

DOW CORNING® BIO-PSA

Standard Silicone Adhesives

FEATURES

- Pressure sensitive adhesive
- Compatible with many drugs
- Permeable to many drugs and excipients
- Non-sensitizing
- Cosmetically acceptable

BENEFITS

- May be custom formulated
- Drug master file on record with US Food & Drug Administration

COMPOSITION

- Adhesive in solvent

BIO-PSA 7-4401, BIO-PSA 7-4501, BIO-PSA 7-4601, BIO-PSA 7-4402, BIO-PSA 7-4502, and BIO-PSA 7-4602 Silicone Adhesives

Non-sensitizing, Pressure Sensitive Adhesives

APPLICATIONS

- Typical applications include transdermal drug delivery systems.

DESCRIPTION

BIO-PSA Standard Silicone Adhesives are pressure sensitive adhesives in solvents specifically designed for pharmaceutical use. These adhesives are permeable to many drugs and excipients and are designed to adhere drug-loaded systems to the skin.

HOW TO USE

BIO-PSA Standard Silicone Adhesives are typically supplied in heptane or ethyl acetate. Adhesives may be provided in other solvent choices by special arrangement.

These adhesives may be applied to a liner, as supplied using conventional tape coating equipment.

These adhesives bond very strongly to many substrates so fluoropolymer release liners are recommended.

These adhesives can also be further diluted with compatible solvents or blended with drugs, excipients or other silicone pressure sensitive adhesives before being coated.

SYNTHESIS AND STRUCTURE

BIO-PSA Standard Silicone Adhesives are produced through a condensation reaction of a silanol endblocked polydimethylsiloxane (PDMS) with a silicate resin, as shown in Figure 1.

BIOCOMPATIBILITY

The solids found in the BIO-PSA Silicone adhesives have passed biocompatibility tests that meet current USP biological reactivity in vivo test requirements.

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

Every production batch of the BIO-PSA Silicone Adhesives is tested for the absence of cytopathic effects using a cytotoxicity test (direct contact method).

HANDLING PRECAUTIONS

Product safety information required for safe use is not included. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The material safety data sheet is available on the Dow Corning website at www.dowcorning.com. You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

USABLE LIFE AND STORAGE

When stored at or below 25°C (77°F) in the original unopened containers, these products have a usable life of 72 months from the date of production. The solvents that carry these adhesives are flammable and typically have very low flash points. Precautions appropriate to the individual solvents must be observed.

PACKAGING

These products are typically supplied in 16kg (35 lb) pails and 180kg (397 lb) drums, net weight.

Samples are available in 0.45kg (1 lb) bottles.

LIMITATIONS

This product is neither tested nor represented as suitable for specific medical or pharmaceutical uses.

MANUFACTURING ENVIRONMENT

These products are 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. This certification through an independent party indicates that Dow Corning operates a quality management system in accordance with the ISO 9001 Quality Standard, ensuring appropriate documentation and traceability.

REGULATORY STATUS

A Drug Master File for BIO-PSA Standard 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, www.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 Dow Corning's 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 the product will meet the Dow Corning 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.

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 1: Typical properties

The BIO-PSA Silicone Adhesives are available in the typical formulations shown below or as custom formulated products designed to meet the unique requirements of specific transdermal drug delivery systems. Contact your Dow Corning sales representative for more information.

Specification writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative prior to writing specifications on this product

CTM†	Property	Unit	Value					
			7-4401	7-4501	7-4601	7-4402	7-4502	7-4602
	Nominal tack value		Low	Medium	High	Low	Medium	High
	Solvent		Heptane	Heptane	Heptane	Ethyl acetate	Ethyl acetate	Ethyl acetate
0086	Solid content	%	60	60	60	60	60	60
	Viscosity	mPa.s	450	700	1000	650	1500	2600
0964A	Peel adhesion	g/cm	-	700	500	-	700	500
0964A	Shear	(kg/6.25cm)	-	16	15	-	16	15
1098E	Rheology Eta* at 0.01 rad/sec at 30°C (86°F)	P	5x10 ⁸	5x10 ⁷	5x10 ⁶	5x10 ⁸	5x10 ⁷	5x10 ⁶

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

Table 2: Biocompatibility of BIO-PSA Silicone Adhesives

Test	Results
Cytotoxicity (in-vitro)	No cytopathic effects
Irritation (USP intra-cutaneous method)	Non-irritating
Sensitization	Non-sensitizing
USP Systemic Toxicity/USP Biological Reactivity	No difference between extract and control
90-Day implant	Equivalent response between control and test material at 90 days
USP Pyrogen test	Met test requirements for absence of pyrogens

Figure 1: Diagram of BIO-PSA Standard Silicone Adhesive synthesis.

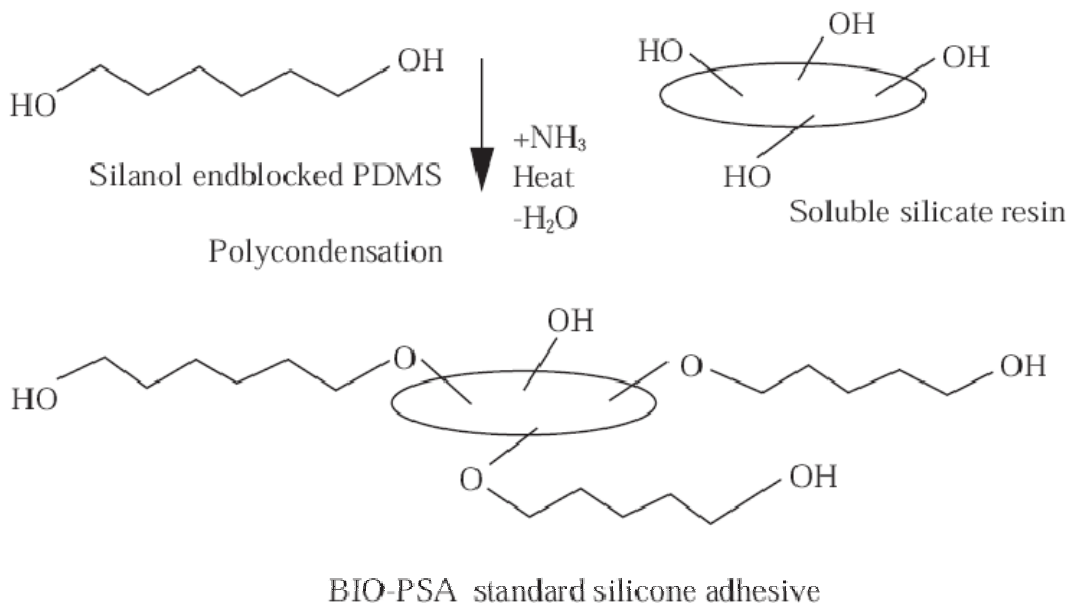


Figure 2: Typical rheological profiles of BIO-PSA Silicone Adhesives.

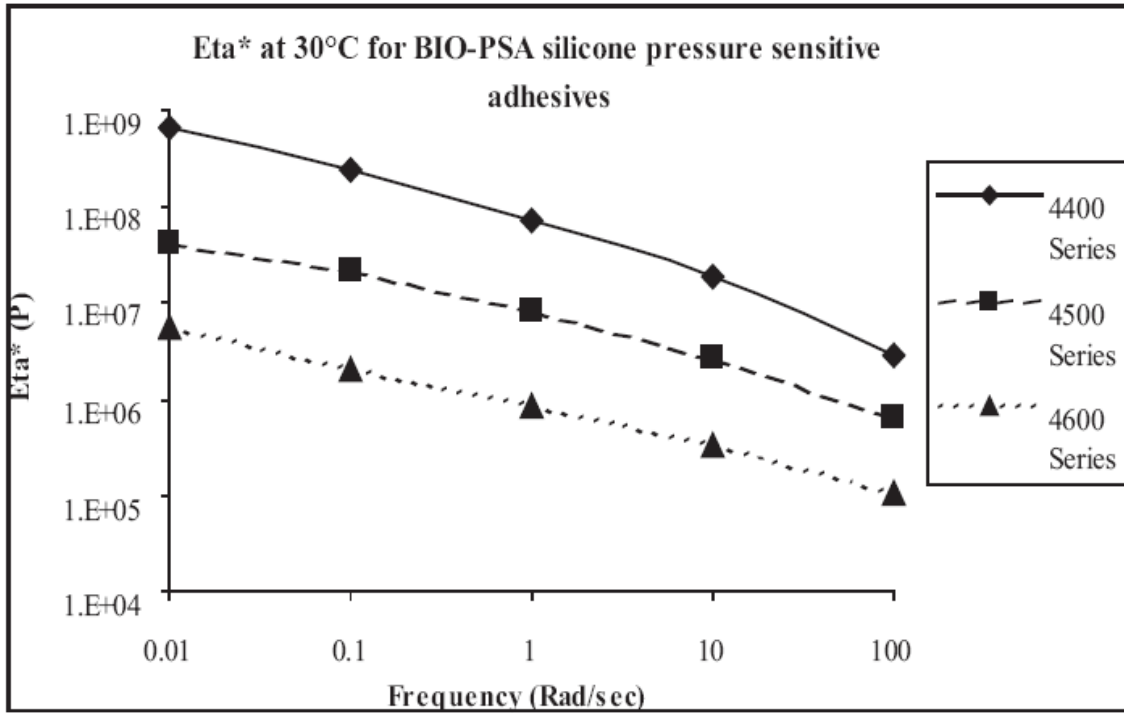


Figure 3: Typical viscosity data of medium tack BIO-PSA standard adhesives solvated in Heptane and Ethyl acetate.

