

# TECHNOVENT

## Technical/User Data Sheet

### *Impression Material (M515,M517,M518)*

#### Overview

The material is designed as a general purpose impression material for use within maxillofacial technology. It is recommended for external use only. The material has been independently dermatologically tested on Humans for Human skin contact in accordance with ISO10993.

The material is a 2-part 1:1 room temperature [RT] platinum addition cure system.

The material is supplied in dual cartridge dispensing system for use with the supplied mixing nozzles and dispensing gun (G802). Extra nozzles are available if required (G801).

Platinum (or addition) cure systems do not shrink on curing.

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#### User Instructions

Gun out the required amount of material onto application site. The material has a work time of approximately 1- 2 minutes dependent on ambient temperature.

The material is sufficiently cured to be removed after approximately 3 minutes with full cure being achieved after approximately 5 minutes again dependent on ambient temperature.

#### Notes on using the cartridge dispensing system

Ensure gun plunger is fully back (if not, press small chrome lever up and pull the plunger back)

Place cartridge into dispensing gun and lock in with hinged flap.

Remove end cap from cartridge by twisting and pump gun a little to ensure free flow of material from the two openings at the cartridge end (a small amount of material should be discharged from EACH hole. If this is not the case, remove any plug/blockage before continuing)

Fit new mixing nozzle by locating onto end of cartridge and twisting to lock.

Pump gun several times to advance the plunger until a little of the mixed material is ejected through the end of the nozzle. This initial quantity is recommended to be discarded as full or even mixing may not have been achieved.

#### Note:

**As with all new materials, it is recommended that performance/operation of this material is confirmed by the customer to be harmonious and compatible with any existing systems within which it is to be incorporated, prior to ongoing use, to ensure no unforeseen/adverse reactions occur.**

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### *Impression Material (M515,M517,M518)*

#### 1. Identification of Substance & Company:

Product Name(s)	Impression Materials
Product Code(s)	M515 (Original Blue), M517 (Coform Soft Thixo Purple), M518 Coform Hard Green)
Medical Device Class	Class I
Product Category/Classification	General
Main Use	Impression material for external use
Company	Technovent Ltd Unit 5 Kingsway Building Bridgend Industrial Estate, Bridgend South Wales, UK. CF31 3YH
Tel (& Emergency Tel )	(44) (0) 1656 768566
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#### 2. Composition / Information on ingredients:

Chemical Nature	Dispersion of fumes silica particles in platinum catalysed (ie. Vinyl terminated) silicone fluid
Hazardous Components	None according to EU Directive 1999/45/EC

#### 3. Hazards Identification:

Critical Hazards	None according to EU Directive 1999/45/EC
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#### 4. First Aid Measures:

Eye Contact	May cause temporary irritation. Irrigate with water for 15 mins, holding eyelid open.
Skin Contact	Remove excess and wash with soap and water.
Inhalation of Vapour	N/a.
Ingestion	May result in gastric disturbances. Seek medical advise

#### 5. Fire Fighting Measures

Hazards during firefighting. None

#### 6. Accidental Release Measures:

Personal Protection	Refer to Section 8.
Environmental Precautions	None.

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### *Impression Material (M515,M517,M518)*

#### 7. Handling & Storage:

Handling	No special precautions necessary Observe good housekeeping practises (HSE guidance note CS17)
Storage	Store at room temperature or refrigerated.

#### 8. Exposure Controls / Personal Protection:

General Protective Measures	None deemed necessary
Components with workplace parameters	None according to EU Directive 88/379/EC
Respiratory Protection	Not deemed necessary
Hand Protection	Not deemed necessary, gloves recommended
Eye Protection	Not deemed necessary, eye glasses recommended
Skin Protection	Not deemed necessary
Hygiene Measures	Do not eat, drink or smoke when handling product

#### 9. Physical & Chemical Properties:

Physical Form	Thixotropic fluid
Colour	M515 – Blue, M517 – Purple, M518 - Green
Odour	None
Flash Point	Not determined
Vapour pressure	N/a
Relative Density	Not determined
pH	Not determined
Viscosity	Not determined

#### 10. Stability & Reactivity:

The product is stable under normal storage conditions (refer to Section 7)	
Incompatible materials	Presence of sulphur may interfere with proper curing reaction

#### 11. Toxicological Information:

Long term experience of this product indicates no danger to health when used correctly

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### *Impression Material (M515,M517,M518)*

#### 12. Ecological Information:

Degradation/elimination	Product does not degrade
Bioaccumulation	No evidence for bioaccumulation
Ecotoxic effects	This product is not classified as Dangerous to the Environment

#### 13. Disposal Considerations:

Waste product should not be discharged directly into drains or waterways.	
Disposal of product and packaging should always comply with local and national regulations	
EU waste code number	No Waste Code Number available

#### 14. Transport Information:

This product is not classified as Dangerous for Carriage
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#### 15. Regulatory Information:

Symbol	Not subject to labelling
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#### 16. Other Information:

All information given in this Health & Safety Data Sheet is to the best of our knowledge true and accurate and is provided solely for making safety assessments. It is not a sales specification or an indication of suitability for a particular use nor does it replace the need for your own risk assessment.

All information presented in accordance with EC Directive 2001/58/EC and is correct at date of publication and is given in good faith but without warranty.

We cannot accept liability for any loss, damage or patent infringement resulting from the use of this information.

As with all materials, care should be exercised when handling.