

# Silicone Adhesives

To assure consistent quality for pharmaceutical drug delivery and wound applications, pressure sensitive adhesive and soft skin adhesive products are manufactured, packaged, and tested at the Healthcare Industries Materials Site utilizing principles of GMP guidelines for Active Pharmaceutical Ingredients (APIs).

## Regulatory Status

FDA Material Application File

Technical<sup>1</sup> and FDA Drug Master File

## Biocompatibility Tests

Cytotoxicity

Mutagenicity/Genotoxicity

Skin Irritation

Skin Sensitization

Pyrogenicity (USP)

Systemic Toxicity

## Medical Device Pressure Sensitive Adhesives

## Transdermal and Topical Drug Delivery Pressure Sensitive Adhesives<sup>2</sup>

### Description

### Typical Applications

Solvent-based non-sensitizing, non-irritating, pressure-sensitive adhesive formulations

• Adhesion of dressings, prosthetics, and other devices to the body

Amine-compatible adhesive in solvent; custom formulation upon solvent selection

• Skin adhesion of transdermal drug delivery systems; specifically designed for compatibility with aminofunctional drugs

Custom adhesive formulations in solvent

• Skin adhesion of transdermal drug delivery systems to the body

Solventless adhesive formulation with adjustable tack (customizable)

• Skin adhesion of transdermal drug delivery systems to the body

Product	Regulatory Status	Biocompatibility Tests	Medical Device Pressure Sensitive Adhesives	Transdermal and Topical Drug Delivery Pressure Sensitive Adhesives <sup>2</sup>
Dow Corning <sup>®</sup> MD7-4502 Silicone Adhesive	•	•	•	•
Dow Corning <sup>®</sup> MD7-4602 Silicone Adhesive	•	•	•	•
Dow Corning <sup>®</sup> BIO-PSA 7-430X Silicone Adhesive	•	•	•	•
Dow Corning <sup>®</sup> BIO-PSA 7-420X Silicone Adhesive	•	•	•	•
Dow Corning <sup>®</sup> BIO-PSA 7-410X Silicone Adhesive	•	•	•	•
Dow Corning <sup>®</sup> BIO-PSA 7-460X Silicone Adhesive	•	•	•	•
Dow Corning <sup>®</sup> BIO-PSA 7-450X Silicone Adhesive	•	•	•	•
Dow Corning <sup>®</sup> BIO-PSA 7-440X Silicone Adhesive	•	•	•	•
Dow Corning <sup>®</sup> BIO-PSA Hot Melt Adhesive	•	•	•	•

## Typical Properties<sup>†</sup>

Property	Value	Units
Solids Content	65	%
Peel Adhesion	Medium	
Tack	High	
Solvent	Ethyl Acetate	
Solution Viscosity at 25°C	2500	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	5 × 10 <sup>7</sup>	
Solids Content	60	%
Peel Adhesion	High	
Tack	High	
Solvent	Ethyl Acetate	
Solution Viscosity at 25°C	2600	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	5 × 10 <sup>6</sup>	
Solids Content	60	%
Peel Adhesion	High	
Tack	High	
Solvent	Heptane or Ethyl Acetate	
Solution Viscosity at 25°C	500 <sup>4</sup> , 1200 <sup>5</sup>	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	5 × 10 <sup>6</sup>	
Solids Content	60	%
Peel Adhesion	Medium	
Tack	Medium	
Solvent	Heptane or Ethyl Acetate	
Solution Viscosity at 25°C	450 <sup>4</sup> , 800 <sup>5</sup>	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	1 × 10 <sup>8</sup>	
Solids Content	60	%
Peel Adhesion	Low	
Tack	Low	
Solvent	Heptane or Ethyl Acetate	
Solution Viscosity at 25°C	150 <sup>4</sup> , 350 <sup>5</sup>	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	1 × 10 <sup>9</sup>	
Solids Content	60	%
Peel Adhesion	High	
Tack	High	
Solvent	Heptane or Ethyl Acetate	
Solution Viscosity at 25°C	1000 <sup>4</sup> , 2600 <sup>5</sup>	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	5 × 10 <sup>6</sup>	
Solids Content	60	%
Peel Adhesion	Medium	
Tack	Medium	
Solvent	Heptane or Ethyl Acetate	
Solution Viscosity at 25°C	700 <sup>4</sup> , 1500 <sup>5</sup>	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	5 × 10 <sup>7</sup>	
Solids Content	60	%
Peel Adhesion	Low	
Tack	Low	
Solvent	Heptane or Ethyl Acetate	
Solution Viscosity at 25°C	450 <sup>4</sup> , 650 <sup>5</sup>	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	5 × 10 <sup>8</sup>	
Solids Content	100	%
Peel Adhesion	Very High	
Tack	Very High	
Solvent	None	
Solution Viscosity at 25°C	25,000 <sup>6</sup>	mPa-s
Rheology – Eta* at 0.01 rad/s at 30°C	5 × 10 <sup>5</sup>	

## Regulatory Status

FDA Material Application File

FDA Drug Master File

## Biocompatibility Tests<sup>3</sup>

Cytotoxicity

Skin Irritation

Skin Sensitization

## Soft Skin Adhesives

### Description

### Typical Applications

Two-part, platinum-catalyzed adhesive, unfilled silicone elastomer

• Clear and soft skin adhesive for wound dressing and pharmaceutical topical or transdermal applications

Product	Regulatory Status	Biocompatibility Tests
Dow Corning <sup>®</sup> 7-9800 A & B	•	•
Dow Corning <sup>®</sup> 7-9700 A & B	•	•

Property	Value	Units
Pot Life <sup>7</sup> at Room Temperature	140	min
Viscosity at 25°C	400	mPa-s
Penetration (62.5 g probe weight) Appearance	Clear	mm/10
Penetration (62.5 g probe weight) Appearance	Clear	mm/10

<sup>1</sup> Dow Corning can provide Technical Files as needed to meet requirements.

<sup>2</sup> X = 1 for heptane, X = 2 for ethyl acetate.

<sup>3</sup> Tested according to ISO 10993-1 standard for skin contact duration ≤30 days.

<sup>†</sup> Specifications Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office prior to writing specifications on these products.

<sup>4</sup> 60% PSA solids in heptane.

<sup>5</sup> 60% PSA solids in ethyl acetate.

<sup>6</sup> Melt viscosity at 185°C.

<sup>7</sup> Time from initial mixing to double viscosity.