

MD® 1045-M

Multipurpose Adhesive for Prefillable Syringes and Injection Devices

APPLICATIONS

- · Glass Prefillable Syringes
- Plastic Prefillable Syringes
- Pen Injectors
- · Auto Injectors
- Single Use Devices

FEATURES

- UV/Visible Light Cure
- LED Curable at 365 nm
- Non Yellowing
- Compatible with Multiple Sterilization Methods
- Very Low Extractables

RECOMMENDED SUBSTRATES

- Glass
- SS
- ABS
- PC

BIOCOMPATIBILITY

- ISO 10993-4 Hemolysis
- ISO 10993-5 Cytotoxicity
- ISO 10993-6 Implantation
- ISO 10993-10 Intracutaneous Irritation
- ISO 10993-11 Systemic **Toxicity**

Dymax MD® 1045-M is designed for rapid assembly of prefillable syringes and other pen or autoinjector devices, especially with glass cartridges or syringes. Dymax MD medical device adhesives contain no nonreactive solvents and cure upon exposure to light. Their ability to cure in seconds enables faster processing, greater output, and lower processing costs. When cured with Dymax light-curing spot lamps, focused-beam lamps, or flood lamps, they deliver optimum speed and performance for device assembly. This material is 100% solids. Dymax lamps offer the ideal balance of UV and visible light for the fastest, deepest cures. This product is in full compliance with RoHS directives 2015/863/EU.

UNCURED PROPERTIES *		
Property	Value	Test Method
Solvent Content	No Nonreactive Solvents	N/A
Chemical Class	Acrylated Urethane	N/A
Appearance	Colorless to Light Yellow Liquid	N/A
Soluble in	Organic Solvents	N/A
Density, g/ml	1.08	ASTM D1875
Viscosity, cP	475 (nominal)	DSTM 502‡
Shelf Life at Recommended Conditions from Date of Manufacture	7 months	N/A

CURED MECHANICAL PROPERTIES *		
Property	Value	Test Method
Durometer Hardness	D78	ASTM D2240
Tensile at Break, MPa [psi]	23.4 [3,400]	ASTM D638
Elongation at Break, %	20	ASTM D638
Modulus of Elasticity, MPa [psi]	1,861.6 [270,000]	ASTM D638

OTHER CURED PROPERTIES *		
Property	Value	Test Method
Refractive Index (20°C)	1.50	ASTM D542
Boiling Water Absorption, % (2 h)	3.8	ASTM D570
Water Absorption, % (25°C, 24 h)	1.0	ASTM D570
Linear Shrinkage, %	0.3	ASTM D2566
Glass Transition Tg, °C	61	ASTM D5418
CTEα1, μm/m/°C	68	ASTM E831
CTEα2, μm/m/°C	206	ASTM E831

ADHESION		
Substrate	Recommendation	
ABS acrylonitrile-butadiene-styrene	~	
PA polyamide	0	
PC polycarbonate	*	
PET poly(ethylene terephthalate)	>	
PETG poly(ethylene terephthalate)glycol	>	
PMMA poly(methyl methacrylate)	0	
PSU polysulfone	>	
PU polyurethane	*	
PVC poly(vinyl chloride)	~	
SAN styrene-acrylonitrile	~	
GL glass (borosilicate, quartz, mica)	~	
SS stainless steel	~	

[✓] Recommended o Limited Applications











st Requires Surface Treatment (e.g. plasma, corona treatment, etc.)

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CURING GUIDELINES

Fixture time is defined as the time to develop a shear strength of 0.1 N/mm² [10 psi] between glass slides. Actual cure time typically is 3-to-5 times fixture time.

Dymax Curing System (Intensity)	Fixture Time or Belt Speed ^A
5000-EC (200 mW/cm ²) ^B	2 s
BlueWave [®] AX-550 RediCure [®] 365 nm (425 mW/cm ²) ^C	1.6 s
BlueWave [®] MX-275 RediCure [®] 365 nm (965 W/cm ²) ^c	1.4 s
BlueWave [®] 200 (10 W/cm ²) ^B	1.4 s
BlueWave [®] MX-150 RediCure [®] 365 nm (15 W/cm ²) [©]	1.6 s

- A Fixture times/belt speeds are typical for curing thin films through 100% UV and light-transmitting substrates. Light-obstructing substrates may require longer cure times.

 B Intensity was measured over the UVA range (320-395 nm) using a Dymax ACCU-CAL™ 50 Radiometer.

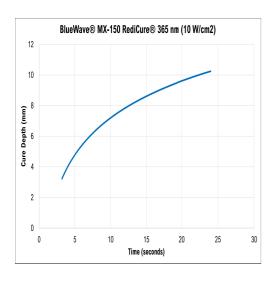
 C Intensity was measured over the UVA/Visible range (350-450 nm) using a Dymax ACCU-CAL™ 50-LED Radiometer.

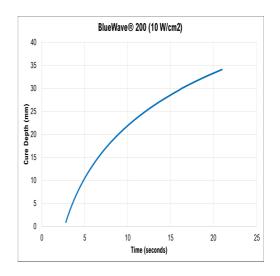
Full cure is best determined empirically by curing at different times and intensities, and measuring the corresponding change in cured properties such as tackiness, adhesion, hardness, etc. Full cure is defined as the point at which more light exposure no longer improves cured properties.

Dymax recommends that customers employ a safety factor by curing longer and/or at higher intensities than required for full cure. Although Dymax Application Engineering can provide technical support and assist with process development, each customer must ultimately determine and qualify the appropriate curing parameters required for their unique application.

DEPTH OF CURE

The graph below shows the increase in depth of cure as a function of exposure time. A 9.5 mm [0.37 in] diameter specimen was cured in a polypropylene mold and cooled to room temperature. It was then released from the mold and the cure depth was measured.







MD® MEDICAL DEVICE ADHESIVES 1045-M Product Data Sheet

OPTIMIZING PERFORMANCE AND HANDLING

- 1. This product cures with exposure to UV and visible light. Exposure to ambient and artificial light should be kept to a minimum before curing. Dispensing components including needles and fluid lines should be 100% light blocking, not just UV blocking.
- 2. All bond surfaces should be clean and free from grease, mold release, or other contaminants prior to dispensing the adhesive.
- 3. Cure speed is dependent upon many variables, including lamp intensity, distance from the light source, required depth of cure, bond gap, and percent light transmission of the substrate.
- 4. Oxygen in the atmosphere may inhibit surface cure. Surfaces exposed to air may require high-intensity UV light to produce a dry surface cure. Flooding the bond area with an inert gas, such as nitrogen, can also reduce the effects of oxygen inhibition.
- 5. Parts should be allowed to cool after cure before testing and subjecting to any loads.
- 6. In rare cases, stress cracking may occur in assembled parts. Three options may be explored to eliminate this problem. One option is to heat anneal the parts to remove molded-in stresses. A second option is to open the gap between mating parts to reduce stress caused by an interference fit. The third option is to minimize the amount of time the liquid adhesive remains in contact with the substrate(s) prior to curing.
- 7. Light curing generally produces some heat. If necessary, cooling fans can be placed in the curing area to reduce the heating effect on components.
- 8. At the point of curing, an air exhaust system is recommended to dissipate any heat and vapors formed during the curing process.

DISPENSING SUPPORT

The Dymax Application Engineering team is ready to discuss your application requirements to provide the most appropriate dispensing and/or spraying solution. Visit our current dispensing equipment portfolio here or consult our global contact phone numbers and online chat feature (available in North America only) during normal business hours for instant support.

STORAGE AND SHELF LIFE

Store the material in a cool, dark place when not in use. Do not expose to light. This product may polymerize upon prolonged exposure to ambient and artificial light. Keep covered when not in use. This material shelf life noted on page 1 of this document, when stored between 10°C (50°F) and 32°C (90°F) in the original, unopened container.

STERILIZATION

Compatible sterilization methods include gamma irradiation and ethylene oxide as well as a limited number of autoclave cycles. It remains the user's obligation to ascertain the effect of sterilization on the cured adhesive.

CLEANUP

Uncured material may be removed from dispensing components and parts with organic solvents. Cured material will be impervious to many solvents and difficult to remove. Cleanup of cured material may require mechanical methods such as ultrasonic bath, water jet, vacuum tweezers, air knife and/or warming to aid in the removal.

BIOCOMPATIBILITY

Polymerized Dymax MD® medical device adhesives are biocompatibility tested in accordance with ISO 10993 and/or USP Class VI. The completed tests are listed on each product data sheet. Copies of the test reports are available upon request. In all cases, it is the user's responsibility to determine and validate the suitability of these adhesives in the intended medical device. These adhesives have not been tested for prolonged or permanent implantation and are only intended for use in short-term (<29 days) or single-use disposable-device applications. Dymax does not authorize their use in long-term implant applications. Customers using these materials for such applications do so at their own risk and take full responsibility for ensuring product safety and biocompatibility.



MD® MEDICAL DEVICE ADHESIVES 1045-M Product Data Sheet

GENERAL INFORMATION

This product is intended for industrial use only. Keep out of the reach of children. Avoid breathing vapors. Avoid contact with skin, eyes, and clothing. Wear impervious gloves. Repeated or continuous skin contact with uncured material may cause irritation. Remove material from skin with soap and water. Never use organic solvents to remove material from skin and eyes. For more information on the safe handling of this material, please refer to the Safety Data Sheet before use.

The data provided in this document are based on historical testing that Dymax performed under laboratory conditions as they existed at that time and are for informational purposes only. The data are neither specifications nor guarantees of future performance in a particular application. Dymax does not guarantee that this product's properties are suitable for the user's intended purpose.

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