Product Information
Healthcare

DOW CORNING® BIO-PSA 7-4560 Silicone Adhesive

FEATURES

- Pressure sensitive adhesive
- Hot melt adhesive
- Solventless
- Permeable to many drugs and enhancers
- Non-sensitizing
- Non-irritating

BENEFITS

- 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.

DESCRIPTION

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

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

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 Figure1.

BIOCOMPATIBILITY

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. 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 25ºC (77ºF) in the original unopened containers, this product has a usable life of 36 months from the date of production.

PACKAGING

This product is typically supplied in 16kg (35 lb) pails and 180kg (397 lb) drums or fiber packs, net weight.

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

LIMITATIONS

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

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 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, 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

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
	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	$5x10^5$
0964A	Peel adhesion	g/cm	300
0964A	Shear	(kg/6.25cm)	11

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

Table 2: Biocompatibility of BIO-PSA Silicone Adhesives

Test	***Results***
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 BIO-PSA 7-4560 Silicone Adhesive synthesis.

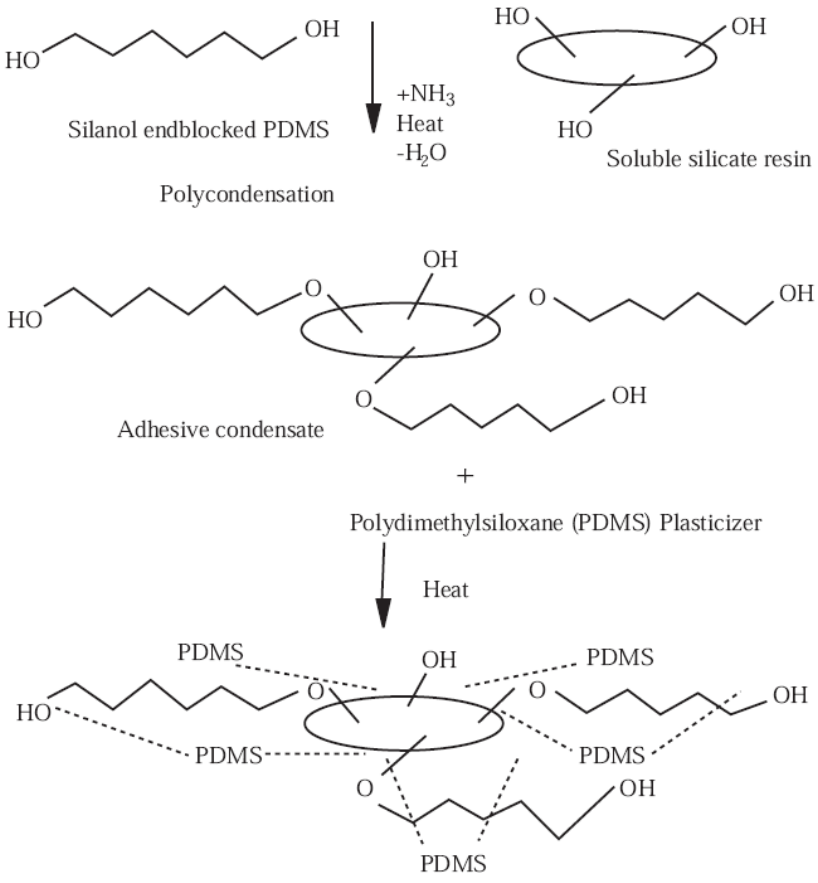


Figure 2. Eta* at 100 rad/sec during dynamic temperature sweep of silicone hot melt pressure sensitive adhesives prepared with various plasticizer levels.

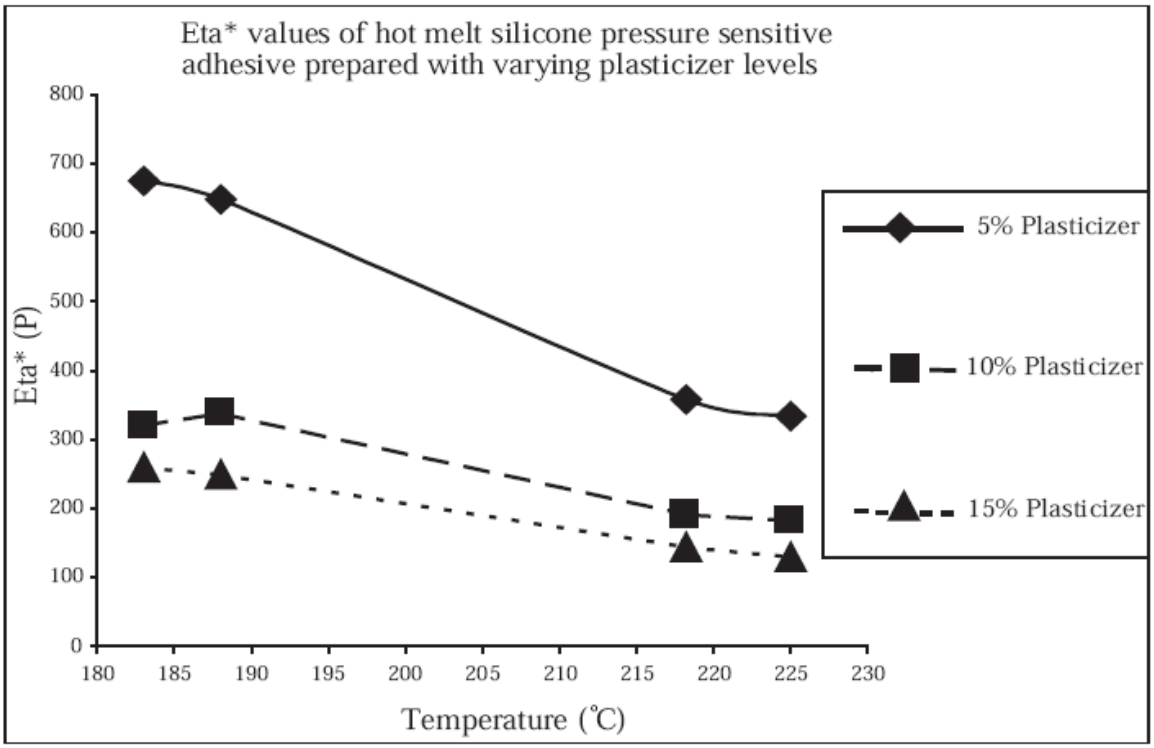
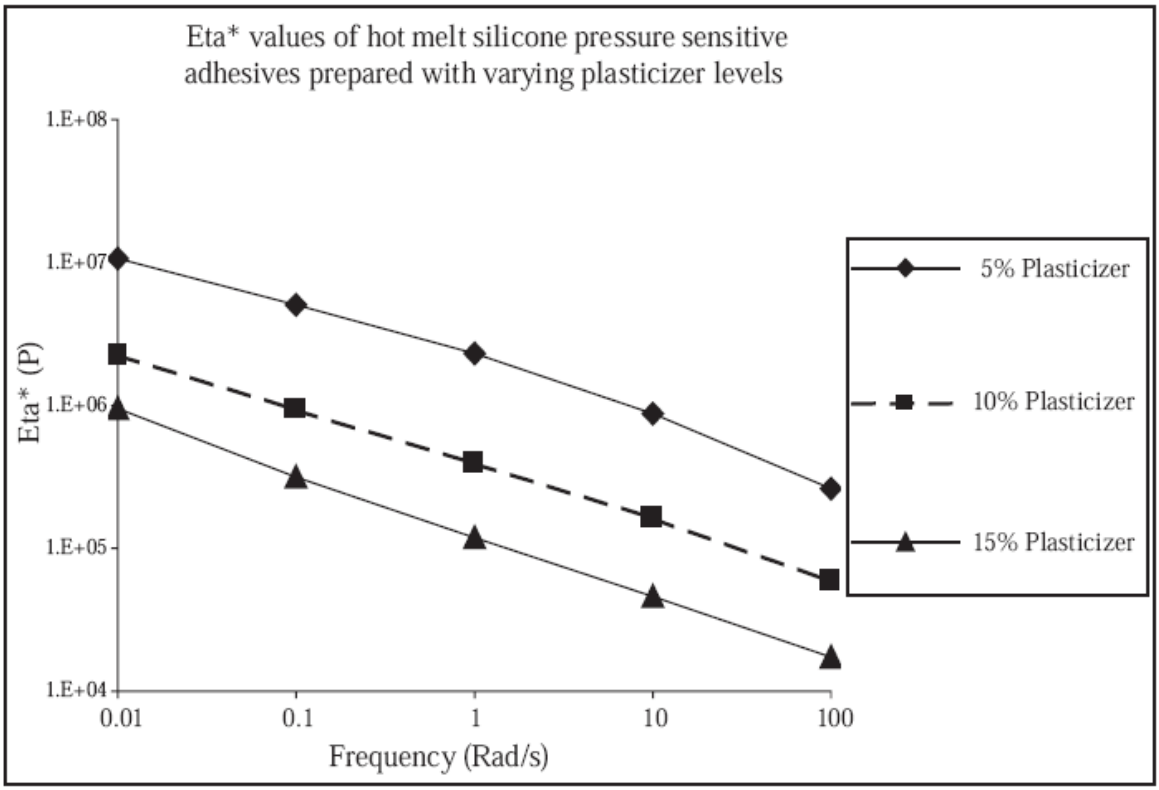


Figure 3. Eta* at 30 °C during dynamic frequency sweep of silicone hot melt pressure sensitive adhesives prepared with various plasticizer levels.



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