



**SAFETY DATA SHEET**  
**PORTUX 3D MODEL ORTHO**  
**DPDDFS-102**

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

1.1 Product Identification:

- Chemical name: Not applicable.
- Generic name: 3D resin for printing of dental models for invisible aligners.
- Synonyms: Stereolithography resin, DLP resin, LCD resin.
- Recommended use and restrictions of product: Manufacturing of dental models used in thermoforming processes of aligner plates for the invisible orthodontic procedure. The product is not biocompatible, so it should not be used in the patient's mouth.

1.2 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.
- Electronic mail of competent person responsible for SDS: Research Analyst, aossa@newstetic.com
- National contact: Technical Director of Medical Devices, dosorio@newstetic.com.

1.3 Emergency number: In case of emergency, contact the following numbers:

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

**2 HAZARDS IDENTIFICATION**



2.1 GHS Classification:

Health	Environment	Physical
Corrosion / skin irritation / Category 2	Acute toxicity Category 1  Chronic toxicity Category 1	N.A.
Severe eye damage / Eye irritation Category 2		
Skin sensitization Category 1		

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2.2 GHS Labeling:

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

2.3 Precaution indications:

P261: Avoid breathing dust/fume/gas/mist/vapors/spray.  
 P280: Wear protective gloves/protective clothing/eye protection/face protection.

- 2.4 Appearance in case of emergency: None.  
 2.5 Potential adverse effects on health: This product does not have implications for health under normal conditions of use, handling, and storage.  
 2.6 NFPA: Not available.  
 2.7 OSHA regulatory status: non-dangerous.

**3 INFORMATION ABOUT COMPOSITION**

HAZARDOUS COMPONENTS		
Common name	Concentration	CAS Number
Methacrylic oligomers and monomers	>94%	Not applicable
Phosphine oxides	<6%	Not applicable

NON-HAZARDOUS COMPONENTS		
Common name	Concentration	CAS Number
Not applicable	Not applicable	Not applicable

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**4 FIRST-AID MEASURES**

4.1 Emergency procedures and first aid in case of:

- Inhalation: Move to a fresh-air zone. Seek medical attention immediately if irritation and prolonged discomfort occurs.
- Contact with eyes: Immediately flush with plenty of water at least during ten minutes. If the discomfort persists, consult an ophthalmologist immediately.
- Contact with skin: Flush with plenty of water and soap. If irritation or swelling occurs, consult a physician immediately.
- Ingestion: Rinse the mouth and drink sufficient water. Do not induce vomit. Get medical attention.

4.2 Major symptoms/effects (acute and/or delayed):

- Inhalation: Increased concentrations of vapor may cause irritations of the respiratory system.
- Contact with eyes: Direct contact with the material in the eyes may cause irritations and discomfort with burning and itching sensations.
- Contact with skin: prolonged exposures may produce irritation, swellings, itching, or dryness.
- Ingestion: Information not available.

4.3 Antidote: Not applicable.

4.4 Information for physicians: Not applicable

**5 FIREFIGHTING MEASURES**

5.1 Flammability properties: Non-flammable product.

5.2 Suitable extinction of fire: Use CO<sub>2</sub> or chemical extinguishing powder to combat larger fires with waterproof foam or alcohol resistant foam.

5.3 Unsuitable extinction of fire: Water may be an ineffective extinguisher agent in this case.

5.4 Instructions for fire extinguishing: Standard procedures for Class A fires.

5.5 Firefighter's protection: Combustion of the product may release toxic vapors. Closed containers that hold the product may break violently.

5.6 Protective equipment and firefighter's protection: Wear normal clothes to combat fire, that is to say, a fire kit (BS EN 469), gloves (BS EN 659) and boots (HO A29 and A30 specification) in combination with a self-contained breathing apparatus for compressed air of open circuit positive pressure (BS EN 137).

**6 ACCIDENTAL RELEASE MEASURES**

6.1 Techniques, procedures, materials, and protective equipment in case of:

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- Small spills: Clean the area manually using absorbent paper. Dispose of the contaminated paper as per the internal chemical waste disposal provisions. Safety goggles and gloves must be worn to do this.
  - Large spills: Use a plastic spatula or water broom to push the spill towards a disposable container. Clean the remainder with alcohol and absorbent cloths.
- 6.2 Environmental precautions: Contain the spill in order to avoid its release through sewers and Canals. Avoid contamination of water bodies.
- 6.3 Other considerations: Contaminated disposable material used to clean up spills, must be disposed of in accordance with the established provisions.

**7 HANDLING AND STORAGE**

- 7.1. Handling: Precautions for safe handling should be taken before handling the product, see all other sections of this Safety Data Sheet. Avoid leakage of the product into the environment. Do not eat, drink, or smoke while handling.
- 7.2. Storage: Store the product sealed before and after its use in dry, fresh facilities, without direct exposure to any type of light at room temperature (< 30°C / 86°F). Keep the product away from ignition sources. Avoid storage near foods and drinks.

**8 EXPOSURE CONTROLS AND PERSONAL PROTECTION**

- 8.1 Conditions to control exposure: Do not consume foods or drinks nor smoke in the job site.
- 8.2 Exposure parameters: Not available.
- 8.3 Engineering controls: Appropriate conditions of venting or extraction must be ensured in order to avoid as much as possible exposure to vapors. Avoid work areas with porous walls and floors.
- 8.4 Personal protective equipment: Wear protective elements such as gloves, gown, and eye protection goggles when handling the product. In case of scarce ventilation in the area, the use of a mouth cover or mask with respiratory filter is recommended.
- 8.5 Control of environmental exposition: Emissions generated by the manufacturing process, including those generated by ventilation equipment, must be verified to ensure compliance with environmental regulations.

**9 PHYSICAL AND CHEMICAL PROPERTIES OF THE PRODUCT**

- Appearance: Viscous, rose color opaque liquid.
- Odor: Acrylic odor.
- Odor threshold: Not available.
- Physical status: Liquid.
- pH: Not available.
- Freeze or fusion point: Not available.

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- Evaporation percentage: Not available.
- Initial point and boiling range: Not available.
- Flash point: >100°C (>212°F).
- Evaporation rate: Not available.
- Flammability (solid gas): Not available.
- Upper/lower flammability or explosion liquid: Not available.
- Vapor pressure: Not available.
- Vapor density: Not available.
- Specific gravity or relative density: Not available.
- Solubility: Not available.
- Partition coefficient n-octanol/water: Not available.
- Self-ignition temperature: Not available.
- Decomposition temperature: Not available.
- Heat value: Not available.
- Particle size: Not available.
- Volatile organic compounds content: Not available.
- Softening point: Not available.
- Pour point: Not available.
- Viscosity: 400 - 500 cP.
- 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: Not available.

**10 STABILITY AND REACTIVITY**

- 10.1 Chemical stability: The product is stable under normal conditions of storage and handling.
- 10.2 Possibility of hazardous reactions: It reacts in the presence of strong oxidizing agents, alkaline materials, and strong acids.
- 10.3 Conditions to avoid: Exposure to ultraviolet and/or sunlight. Keep the product in the appropriately closed container, away from any exposure to light.
- 10.4 Incompatibility with other materials: Strong acids, strong alkalis, organic peroxides, and hydro peroxides.
- 10.5 Hazardous decompositions products: Not available
- 10.6 Hazardous polymerization: Not available

**11 TOXICOLOGICAL INFORMATION**

- 11.1 Possible routes of exposure: Respiratory, cutaneous, and digestive.
- 11.2 Acute toxicity: No data available.
- 11.3 Chronic toxicity: No data available.

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11.4 Additional information: This product is not biocompatible and its printings must not be used in direct contact with the patients.

**12 ECOLOGICAL INFORMATION**

- 12.1 Ecotoxicity: There are not collected data to support this item. However, discarding large amounts of the product in a liquid state to water sources can be harmful to the ecosystem.
- 12.2 Persistence and degradability: not available.
- 12.3 Bioaccumulation potential: not available.
- 12.4 Mobility in soil: not available.
- 12.5 Other adverse effects: not available.

**13 DISPOSAL CONSIDERATIONS**

Do not discard the product in water sources and sewers. This product must not be disposed of in soils/subsoil. Dispose this product in accordance with the local regulations for residues management. This product should not be disposed of on floors or subsoils. Disposal must be done through an authorized waste management company, according to the national and local regulations.

Solid waste may be suitable for disposal in a licensed landfill and must be recovered or disposed in accordance with national waste management regulations.

WARNING: Law, regulations, and local restrictions can change or be reinterpreted from one country to another and also, they can be different from the ones being into effect in Colombia. This is why considerations about waste disposal of product and its packing may differ from the ones appearing in this document.

**14 TRANSPORT INFORMATION**

- 14.1 Hazardous material: Non-hazardous material.
- 14.2 Class of risk: None.
- 14.3 UN Number: 3082.
- 14.4 IATA Classification: Not applicable.
- 14.5 Packaging group: None.
- 14.6 Marine contaminant (yes/no): Yes.

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**15 REGULATORY INFORMATION**

- 15.1 In Colombia: No component listed or revise the current local regulations.
- 15.2 International: No component listed or revise the current local regulations.

**16 OTHER IMPORTANT INFORMATION**

The information 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 in accordance with:

- Globally Harmonized System of Classification and Labelling of Chemicals – GHS.
- Colombian Technical Standard NTC 4435:2010. Merchandise Transport. Safety Data Sheets for Materials. Preparation.

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