



MOMENTIVE
performance materials

StatSil* Antimicrobial Elastomers for medical device applications

Product Description

The heightened concern in the healthcare setting over microbial growth in or on the human body has prompted many design engineers to seek high-performance material solutions with built-in antimicrobial protection. Responding to that trend, Momentive Performance Materials has developed a custom elastomer platform technology based on the direct incorporation of a silver-based antimicrobial additive into the base silicone elastomer. StatSil antimicrobial elastomer technology may provide end users with greater design flexibility and performance in applications where controlling the growth of microbes in or on the body is of concern. Customers can choose from Momentive's globally recognized LIM* or LSR liquid silicone rubber and HCE base elastomers, ranging in durometers from 3 to 80 shore A. USP Class VI, ISO10993, FDA Indirect Food Contact, and/or European Pharmacopoeia compliant bases may be available. (Note 1).

Why Silver?

Silver has long been shown to have antimicrobial activity versus a broad spectrum of both gram-positive and gram-negative bacteria, as well as, mold and fungi. Its effectiveness against a variety of microorganisms has been demonstrated in several published studies. The mechanism of action in which silver works as an effective antimicrobial has been described in the following way: The ionic silver carries a strong positive charge so it has a high affinity for negatively charged groups of biological molecules. It works by altering the molecular structure of biological molecules and rendering it worthless to the cell. This attack on multiple sites within a cell simultaneously has been described to inactivate many functions such as cell wall synthesis, membrane transport, nucleic acids synthesis and translation, and protein folding and function, thus resulting in inhibition of bacterial/microbial growth.

Momentive Performance Materials provides versatile materials as the starting point for our creative approach to ideas that help enable new developments across hundreds of industrial and consumer applications. We are helping customers

solve product, process, and performance problems; our silanes, fluids, elastomers, sealants, resins, adhesives, urethane additives, and other specialty products are delivering innovation in everything from car engines to biomedical devices.

From helping to develop safer tires and keeping electronics cooler, to improving the feel of lipstick and ensuring the reliability of adhesives, our technologies and enabling solutions are at the frontline of innovation.

Key Features and Typical Benefits

- Low additive loading levels
- Silver based additive
- Ready to use formulations
- Additive dispersed throughout the polymer matrix
- Customized formulations
- Maintain key physical properties
- Broad spectrum of activity
- No secondary operations (*i.e.* coatings)
- Won't abrade off, longer lasting effects
- Design flexibility

Typical Physical Properties

Hardness, Shore A	70	73
Tensile Strength, psi	1230	1550
Elongation, %	400	386
Tear B, ppi	114	147
100% Modulus, psi	370	450

Potential Applications

Control of Microbial Growth in or on the Human Body

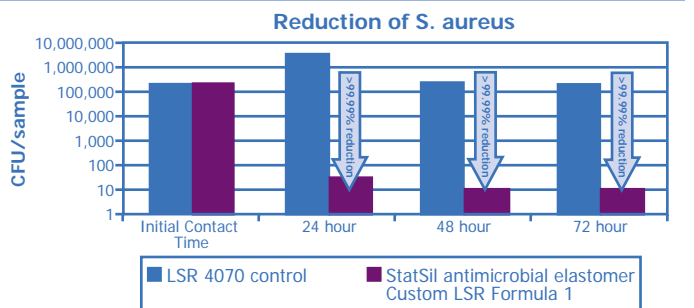
The U.S. EPA generally regulates antimicrobial materials (including antimicrobial-containing articles) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA exempts from pesticide regulation articles where the antimicrobial additive is intended to control the growth of microbes in or on the human body, *e.g.* catheters, wound drains and needleless access valves (Note 2). StatSil antimicrobial elastomer may be considered only for such potential uses, and should not be claimed to be used for other purposes, *e.g.*, to control microorganisms outside the human body.

Performance

Efficacy of StatSil antimicrobial elastomer

The efficacy of StatSil antimicrobial custom LSR formula 1 was assessed for two common bacteria using a standard quantitative test method, AATCC 100, modified for silicone elastomers. All testing was conducted at an independent test facility. The following tests are solely to show the efficacy of the antimicrobial additive when incorporated into silicone elastomers vs. a control sample with no antimicrobial additive. End users are solely responsible for insuring that the elastomer is appropriate for their end use, including claims restricted to control of microorganisms in or on the human body, and for complying with all applicable FDA and/or EPA regulations when using these materials. (Note 3)

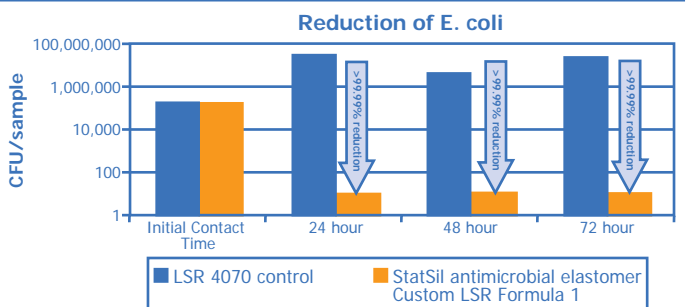
Figure 1: Microbial Challenge Test (gram +)



Test Method	AATCC method 100/Film Contact method	Innoculum Concentration	S. aureus
Culture Medium	Tryptic Soy Broth	(CFU/0.4mL)	ATCC #6638
Sample Size	35 mm x 35 mm	24 hour test	1.4×10^5
Innoculum Carrier	Sterile Saline/0.2% Nutrient Broth	48 hour test	2.4×10^5
		72 hour test	1.4×10^5

Test results. Actual results may vary.

Figure 2: Microbial Challenge Test (gram -)



Test Method	AATCC method 100/Film Contact method	Innoculum Concentration	E. coli
Culture Medium	Tryptic Soy Broth	(CFU/0.4mL)	ATCC #8739
Sample Size	35 mm x 35 mm	24 hour test	1.6×10^5
Innoculum Carrier	Sterile Saline/0.2% Nutrient Broth	48 hour test	1.9×10^5
		72 hour test	1.1×10^5

Test results. Actual results may vary.

Customized Solutions

Momentive Performance Materials custom elastomer formulation services can help you identify a material engineered to the performance, processing, and production demands unique to your requirements. The same applies to our antimicrobial product offering. Our chemists can customize a solution for you based on the environmental conditions and level of performance needed for your application.

Notes:

1. Based upon testing of representative samples. Only the base material has been tested. Antimicrobial-containing elastomers not yet tested.
2. Availability for needleless access valves subject to pending regulatory review by EPA.
3. Momentive is a supplier of industrial grade raw materials. Momentive uses appropriate quality assurance procedures but is not a GMP facility. The customer has the sole responsibility for the determination of suitability and safety of any Momentive material in its end use application.

Patent Status

Technical subject matter in this publication is described and protected by one or more pending US patent applications and foreign counterparts.

Product Safety, Handling and Storage

Customers considering the use of this product should review the latest Material Safety Data Sheet and label for product safety information, handling instructions, personal protective equipment if necessary, and any special storage conditions required. Material Safety Data Sheets are available at www.momentive.com or, upon request, from any Momentive Performance Materials representative. Use of other materials in conjunction with Momentive Performance Materials 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.

Emergency Service

Momentive Performance Materials maintains an around-the-clock emergency service for its products. The American Chemistry Council (CHEMTREC), Transport Canada (CANUTEC), and the Chemical Emergency Agency Service also maintain an around-the-clock emergency service for all chemical products:

Location	Momentive Performance Materials Products	All Chemical Products
Mainland U.S., Puerto Rico	518.233.2500	CHEMTREC: 800.424.9300
Alaska, Hawaii	518.233.2500	CHEMTREC: 800.424.9300
Canada	518.233.2500	CANUTEC: 613.996.6666 (collect) or CHEMTREC: 800.424.9300
Europe, Middle East, Africa	+32.(0)14.58.45.45 (Belgium)	CHEMTREC: +1-703.527.3887 (collect)
Latin America, Asia/Pacific, all other locations worldwide	+518.233.2500	CHEMTREC: +1-703.527.3887 (collect)
At sea	Radio U.S. Coast Guard, which can directly contact Momentive Performance Materials at 518.233.2500 or CHEMTREC at 800.424.9300.	

DO NOT WAIT. Phone if in doubt. You will be referred to a specialist for advice.

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• RTV's and Elastomers	T +1.800.332.3390	F +1.304.746.1623
• Consumer Sealants & Construction Sealants and Adhesives	T +1.877.943.7325	F +1.304.746.1654

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