

1. INTRODUCTION

The following instructions for use are for dental professionals who use Structomer® Model as a dental modelling 3D printing material. Structomer® Model is intended for professional dental and orthodontic models. This instruction for use also provides information about safety and environmental aspects. Safety datasheet (MSDS) corresponding to the Structomer® Model material is available on <https://www.structo3d.com/> and with the local dealers.

2. INTENDED USE / INDICATION

Structomer® Model resin is intended to be 3D printed into orthodontic models for use in dental applications. The models are individually manufactured by dental professionals.

3. HARDWARE REQUIREMENTS

Structomer® Model can be used in combination with all laser, DLP and LCD based 3D printers which support Structomer® Model materials. Information about supported 3D printers can be obtained from Structo Pte. Ltd. (see Contact Information below).

Please follow the hardware instructions provided by the hardware manufacturer concerning the printing parameters and support structure recommendations for Structomer® Model.

4. CONTRAINDICATION

Any deviation from this instruction for use is not recommended. In case of an allergic reaction, please discontinue use and contact a medical physician.

5. SAFETY INSTRUCTIONS

Structomer® Model is produced and tested according to the most stringent quality standard. To ensure optimum processing and personal safety, please read the information contained in the IFU and MSDS carefully. Improper use and failure to observe the information can have a detrimental effect on device quality and adverse effects on health.

Nitrile gloves, goggles and lab coats should be worn as means of personal protection during resin handling. For proper handling of the resin, refer to Structomer® Model material safety datasheet (MSDS). However, tolerance and sensitivity to particular resin components may vary for each individual, possibly resulting in adverse effects. In such cases, the respective user should discontinue use of Structomer® Model.

6. MANUFACTURING PROCESS

Prepare

- Make sure that printer used is compatible with Structomer® Model.
- Define the printing parameters desired.
- Define support structures required.
- Perform the steps below in a well-ventilated area.

Shake

- Shake bottle well before use for a minimum of 2 mins.
- Pour Structomer® Model into printer reservoir.
- To ensure resin homogeneity, gently scrape the bottom of the printer reservoir to re-mix sitting resin material.

Build

- 3D print the desired dental models.

Remove

- Remove build platform off the 3D printer.
- Remove printed objects off the build platform.

Clean

- Rinse the printed objects, utilizing ultrasonic bath (duration: 5 minutes) to get rid of any excess materials.
- Isopropanol with at least 90% concentration should be used as the cleaning agent.

Remove

- Remove support structures if any is used.

Clean

- Rinse the printed objects again, utilizing ultrasonic bath (duration: 5 - 10 minutes) to clean the printed objects fully.
- **Fresh** Isopropanol with at least 90% concentration must be used as the cleaning agent.

Dry

- Dry the printed objects with compressed dry air to avoid residues of IPA on the object surface.
- In the absence of compressed dry air, the printed objects should be wiped with lint-free cloth and sufficient time for natural drying should be given.

Post-Cure

- Use hardware manufacturer's recommended post curing duration.
- Combination of UV-A (315 - 400 nm) and UV-Blue (400 - 550 nm) wavelengths should be used to achieve full polymerization.

Note: Full polymerization of printed object by post curing is critical to achieve desired material properties and to provide a functional end-product. The manufacturer's recommended processing time is 20 minutes. The value was measured using a device with the following output; six 18W/71 lamps (Dulux L Blue); and six 18W/78 lamps (Dulux Blue UV-A).

Note: Post-curing light sources need routine maintenance following manufacturer's instruction.

7. GENERAL INFORMATION ON HANDLING

7.1. Delivery

Structomer[®] Model is supplied in 1kg tightly sealed bottles. Check the following upon receipt of the materials:

- Integrity of the bottle & packaging.
- Bottle cap seal is intact and not broken.
- Received quantity against delivery order.
- Shipping documents and label designations
- Materials received not past its 'Use-by' date.

7.2. Storage

Structomer[®] Model must be stored in its original sealed bottle and kept away from sunlight to avoid undesired polymerization as the material is photo-sensitive. The expiry date printed on the product must be observed. Satisfactory processing cannot be guaranteed if materials which have exceeded their expiry date are used.

7.3. Cleaning

Fully cured dental models made from Structomer[®] Model can be easily cleaned with non-chemical products and disinfected with ethanol.

7.4. Disposal

Residual waste material in its liquid state (unused Structomer[®] Model or used isopropanol) should be delivered to a collection point for chemical waste material. Structomer[®] Model in its polymerized form is not harmful to the environment.

8. HAZARDS AND PRECAUTIONS

8.1. Hazard Statements

H302	Harmful if swallowed.
H315	May cause skin irritation.
H317	May cause an allergic skin reaction.
H319	May cause serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child.
H413	May cause long lasting harmful effects to the aquatic life.

8.2. Precautionary Statements (Prevention)

P280	Wear protective gloves.
P261	Avoid breathing dust / fumes / gas / mist / vapors / spray.
P273	Avoid release to the environment.
P272	Contaminated work clothing should not be allowed out of the workplace.
P264	Wash skin thoroughly after handling.

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8.3. Precautionary Statements (Response)

P302 + P352	IF ON SKIN (or hair): Wash with plenty of soap and water.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and continue rinsing.
P312	Call a POISON CENTER or doctor / physician if you feel unwell.
P321	Special treatment (see supplementary first aid instructions on this label).
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.

9. LABEL SYMBOLS



Warning



Use-by date



Consult
 Instructions
 for use



Manufacturer



Batch code



Keep away
 from sunlight

10. CONTACT INFORMATION

10.1. Distribution & Manufacturer

Sales & Distribution:

Structo Pte.Ltd.
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Manufacturer:

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