- 14.6 Marine pollutant (Yes/No): Yes

### 15 REGULATORY INFORMATION

- 15.1 In Colombia: Not applicable.
- 15.2 International: This product complies with EEC Regulations. According to lists from the EC and directives contained in the EEC/Regulations on dangerous substances, this product does not need to be labeled.

### 16 OTHER IMPORTANT INFORMATION

The information registered in this document is based on our current knowledge and it is given in good faith but is not given an assurance express or implicit; neither is assumed any responsibility for the incorrect use of the product. This document is prepared according to:

- Globally Harmonized System of Classification and Labeling of Chemicals – GHS.
- Regulation (EC) No. 1272/2008 (CLP).

Creation Date		Elaborated by:	Revised by:	
2024-06-13		Research Analyst	Documentary Analyst of Medical Devices Director of Research and Technological Management Technical Coordinator of Medical Devices	
Class	Page	Approved by:	Update:	Version
E	7 of 7	Technical Director of Medical Devices	2024-10-22	01

REFERENCE DOCUMENT: DPDDPR-003  
UPDATE: 2023-11-29  
VERSION: 07