



Dow Corning® BIO-PSA 7-4560 Silicone Adhesive

FEATURES & BENEFITS

- Pressure sensitive adhesive
- Hot melt adhesive
- Solventless
- Permeable to many drugs and enhancers
- Non-sensitizing
- Non-irritating
- Solventless adhesive, which softens upon heating, then cools to a nearly flowless state
- May be custom formulated
- Drug master file on record with US Food & Drug Administration

COMPOSITION

- Solid adhesive with hot melt capability

Hot melt silicone pressure sensitive adhesive

APPLICATIONS

- Typical applications include transdermal and medical device adhesion where a solvent carried adhesive is not desirable.

TYPICAL PROPERTIES

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

Test*	Property	Unit	Result
	Nominal tack value		Very High
	Melt viscosity at 185°C (365°F)	mPa.s	25,000
0086	Solid content	%	100
1098E	Rheology Eta* at 0.01 rad/sec at 30°C (86°F)	P	5 x 10 ⁵
0964A	Peel adhesion	g/cm	300
0964A	Shear (kg/6.25 cm)		11

*CTM: Corporate Test Method, copies of CTMs are available on request.

DESCRIPTION

Dow Corning® BIO-PSA 7-4560 Silicone Adhesive is a pressure sensitive adhesive specifically designed to adhere transdermal drug delivery systems and medical devices to the skin. It can be melted for coating, and then will return to a generally flowless state upon cooling.

HOW TO USE

Dow Corning BIO-PSA 7-4560 Silicone Adhesive is supplied as a solid resinous material. As supplied, this adhesive may be applied to a liner using conventional hot melt coating equipment. Release liners composed of a fluoropolymer are recommended for use with this adhesive.

SYNTHESIS AND STRUCTURE

Dow Corning BIO-PSA 7-4560 Silicone Adhesive is produced through a condensation reaction of a silanol endblocked polydimethylsiloxane (PDMS) with a silicate resin. The addition of a polydimethylsiloxane plasticizer to the condensate provides the adhesive's hot melt characteristics. The schematic diagram illustrates the adhesive's synthesis Figure 1.

BIOCOMPATIBILITY

Dow Corning BIO-PSA 7-4560 Silicone Adhesive solids have passed biocompatibility tests that meet current USP Biological Reactivity in vivo test requirements. USP intracutaneous reactivity tests indicate the adhesive is also non-irritating.

Adhesive extracts were further evaluated for acute toxicity effects using direct topical application of the adhesive extracts. The material did not produce a sensitization reaction when applied to the skin of albino guinea pigs. The results of all biocompatibility studies performed on this adhesive are shown in Table 2.

HANDLING

PRECAUTIONS

PRODUCT SAFETY

INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE SAFETY DATA SHEET IS AVAILABLE ON THE DOW CORNING WEBSITE AT DOWCORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

USABLE LIFE AND STORAGE

When stored at or below 25°C (77°F) in the original unopened containers, this product has a usable life of 24 months from the date of production.

PACKAGING INFORMATION

This product is typically supplied in 180 kg (397 lb), net weight.

LIMITATIONS

This product is not tested for specific pharmaceutical or medical device use(s). Should you wish to use this product in a pharmaceutical or medical device application, please contact Dow Corning to discuss such potential use.

It remains the User's responsibility to ensure the safety, efficacy and legal and regulatory compliance in each relevant jurisdiction (including

targeted geographic regions of manufacture and supply) of these materials for its intended uses.

Dow Corning makes no representation concerning the suitability of these products for any particular medical or pharmaceutical application. Under no circumstances should these materials be considered for implantation into the human body for periods that exceed 30 days in duration.

MANUFACTURING ENVIRONMENT

This product is manufactured, tested and packaged using appropriate principles of current Good Manufacturing Practice (cGMP) regulations for Bulk Pharmaceutical Products at the Healthcare Industries Materials Site (Hemlock MI). The Healthcare Industries Materials Site is dedicated to the production of silicone materials for healthcare applications. The site is registered with the United States Food and Drug Administration (FDA) as a drug establishment (CFN 1816403). Dow Corning is globally registered to the ISO 9001 Quality Standard. Certification to ISO 9001 through an independent party indicates that Dow Corning operates a quality management system in accordance with the standard, ensuring appropriate documentation and traceability.

REGULATORY STATUS

A Drug Master File for *Dow Corning* BIO-PSA 7-4560 Silicone Adhesives is on file with the United States Food and Drug Administration. Comparable regulatory filings have also been prepared in Europe and Japan. Customers wishing authorization to reference the files must contact Dow Corning Corporation.

HEALTH AND ENVIRONMENTAL INFORMATION

To support customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance

(PS&RC) specialists available in each area.

For further information, please see our website, dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION – PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that our products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that our products will meet the sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 2: Biocompatibility of Dow Corning BIO-PSA Silicone Adhesives

Test	Result
USP Systemic Toxicity/USP Biological Reactivity	No difference between extract and control
Irritation (USP intra-cutaneous method)	Non-irritating
Cytotoxicity (in-vitro)	No cytopathic effects
Sensitization	Non-sensitizing

Figure 1. Diagram of Dow Corning BIO-PSA 7-4560 Silicone Adhesive synthesis

