

(M512) Maxillofacial Gel HEAT CURE**Overview**

The material is a 2-part 10:1 platinum (vinyl addition) cure system and is supplied in wide necked tubs for easy removal during use.

The gel base is provided with three different catalysts – each of which yield a different final cure hardness. The catalysts are interblendable so can be mixed to achieve intermediate hardnesses if so desired.

The product is intended for use with M511 Maxillofacial Rubber as an outer skin.

Platinum, or vinyl addition, cure systems do not give off any vapours when curing, consequently there is no shrinkage of the final piece.

User Instructions**Mixing**

Use 10 part A to 1 part of B

ie. 10g part A to 1g part B = 11g total

Please note – if blending different catalysts, it is important to keep the 10:1 ratio constant

ie. 10g part A to 1g part B (0.5g Soft + 0.5g Medium, for example) = 11g total

Curing

	Work Time (at room temp)	Cure time (at room temp)	Cure time (at 100deg C)
Gel (M512)	1hr	n/a	1hr

Please note: Work times are dependent on ambient working temperature.

Ensure that both parts are uniformly and evenly mixed.

Degassing in a vacuum chamber is recommended for bubble-free results.

Designed for external use only. Avoid use on broken skin.



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Using the Gel

Stipple or paint a very thin layer of M511 Maxillofacial Rubber onto both surfaces of the mould. Make sure that a thin, even coating is applied, ensuring that there are no uncovered patches.

Place both halves in an oven at 100deg C for 10-15 mins in order to start the rubber curing process.

NB: Take care not to leave in the oven for too long as it is not intended that the rubber should fully cure at this stage.

Remove the two mould halves from the oven and spatulate a quantity of the catalysed Maxillofacial Gel onto the mould surfaces, ensuring full coverage of the mould.

NB: Take care not to scratch through the rubber skin layer.

Close the mould and clamp in the normal way.

Place the mould in an oven at 100deg C for approx 1 hour for full cure.

Take care when removing the cured prosthesis from the mould.

A word of warning...(applies predominantly to Platinum cured materials)

Take care when using tin catalysed silicones in conjunction with platinum catalysed systems, as the platinum systems are very easily 'poisoned' which can lead to the material not curing up as expected.

This becomes a problem when moulds previously used for curing tin (or latex, etc) systems are then used for platinum systems – it is recommended, therefore, that, where possible, different moulds are used for these two systems.

It is also recommended when using platinum catalysed systems that latex free disposable gloves are used in preference to those which contain latex, if such protection is used, to avoid poisoning the platinum catalyst.

As with all systems, however, a degree of accuracy when weighing and mixing is essential. Good bench practices will assist in the correct, trouble free curing of these materials.



Health & Safety Data Sheet

Maxillofacial Gels (M512)

1. Identification of Substance & Company:

Product Name(s)	Maxillofacial Gels
Product Code(s)	M512 (Heat Cure Gel),
Medical Device Class	Class I (according to Annex IX of EC Directive 93/42/EEC)
Product Category /Classification	G5 (according to Annex IX of EC Directive 93/42/EEC)
Main Use	Manufacture of custom prostheses
Company	Technovent Limited 5 York Park Bridgend South Wales, UK. CF31 3TB
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2. Composition / Information on ingredients:

Chemical Nature	Dispersion of fumed 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 advice

5. Fire Fighting Measures:

Hazards during firefighting	None
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6. Accidental Release Measures:

Personal Protection	Refer to Section 8
Environmental Precautions	None
Methods for clean-up	Collect with tissue or likewise and dispose as Section 13

7. Handling & Storage:

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

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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	Viscous fluid
Colour	Clear
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

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

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.