



Silicone
Elastomers
FOR HEALTHCARE





The Power of Possibilities

At Momentive, the most important question we ask is "What if?" It's a question that speaks directly to what we believe. Like an exploring spirit, and a dedication to discovering the new, and the better. In approaching each opportunity with tenacity and technology. In knowing that collaboration and partnership yields exponential results. And we believe that together, with you, we can push the boundaries of what we all thought possible.

For more than 75 years we've fostered an unexpected, innovative way of looking at and solving challenges. From the soles of the boots that first walked on the moon to tires that more tightly hug the roads here on earth, we invent solutions that work solutions that deliver real results. We are a tenacious partner with a thirst to understand your challenges. We have the deep industry knowledge and the vast collective experience that inspires both bold approaches and breakthrough innovations. We believe in asking "What if?" Then, together, inventing something that makes "What if?" real.

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Silicones in Healthcare

Strong Solutions for Healthcare

Finely tuned formulations are nowhere more important than in healthcare applications. Momentive silicone elastomers can meet healthcare's rigorous challenges. We help medical manufacturers produce strong yet comfortable orthopedic devices, optically transparent yet flexible medical tubing, sterilization-tolerant yet durable dental and surgical devices.

From ease of processability in manufacturing to easy tolerance when in contact with the human body, Momentive silicones can meet the exacting demands of the healthcare industry. Our decades of biomedical collaboration have led to a range of products that have made new equipment possible and standard equipment work better. Our breadth of experience ensures that wherever there is a need, we'll have the industry knowledge and expertise to help our customers meet it.

Exceptional Range

The exceptional performance properties of silicone elastomers – purity, clarity, strength, thermal stability – coupled with ease of processability, have allowed their use in a broad range of medical device applications.

Typical applications include, but are not limited to:

- Dental / surgical devices
- Diagnostics / imaging
- Fluid and drug delivery devices
- Orthopedics / prosthetics
- Advanced Wound Care & Scar Management
- Septa / stoppers / laboratory accessories
- Medical tubing
- Wound drains and bulbs
- Sterilization mats
- Pharmaceutical closures
- Instrument grips
- Positioning devices
- Catheters
- Seals / dialysis o-rings / valves
- Respiratory / anesthesia
- Medical equipment keypads

Whether it is self-bonding for two component molding, low hysteresis for improved pump life performance, the ability to withstand repeated sterilization, or radio-opaque materials to enable x-ray detection, Momentive has a product with the characteristics that can meet even the most challenging medical design requirements.



Silicone's Key Features and Typical Benefits for Healthcare

Silicones:

- **Endure repeat sterilization.** Medical devices that incorporate silicone maintain their performance characteristics after many rounds of sterilization with steam, ethylene oxide, gamma or e-beam radiation. Silicone's high thermal and chemical stability helps make this possible.
- **Provide optical transparency** due to their high clarity.
- **Offer biocompatibility.** Silicones are generally compatible with both body fluids and medications, and are skin friendly and atraumatic.
- **Innately create comfort and good ergonomics.** Without plasticizers or other organic additives, silicones can provide elasticity, high friction, soft grip, minimal insertion force and smooth operation. They also possess neutral odor and taste.
- **Generate long service life.** Silicones exhibit resiliency and recovery after puncture. They can reduce material fatigue and endure dynamic stress.
- **Comply with regulations.** Momentive silicones are tested to meet or exceed USP Class VI and/or ISO 10993 biocompatibility standards.

Antimicrobial

Addressing the heightened concern over microbial contamination on critical medical device surfaces, our StatSil* antimicrobial silicone elastomers can offer medical device designers an added layer of built-in protection, to help minimize microbial growth in or on the human body.

Comfort

Contributing to the comfort and care of patients, which has become an essential factor in device design, our low-durometer elastomers and visco-elastic gels can deliver enhanced cushioning and pressure care relief.

Biocompatibility

At Momentive, we offer a comprehensive portfolio of silicone products that are ISO 10993 and/or USP Class VI compliant.

Clarity

Optical transparency is increasingly important in both medical electronics and healthcare devices. Whether it is light guides, respiratory masks, or endoscopic device components, Momentive's ultra-clear liquid silicone rubbers (LSRs) can provide glass-like transparency coupled with elastomeric functionality.

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Segments

Typical Healthcare Application Areas

- Dental + Surgical Devices
 - Dental Impression Molds
 - Fluid + Drug Delivery Devices
 - Respiratory + Anesthesia Devices
 - Orthopaedics + Prosthetics + Pressure Care
 - Medical Electronics
 - Catheters
 - Wound Drainage
-

Advanced Wound Care and Scar Management

- Sterilization Mats + Brackets
- Diagnostic + Imaging Equipment Components
- Pharmaceutical Transfer Hose + Tubing
- Septa + Stoppers + Laboratory Accessories
- Peristaltic Pump Tubing



Silicone Gels for Advanced Wound Care

Innovative Materials with the Patient in Mind

The health care industry is faced with a growing challenge of developing products that can improve patient care and adhere to the highest safety standards, while also contributing to cost-effective production. With our long history as a leading provider of silicones to the medical field, Momentive prides itself on the innovative material solutions we have created to help solve tough manufacturing challenges.

Equipped for both open and closed wound applications, Momentive's silicones for wound care combine atraumatic properties and high adhesion with biocompatibility to help improve production efficiencies.

Silicones Enable Advanced Wound Care

Momentive's Silopren* silicone gel product family, with its inherent water vapor and gas permeability properties, promotes wound healing through improved moisture transport. Even when applied to the fragile skin of elderly and medically compromised patients, the Silopren silicone gel family enables both secure skin adhesion and atraumatic removal.

These properties make Silopren silicone gels an exceptional choice for patients requiring repeated wound care application and removal over the same area. Silopren silicone gel also enables easy repositioning of wound dressings.

The high tack of Silopren silicone gels facilitates the manufacture of wound care dressings at lower silicone coat weights, which can enable production efficiencies. The Silopren silicone gel product family for advanced wound care includes kit matched, addition-cure, solvent-free, and transparent two-component (1:1 mix ratio) silicone rubber gels that are compatible with most coating processes.

Self-Lubricating LSR for Healthcare

Productivity & Performance for Molded Parts

Momentive's family of liquid silicone rubber (LSR) materials enable health care device designers and equipment manufacturers to improve material functionality for critical applications such as needle-free access valves, o-rings, stoppers, seals and assembled parts. One especially significant advancement is our line of self-lubricating LSRs, which includes Silopren LSR 4655 SL.

Lubrication produces a high-slip surface (low coefficient of friction), which can improve mounting efficiency of molded parts during the assembly of medical devices. Traditional silicone molded parts cannot achieve high slip, leaving manufacturers to employ secondary lubrication processes.

Silopren LSR 4655 SL is a two-component, self-lubricating LSR for injection molding processes. Without the need for a secondary lubrication process, Silopren LSR 4655 SL can provide a lubricious surface on the molded part after vulcanization. The product's delayed lubricant surface bloom after vulcanization helps prevent mold fouling. It also helps improve part longevity, and reduce the occurrence of self-healing of slit valves.

Silopren LSR 4655 SL can be customized in a range of durometers and lubricant load levels to meet specific performance requirements.

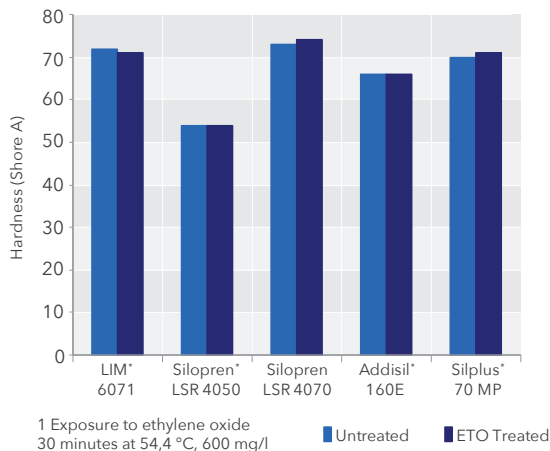
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Sterilization Performance

The strength of the silicone-oxygen backbone leads to high thermal stability of silicone elastomers. Due to this property, silicone elastomers are excellent candidates for products and applications requiring sterilization, whether by steam autoclave, ETO, or gamma radiation. These charts depict the performance of a sampling of our products after exposure to sterilization.

Effects of ETO Sterilization

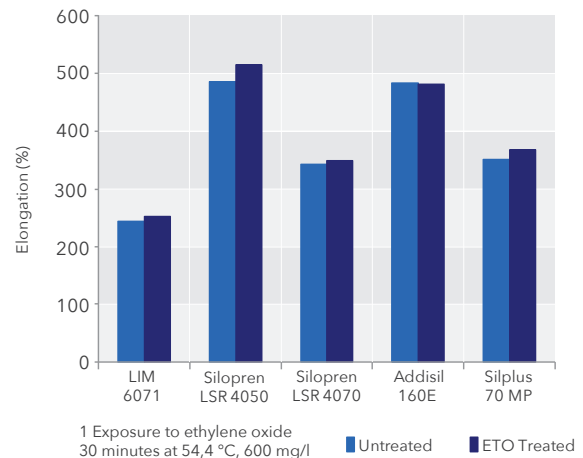
ETO Sterilization resistance¹ Hardness



After ETO exposure, minor changes were measured vs. baseline values.

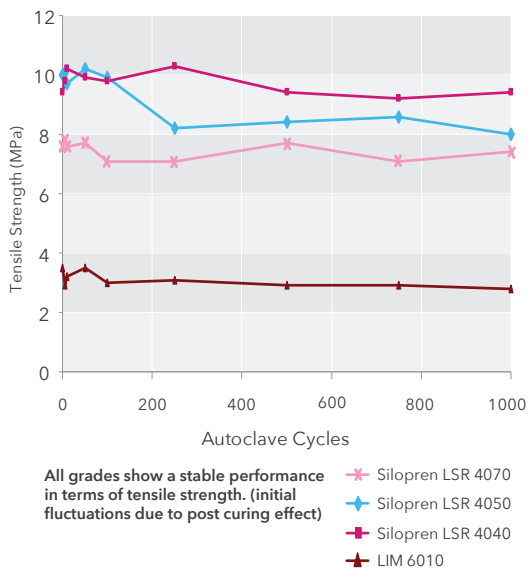
Note: Test data. Actual results may vary.

ETO Sterilization resistance¹ Elongation



After ETO exposure, minor changes were measured vs. baseline values.

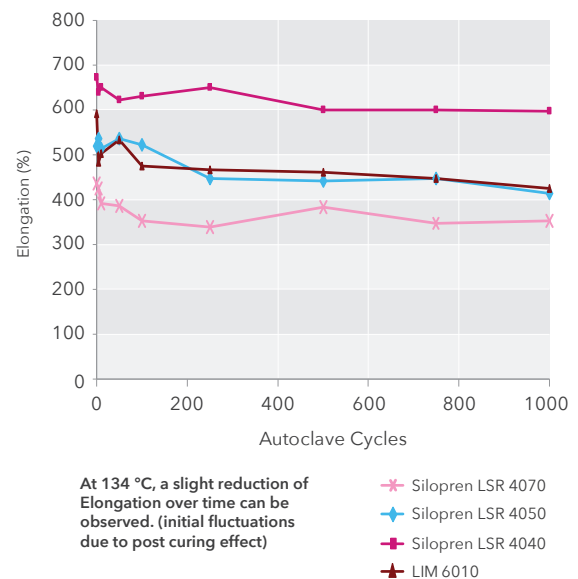
Sterilization resistance at 134 °C Tensile Strength - LSR



Note: Test data. Actual results may vary.

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Sterilization resistance at 134 °C Elongation - LSR

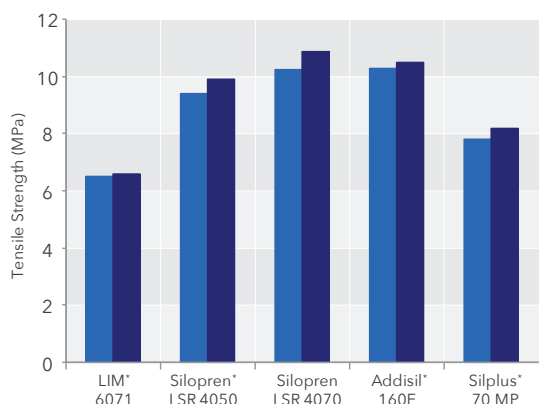


Conditions

ETO concentration	600 mg/L
ETO pressure	26.6 psia
Pre-humidification time at 60% RH	30 min
Pre-vacuum	1.5 psia

Chamber Temperature	54.4 °C
Exposure Time	2 h
Post vacuum	1.45 psia
Air washes	3

ETO Sterilization resistance¹ Tensile Strength

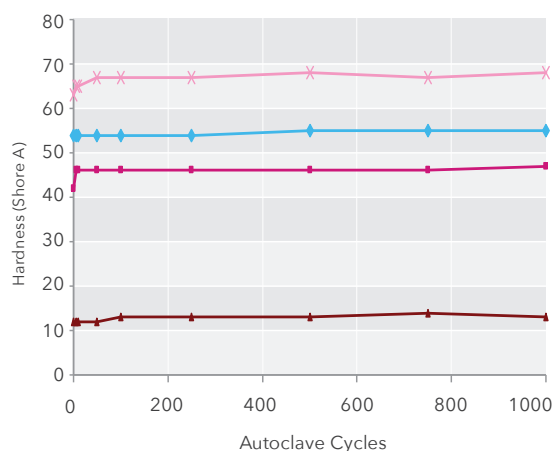


¹ Exposure to ethylene oxide
30 minutes at 54.4 °C, 600 mg/l

After ETO exposure, minor changes were measured vs. baseline values.

Note: Test data. Actual results may vary.

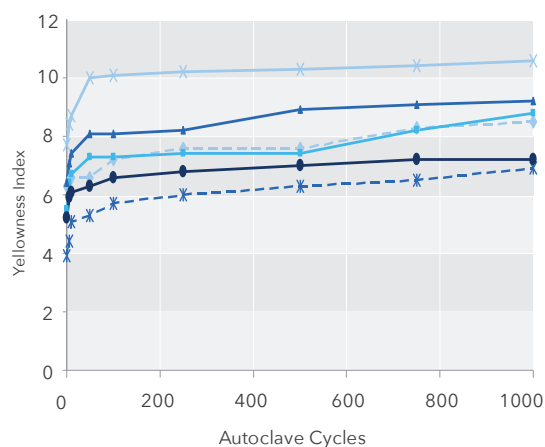
Sterilization resistance at 134 °C Shore A Hardness - LSR



No significant impact on hardness,
independent of hardness level.

* Silopren LSR 4070
 ◆ Silopren LSR 4050
 ■ Silopren LSR 4040
 ▲ LIM 6010

Sterilization resistance at 121 °C Yellowness Index - LSR



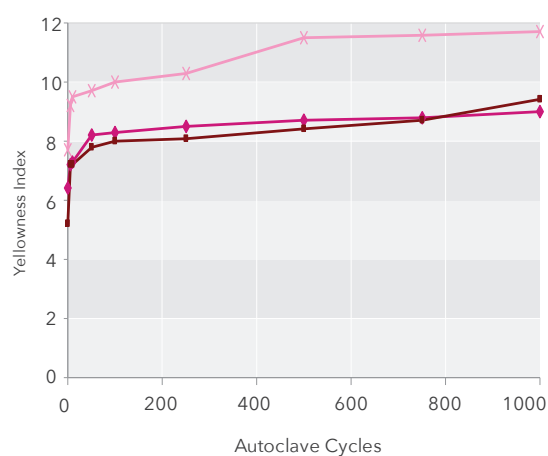
In most cases yellowing will occur
during the first 100 cycles,
independent of grades used.

* Silopren LSR 4070
 ◆ Silopren LSR 2070 Top Coat
 ■ Silopren LSR 4050
 ▲ Silopren LSR 4040
 * Silopren LSR 4040 Blue
 ● LIM 6010

Note: Test data. Actual results may vary.

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Sterilization resistance at 134 °C Yellowness Index - LSR



In most cases yellowing will occur during
the first 100 cycles, independent of grades
used. Yellowing at 134 °C is slightly
higher compared to sterilization
at 121 °C.

* Silopren LSR 4070
 ■ Silopren LSR 4040
 ▲ LIM 6010

Liquid Silicone Rubber (LSR) for Healthcare

Product Name	USP Class VI ^a	ISO10993 ^b	BIR ^c	FDA Indirect Food Contact ^d	European Pharmacopoeia ^e	Appearance	Density g/cm ³	Hardness/Durometer Shore A	Tensile Strength MPa	Elongation %	Tear Strength, Die B N/mm	Compression Set % (post-cured)
Healthcare												
Silopren* LSR 4020	•	•	+	•	-	Translucent	1.08	22	7.0	1000	15	20
Silopren LSR 4030	•	•	+	•	•	Translucent	1.10	31	8.0	800	18	15
Silopren LSR 4040	•	•	+	•	•	Translucent	1.12	40	9.0	750	25	25
Silopren LSR 4050	•	•	+	•	•	Translucent	1.12	51	10.0	600	35	25
Silopren LSR 4060	•	•	+	•	•	Translucent	1.13	60	10.0	450	30	25
Silopren LSR 4070	•	•	+	•	•	Translucent	1.14	70	9.0	400	20	25
Silopren LSR 4080	•	•	+	•	•	Translucent	1.13	79	7.0	150	5	25
Fast Cure/High Tear												
Silopren LSR 4640	•	•	+	•	-	Translucent	1.12	42	8.0	600	45	25
Silopren LSR 4650	•	•	+	•	-	Translucent	1.12	52	10.0	550	50	25
Silopren LSR 4660	•	•	+	•	-	Translucent	1.13	62	9.0	400	45	20
Silopren LSR 4670	•	•	+	•	-	Translucent	1.13	69	10.0	350	30	20
LIM* 6010	•	•	+	+	-	Translucent	1.05	15	3.0	440	10	-
LIM 6030	•	•	+	•	-	Translucent	1.12	35	9.0	675	31	-
LIM 6040	•	•	+	•	-	Translucent	1.12	42	9.0	600	39	-
LIM 6045	•	•	+	•	-	Translucent	1.12	44	9.0	650	39	-
LIM 6050	•	•	+	•	-	Translucent	1.12	53	9.0	530	43	-
UV LSR												
Silopren UV LSR 4030	•	•	+	•	-	Translucent	1.10	28	8.0	750	20	-
Silopren UV LSR 4060	•	•	+	•	-	Translucent	1.15	59	13.0	500	25	-
Self-Lubricating												
Silopren LSR 4655 SL	•	•	-	-	-	Translucent	1.13	55	8.0	450	45	-
Reduced Self-Healing												
Silopren LSR 4040 RSH	•	•	+	•	-	Translucent	1.12	40	11.0	700	30	12
Silopren LSR 4650 RSH	•	•	+	•	-	Translucent	1.13	51	10.5	550	48	-
Self-Bonding												
Silopren LSR 4739	•	•	-	-	-	Translucent	1.1	32	8.0	650	30	-
LIM 8040	•	-	-	-	-	Translucent	1.08	43	5.0	390	37	>50
CLS 8150	•	•	-	-	-	Translucent	1.10	52	8.0	515	34	-
CLS 5000	•	•	-	-	-	Translucent	1.12	67	11.0	460	44	-
CLS3060	•	•	-	-	-	Translucent	1.12	59	11.0	500	35	-
Radio Opaque (X-Ray Detectability)												
LIM 6041	•	-	•	•	-	White	1.19	45	7.0	700	32	-

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Heat Cured Rubber (HCR) for Healthcare

Product Name	USP Class VI ^a	ISO10993 ^b	BfR ^c	FDA Indirect Food Contact ^d	European Pharmacopoeia ^e	Appearance	Density g/cm ³	Hardness/Durometer Shore A	Tensile Strength MPa	Elongation %	Tear Strength, Die B N/mm	Compression Set % (post-cured)
Addisil* Extrusion												
140 E	•	•	•	•	•	Translucent	1.15	45	10.0	700	35	-
150 E	-	-	•	•	•	Translucent	1.15	52	10.0	650	36	-
160 E	•	•	•	•	•	Translucent	1.16	61	10.5	530	32	-
170 E	•	•	•	•	•	Translucent	1.20	71	9.5	470	32	-
440 E/442 E	-	-	+	•	-	Translucent	1.13	40	11.5	800	35	-
450 E/452 E	-	-	+	•	-	Translucent	1.14	50	11.5	800	43	-
460 E/462 E	-	-	+	•	•	Translucent	1.14	60	11.0	600	37	-
470 E/472 E	-	-	+	•	-	Translucent	1.17	72	10.5	500	41	-
480 E/482 E	-	-	+	•	-	Translucent	1.19	81	9.0	400	30	-
Tufel II Low Volatile Extrusion or Molding												
9420X	•	-	+	•	-	Translucent	1.07	22	8.2	1000	22	-
9430X	•	-	+	-	-	Translucent	1.10	28	9.3	1050	30	-
9440X	•	-	+	-	-	Translucent	1.11	43	9.6	780	40	-
9450X	•	-	+	-	-	Translucent	1.15	52	9.7	880	47	-
9460X	•	-	+	-	-	Translucent	1.19	62	8.6	690	46	-
9470X	•	-	+	-	-	Translucent	1.22	62	9.2	580	57	-
Tufel III Biocompatible Extrusion - Low Hysteresis/ High Resilience												
92506	•	•	-	+	-	Translucent	1.12	50	7.6	500	18	-
92656	•	•	-	•	-	Translucent	1.14	65	8.9	350	21	-
UV Extrusion												
Addisil UV 450 EX	•	•	+	•	-	Translucent	1.16	50	12.1	920	45	-
Addisil UV 460 EX	•	•	+	•	-	Translucent	1.17	60	10.5	580	47	-
Addisil UV 450 EX	•	•	+	•	-	Translucent	1.20	66	9.6	420	29	-
Radio Opaque (X-Ray Detectability)												
Addisil 60 X-Ray Detectability	-	-	-	-	-	White	1.2	-	-	-	-	-

The aforementioned test results are average data derived from a sampling of a finite number of lots of material. While lot-to-lot variance would not be expected to show significantly different results, these average data are not to be used as or to develop product specifications. It is the user's sole responsibility to determine the suitability and safety of any Momentive material in its end use application.

All LSR grades are platinum cured materials. The mixing ratio is 1:1 by weight, except for the UV-curing LSR the mixing ratio is 100:2.

Laboratory Vulcanization Conditions: exposure to a Hg-(Fe-doped) middle pressure lamp for 2 min at 80 mW/cm² intensity, without further heat curing

a Based upon USP Class VI testing, on a representative sample of the product, for intramuscular implantation, intracutaneous injection and systemic injection. For some products, additional testing has been conducted. Please contact the Product Regulatory Group for details.

b Based upon ISO 10993 part 6, 10, and 11 testing conducted on a representative sample of the product. For some products additional testing has been conducted. Please contact the Product Regulatory Group for details.

c Based on listing of ingredients in the BfR recommendation XV "Silicones".

c¹ Producer of the final article needs to test and confirm that the final product meets the analytical and extractive requirements of BfR XV.

d Based on compositional compliance with the requirements of 21 CFR 177.2600 - Rubber articles intended for repeated use and have been found, through extractive testing of a representative sample, to meet the extractives limitations in 21 CFR 177.2600(e) and/or (f).

d¹ It is the responsibility of the user to determine that the final product complies with the extractive limitations and other requirements of 21 CFR 177.2600 under their specific manufacturing procedures.

e Based on testing conducted on a representative sample of a single lot of the product as per the test requirements of EP 3.1.9.

• = Meets the requirements for passing the test standard, + = Product is compositionally compliant, - = Not tested.

Additional information may be contained on the technical datasheet.

For custom opportunities, please contact your local Momentive sales representative.

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Patent Status

Nothing contained herein shall be construed to imply the nonexistence of any relevant patents or to constitute the permission, inducement or recommendation to practice any invention covered by any patent, without authority from the owner of the patent.

Product Safety, Handling and Storage

Customers should review the latest Safety Data Sheet (SDS) and label for product safety information, safe handling instructions, personal protective equipment if necessary, emergency service contact information, and any special storage conditions required for safety. Momentive Performance Materials (MPM) maintains an around-the-clock emergency service for its products. SDS are available at www.momentive.com or, upon request, from any MPM representative. For product storage and handling procedures to maintain the product quality within our stated specifications, please review Certificates of Analysis, which are available in the Order Center. Use of other materials in conjunction with MPM products (for example, primers) may require additional precautions. Please review and follow the safety information provided by the manufacturer of such other materials.

Limitations

Customers must evaluate Momentive Performance Materials products and make their own determination as to fitness of use in their particular applications.

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