

***Dow Corning*[®] BIO-PSA Amine- Compatible Silicone Adhesives**

***Dow Corning*[®] BIO-PSA 7-4101 Silicone Adhesive**

***Dow Corning*[®] BIO-PSA 7-4201 Silicone Adhesive**

***Dow Corning*[®] BIO-PSA 7-4301 Silicone Adhesive**

***Dow Corning*[®] BIO-PSA 7-4102 Silicone Adhesive**

***Dow Corning*[®] BIO-PSA 7-4202 Silicone Adhesive**

***Dow Corning*[®] BIO-PSA 7-4302 Silicone Adhesive**

FEATURES & BENEFITS

- Pressure sensitive adhesive
- Compatible with many drugs
- Permeable to many drugs and excipients
- Non-sensitizing
- Non-irritating
- Enhanced chemical stability in the presence of amine-functional drugs
- May be custom formulated
- Drug master file on record with US Food & Drug Administration

COMPOSITION

- Adhesive in solvent

Non-sensitizing, Pressure Sensitive Adhesives

APPLICATIONS

- Typical applications include transdermal drug release products due to the adhesive's enhanced chemical stability in the presence of amine-functional drugs, excipients and enhancers.

DESCRIPTION

Dow Corning[®] BIO-PSA Amine-Compatible Silicone Adhesives are pressure sensitive adhesives in solvents specifically designed for pharmaceutical use. They are designed to adhere transdermal drug delivery systems to the skin and show enhanced chemical stability in the presence of amine-functional drugs, excipients and enhancers.

HOW TO USE

Dow Corning BIO-PSA Amine-Compatible 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

Dow Corning BIO-PSA Amine Compatible Silicone Adhesives are produced through a condensation reaction of a silanol endblocked polydimethyl-siloxane (PDMS) with a silicate resin. The residual silanol functionality is then capped with trimethylsiloxy groups to yield the chemically stable amine-compatible adhesive as shown in Figure 1.

BIOCOMPATIBILITY

The solids found in the *Dow Corning* BIO-PSA Amine-Compatible Silicone Adhesives have passed biocompatibility tests that meet current USP biological reactivity in vivo test requirements. USP intracutaneous reactivity tests performed on the adhesives indicate the adhesive solids are also non-irritating.

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 *Dow Corning* 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 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, 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 INFORMATION

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

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

SHIPPING LIMITATIONS

These products contain a flammable solvent. Refer to product packaging and SDS for additional information.

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.

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 1: Typical Properties

The *Dow Corning* BIO-PSA Amine-Compatible Silicone Adhesives are available in the standard formulations shown below or as custom formulated products designed to meet the unique requirements of specific transdermal drug delivery systems.

- *Dow Corning*® BIO-PSA 7-4101 Silicone Adhesive
- *Dow Corning*® BIO-PSA 7-4201 Silicone Adhesive
- *Dow Corning*® BIO-PSA 7-4301 Silicone Adhesive
- *Dow Corning*® BIO-PSA 7-4102 Silicone Adhesive
- *Dow Corning*® BIO-PSA 7-4202 Silicone Adhesive
- *Dow Corning*® BIO-PSA 7-4302 Silicone Adhesive

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 | Results | | | | | |
|--|--|------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| <i>Dow Corning</i>® BIO-PSA Amine-Compatible Silicone Adhesives | | | | | | | | |
| | | | 7-4101 | 7-4201 | 7-4301 | 7-4102 | 7-4202 | 7-4302 |
| | 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 | 150 | 450 | 500 | 350 | 800 | 1200 |
| 0964A | Peel adhesion | g/cm | – | 900 | 700 | – | 900 | 700 |
| 0964A | Shear | kg/6.25 cm | – | 17 | 14 | – | 17 | 14 |
| 1098E | Rheology Eta* at 0.01 rad/sec at 30°C (86°F) | P | 1 x 10 ⁹ | 1 x 10 ⁸ | 5 x 10 ⁶ | 1 x 10 ⁹ | 1 x 10 ⁸ | 5 x 10 ⁶ |

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

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

| Test | Result |
|---|--|
| 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 control and test material (30 and 90 days) |
| 90-Day implant | Equivalent response between control and test material (30 and 90 days) |
| USP Pyrogen test | Met test requirements for absence of pyrogens |

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Figure 1. Diagram of Dow Corning BIO-PSA Amine-Compatible silicone adhesive synthesis

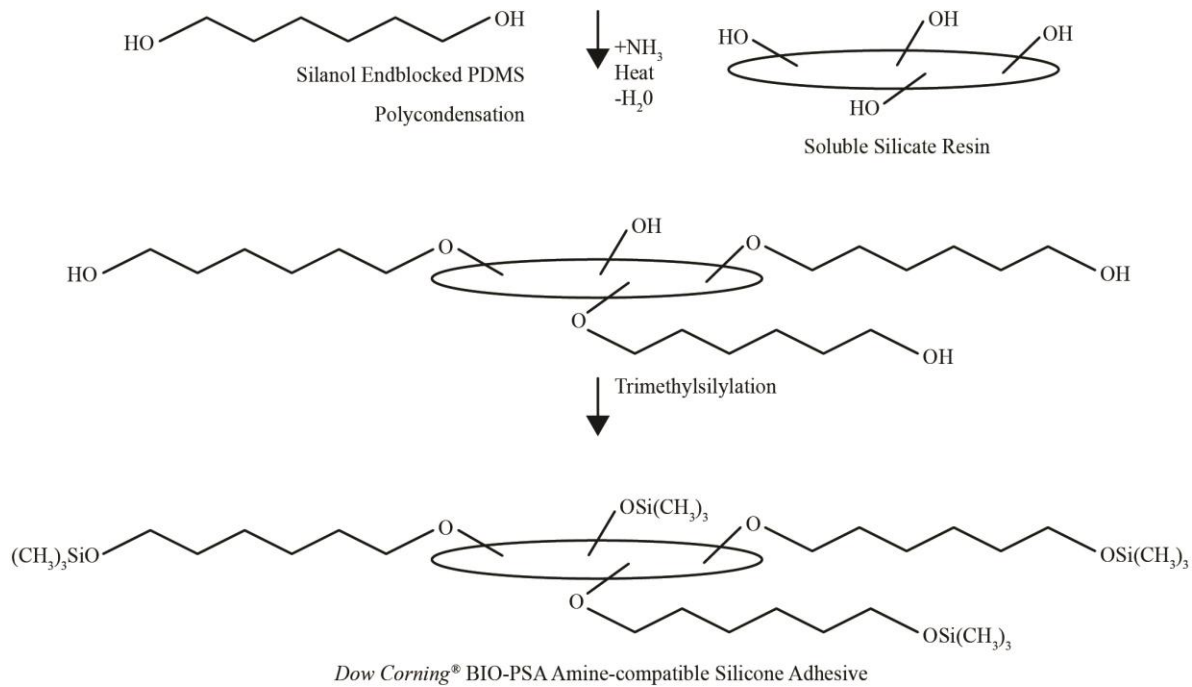


Figure 2. Typical rheological profiles of Dow Corning BIO-PSA Amine-Compatible adhesives

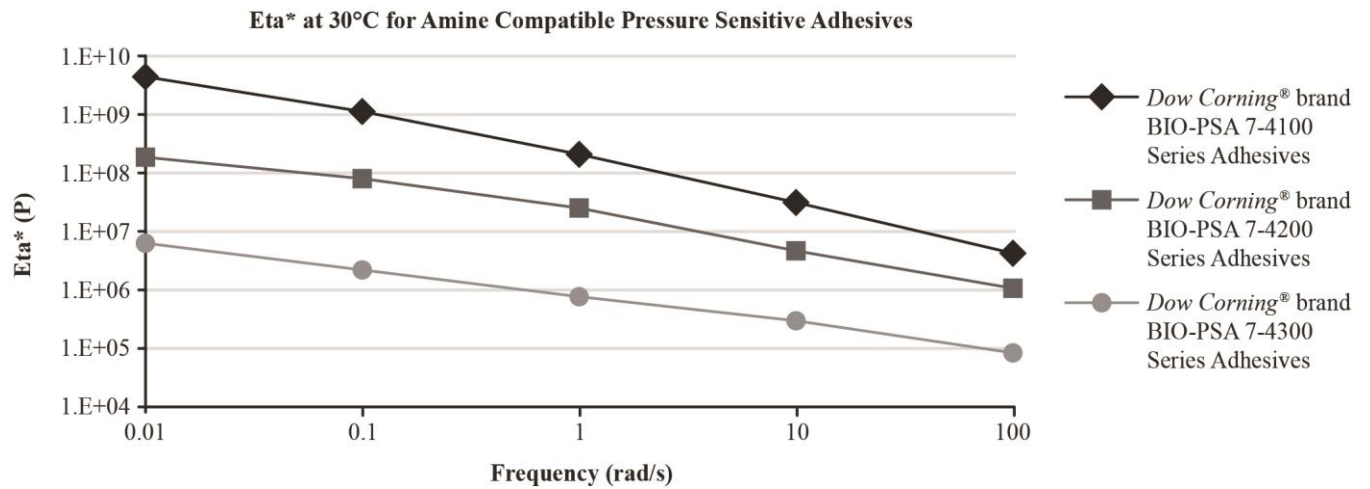


Figure 3. Typical viscosity data of medium tack Dow Corning BIO-PSA Amine-Compatible

