



Technical/User Data Sheet

Tacky Gel (G511 & G512)

Overview

The material is a 2-part 1:1 room temperature [RT] platinum addition cure system with a low cross-linking level, producing a very soft, high tack gel. This gel, while holding/bonding well to various substrates, demonstrates easy release from skin without bonding onto hair. The adhesive is available in its original version or as a lower viscosity gel in a range of tack strengths. The material is supplied in dual cartridge dispensing system for use with the supplied mixing nozzles and dispensing gun (G802). Extra mixing nozzles are available (G801).

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

Please note: This material preferentially bonds to the Technovent Series range of silicone rubbers and gels.

User Instructions

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

Remove end cap from cartridge by twisting and pump gun 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 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 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.

When finished with, ensure end cap is securely replaced.

Applying

Apply a little of the gel to the back of the prosthesis to be fitted and evenly smooth over the area to be adhered. Allow to cure –

Curing

While, chemically, the system is room temperature curing, the rate of cure can be accelerated with heating in an oven.

At room temp (approx 22 deg C) – allow approx 1-2 hours (**RECOMMENDED**)

At elevated temp (eg, 90 deg C dry oven) - approx 5 minutes.



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DO NOT CURE FOR LONGER THAN 10 MINUTES IN OVEN AS THIS MAY REDUCE ULTIMATE TACK.

Prepare the skin surface with a suitable cleansing agent (alcohol wipe, or similar skin prep product) to remove excessive grease/oil.

Fit prosthesis as normal – take care, as the back will be highly tacky – ensure that the edges do not fold in on themselves.

Alternative fitting procedure

If so desired, the gel may be applied directly to the prepared skin surface in its 'wet' state (ie, directly from the cartridge), and distributed finely over the area to be covered.

Apply the prosthesis to the uncured gel and retention will be of a mechanical nature. This allows the prosthesis to slide over the skin on the wet silicone. The heat of the skin will cause the gel to cure in approximately 30-60 minutes depending on ambient temperature conditions, thus producing the tacky effect in situ – retention is now full and the gel will preferentially bond to the prosthesis rather than the skin to allow for easy removal.

Please note: This method of retention allows for a 'no-solvent' solution, thus reducing any source of skin irritation and enhancing patient/subject comfort.

If required/desired a standard skin adhesive (G609) may be used in order to more securely retain fine edges.

Removal

It is possible to remove the prosthesis from the skin simply by peeling from the edge (depending on prosthesis thickness/strength, etc and whether any other skin adhesives have been used during retention). As the prosthesis is removed the gel will preferentially adhere to the back and peel away from the skin with no need for harsh solvents or vigorous action. The skin will be left clean and free from residual gel. If the piece is removed in a careful manner and is not damaged, etc, it should be possible to reuse it as the gel will not lose its tack with repeat application – thus reducing recasting requirements. We have found that, as long as the prosthesis is relatively flat, a piece of clean glass acts well as a storage medium for the prosthesis.

Note: Tacky Gel cures best against other platinum curing systems within the Cosmesil range of materials, rather than the tin cure systems as the presence of tin may inhibit the cure of the Tacky Gel – however, if the tin rubber or gel is to be used, it is recommended to be encapsulated as this then will not be so prone to poisoning of the platinum catalyst in the Tacky Gel.

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



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1. Identification of Substance & Company

Product Name(s)	Ancillary Materials - Tacky Gel
Product Code(s) strength)	G511 (original) & G512 (low viscosity high, medium & low tack
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	MBI Wales Ltd 5 York Park Bridgend South Wales, UK. CF31 3TB
Tel (& Emergency Tel)	(44) (0) 1656 768566
Fax	(44) (0) 1633 896588
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2. Composition

Chemical Nature	Platinum catalysed 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
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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