HEALTHCARE | MEDICAL TECHNOLOGY

SILICONES FOR MEDICAL TECHNOLOGY

CREATING TOMORROW’S SOLUTIONS
EXPERIENCE MULTIMEDIA

PRODUCT INNOVATIONS

As an innovative chemical company, WACKER develops intelligent solutions that satisfy customer needs and also contribute significantly to a higher quality of life worldwide.

Clearly focused on the future, we intend to continuously enhance the quality of our products and improve our services. Close, two-way customer relationships play an essential role here. In today’s digital age, electronic media are the main channel for enabling both this direct exchange and our modern brand communications.

We want to use these state-of-the-art media to present our product innovations and solutions to you in an even better, more fascinating way.

Enter the Multimedia World of WACKER with WACKER Square

Our “WACKER Square” app delivers in-depth news about products, industries and the WACKER Group to your mobile device and – with a click on “MyOrders” – directly to your home. Alongside high-quality videos, images and press releases, the app offers you comprehensive brochures for your personalized “MySquare” media collection – and for subsequent offline use or for sharing with others.

You can also use our “WACKER Square AR” app. It allows you to experience augmented-reality applications firsthand. Be amazed by previously unimaginable insights as augmented reality merges reality, visions of the future and knowledge – adding value through information.

It’s so easy:

Open

Download the WACKER Square AR app

Scan

Experience

DISCOVER A BROAD RANGE OF MEDICAL APPLICATIONS IN 3D

For more detailed information, use our WACKER Square AR app. With your mobile device, just scan the printed graphics marked with this sign.

Why not experience this new application right away, on this page?
Silicones are modern synthetic materials, whose versatile performance is due to their chemical structure and the many different ways they can be modified.

Thanks to the high energy of the Si-O bond, silicones do an excellent job of resisting the elements. Silicones stand for chemical resistance, thermal stability and outstanding mechanical properties.

Interesting Facts about Silicones

- The term “silicone” was coined by F. S. Kipping (1883-1949)
- Silicones consist of a polymer backbone built of alternating silicon and oxygen atoms
- In nature, silicon occurs exclusively in the form of silicon dioxide and silicates
- Silicon is the second most abundant element in the earth’s crust (26 percent by weight)
- The energy of a Si-O bond is significantly greater than that of a C-C bond
- The thermal and oxidative stability of silicones is higher than that of organic plastics
- Silicones are highly resistant to UV, $\beta$, and $\gamma$ radiation

SILICONES IN MEDICINE

Regardless of the challenges the future holds, SILPURAN® and ELASTOSIL® offer you a future-proof solution that satisfies the highest standards.

The average age of the population is increasing steadily. At the same time, more and more people are gaining access to modern healthcare, resulting in increasingly strict legal requirements for medical products and services. As a result, the healthcare industry faces ever-increasing demands with regard to the safety and efficiency of its solutions. WACKER has responded to this development with silicone products from its SILPURAN® and ELASTOSIL® lines: future-proof silicone elastomers for the most exacting standards.

As a global market leader for silicone production, WACKER’s strength lies both in its unique expertise and pioneering research, and in its integrated raw-materials system. That means customers can place their confidence in future-proof solutions that meet the highest German quality standards.

The WACKER CLEAN OPERATIONS program ensures the outstanding levels of purity that SILPURAN® must possess to fulfill the medical requirements of today and tomorrow.

Much more than just two products: SILPURAN® and ELASTOSIL® always stand for the best service available, ensuring your success. Our teams of experts are always at the ready to help you exploit the virtually unlimited flexibility and innovative strength of these products so that they best meet your needs. The resulting customized solutions will help secure lasting success for your business.

SILPURAN® and ELASTOSIL® are available as solid or liquid rubber compounds (HTV or LSR, respectively) and as room-temperature-curing products (RTV-1 and RTV-2).

WACKER SILICONE RUBBER

Regardless of the challenges the future holds, SILPURAN® and ELASTOSIL® offer you a future-proof solution that satisfies the highest standards.

AS-versatile AS MODERN MEDICINE

Their special property profile makes SILPURAN® silicone elastomers ideal for medical applications. Just three of the many reasons for using these pure materials are that they can be sterilized and offer excellent chemical and physical resistance with no need for additional stabilizers.

Extrudable solid silicone rubber compounds are extremely tear resistant, highly elastic and remarkably resilient at the same time. They are used in numerous pharmaceutical and medical technology tubing applications, such as drainage, peristalsis, breathing and feeding tubes, urinary catheters and tubes for fluid transfer.

Suitable for use in injection and compression molding, SILPURAN® and ELASTOSIL® solid silicone rubber compounds have excellent mechanical properties, are very durable, serve as good elastic sealing materials and are soft and pleasing to the touch.

Their high level of transparency means they do not restrict the coloring possibilities for your products in any way.

Applications range from seals, valves, septa, filters and membranes (such as those in syringe seals or membranes for needle-free injection systems), to respirators and respiratory bellows, handles for equipment and instruments or mats for sterilization trays.
**SILPURAN® FOR MEDICAL TECHNOLOGY**

**Medically Relevant Properties**

The SILPURAN® product line offers a compelling property profile to meet medical-technology needs:
- Available in a broad range of hardnesses (Shore A)
- Excellent heat resistance as well as chemical and physical resistance with no additional stabilizers
- Highly transparent and good for pigmentation
- Good resistance to UV radiation and X-rays
- Certified biocompatibility (ISO 10993: cytotoxicity, sensitization, pyrogenicity; USP Class VI: systemic toxicity, intracutaneous toxicity, and implantation for 5 days; further tests on request)

**Resistance in Standard Sterilization Procedures**

All potential hygienic hazards must be ruled out for medical products, which is why manufacturers implement various sterilization procedures based on heat (dry heat / steam), chemical substances (ethylene oxide) or radiation ($\gamma$, $\beta$ radiation). Single-use articles are usually sterilized in their packaging using $\gamma$/$\beta$ radiation, or ethylene oxide. Medical products intended for repeated use in settings such as hospitals are generally steam-sterilized.

Ideally, product properties should not be influenced by these procedures.

Mechanical properties are not influenced by ethylene-oxide sterilization, see Fig. 1. Very slight changes in mechanical properties occur during steam sterilization at 134 °C and up to 500 cycles (Fig. 2). The use of ionizing radiation may result in changes to the polymer network. Series of tests have shown that sterilization procedures using $\gamma$/$\beta$ radiation make soft materials (5 to 50 Shore A) moderately more brittle and influence other mechanical properties as well. Only minor changes occur with harder materials (Fig. 3). However, deterioration of mechanical properties is not critical for most applications: application specifications are usually not compromised and the functionality of the end product remains intact.

**Medically Relevant Properties**

The SILPURAN® product line offers a compelling property profile to meet medical-technology needs:

- Available in a broad range of hardnesses (Shore A)
- Excellent heat resistance as well as chemical and physical resistance with no additional stabilizers
- Highly transparent and good for pigmentation
- Good resistance to UV radiation and X-rays
- Certified biocompatibility (ISO 10993: cytotoxicity, sensitization, pyrogenicity; USP Class VI: systemic toxicity, intracutaneous toxicity, and implantation for 5 days; further tests on request)

**Resistance in Standard Sterilization Procedures**

All potential hygienic hazards must be ruled out for medical products, which is why manufacturers implement various sterilization procedures based on heat (dry heat / steam), chemical substances (ethylene oxide) or radiation ($\gamma$, $\beta$ radiation). Single-use articles are usually sterilized in their packaging using $\gamma$/$\beta$ radiation, or ethylene oxide. Medical products intended for repeated use in settings such as hospitals are generally steam-sterilized.

Ideally, product properties should not be influenced by these procedures.

Mechanical properties are not influenced by ethylene-oxide sterilization, see Fig. 1. Very slight changes in mechanical properties occur during steam sterilization at 134 °C and up to 500 cycles (Fig. 2). The use of ionizing radiation may result in changes to the polymer network. Series of tests have shown that sterilization procedures using $\gamma$/$\beta$ radiation make soft materials (5 to 50 Shore A) moderately more brittle and influence other mechanical properties as well. Only minor changes occur with harder materials (Fig. 3). However, deterioration of mechanical properties is not critical for most applications: application specifications are usually not compromised and the functionality of the end product remains intact.
MANUFACTURING PROCESSES FOR HTV/LSR RUBBER

SILPURAN® and ELASTOSIL® HTV/LSR can be processed using numerous methods, such as extrusion, coextrusion, compression molding, transfer molding or injection molding. The two main processes are described below.

Extrusion
Extrusion is a continuous manufacturing process in which silicone rubber is forced through a die and then vulcanized. The die is responsible for giving the extruded material its shape. The necessary pressure is produced via a conveying screw, in which the material is homogenized, compacted and degassed. One example of products made this way is tubing for the medical and pharmaceutical industries. Solid silicone rubber from the SILPURAN® product line is delivered in blocks (profile diameter = approx. 90 x 100 mm) that are wrapped in an antistatic film and heat-sealed in a bag. The customer can thus be sure that the material is not contaminated before it reaches the cleanroom.

Injection Molding
Injection molding is currently the most popular and efficient method for processing large quantities of silicones meeting strict demands for consistently high product quality. Liquid and solid grades of SILPURAN®/ELASTOSIL® silicone rubber can each be used in the production of seals, membranes and valves – the process is fully automatic.

A SAFE BET FOR FUTURE SUCCESS

Future-Proof Quality Right from the Start
WACKER’s internal raw materials network ensures the future availability of raw materials, guaranteeing the finest quality and maximizing traceability back to the original source. This provides the ideal basis for further processing in accordance with stringent quality criteria.

Investing in Pioneering Solutions
Investment in research and development far exceeding the global chemical-industry average paves the way for cutting-edge innovations, ensuring that SILPURAN® and ELASTOSIL® always fulfill the ever-increasing demands of industry.

Keeping Ahead of Challenges with Confidence
SILPURAN® is tested for biocompatibility and complies with current standards for modern medical technology. (See info box on the right: "Certified Safe")

Safety Features for the Challenges Facing You in the Future.
In addition to their extraordinary purity, compelling properties of SILPURAN® and ELASTOSIL® also include excellent tolerability and utter reliability. These silicones are steam-sterilizable, resistant to heat and radiation, highly flexible and available across a very broad range of Shore hardness values. Moreover, silicones do not contain any phthalates, other organic plasticizers, latex, plant proteins, organic stabilizers or animal-based materials. Please note that WACKER SILICONES HEALTH CARE POLICY limits the use of WACKER silicones for certain medical applications. More information on this topic can be found on our website www.wacker.com.

Progress Rooted in Tradition
As early as 1947, WACKER became the first European company to venture into research in the field of silicones. This was the beginning of a success story which established WACKER as a European pioneer in silicone chemistry, and made it into one of the world’s leading silicone manufacturers.

Reliable Application Characteristics
- Biocompatibility
- Biodurability: low surface tension, thermal stability, chemical stability, excellent mechanical properties
- Good resistance to a large number of solvents and chemicals
- Sterilizable for single and repeated use (sterilizable with steam, ethylene oxide, electron beams and γ-rays)
- Good weathering, UV and aging resistance
- Highly transparent
- Silicones do not support microbial growth

Certified Safe
- The SILPURAN® product line has been certified as biocompatible according to selected ISO 10993 and USP Class VI tests
- Numerous SILPURAN® and ELASTOSIL® LSR/HTV grades comply with the requirements of the BfR (German Institute for Risk Assessment, XV Silicones, Section III, Silicone Elastomers) and the FDA (CFR 21 Sec. 177.2600 “Rubber articles intended for repeated use”), making them suitable for food contact.
ULTRA-HIGH PURITY TO MEET THE MOST EXACTING DEMANDS

Silicones used in medical applications are in direct contact with the human body and must therefore fulfill extremely rigorous requirements. Our cutting-edge WACKER CLEAN OPERATIONS production standard, which takes into account selected GMP criteria, ensures that all SILPURAN® products meet modern medicine’s ever-increasing safety requirements.

This means we can verify purity, tracing it from the end product back to the raw-material source. SILPURAN® contains only precisely defined ingredients, such as siloxanes, silica and crosslinkers/catalysts. Since the glass transition temperature is low (\(T_g = -125^\circ\text{C}\)), there is no need to add organic plasticizers, which could separate from the rubber.

SILPURAN® silicone rubber is dispensed or packaged in cleanrooms to prevent contamination by coarse particles. Visual inspection and 50 μm filters ensure that silicone products reach our customers in an absolutely pure and clean state.

**Purity**
- Dispensed and packaged under clean-room conditions (meeting Class 8 specifications as required in EN ISO 14644)
- LSR/RTV blended in a specially designated cleanroom with limited access, pest control measures and no dust-forming ingredients
- 50 μm filtration with individually sealed strainer filters (where technically feasible)
- Solid silicone rubber: wrapped rubber blocks are heat-sealed in an antistatic liner in order to prevent contamination (due to static charges, etc.) during transport and storage
- Specially trained, qualified employees prevent contamination

**Attention to Detail**
- Select GMP criteria taken into account
- Batch-to-batch consistency
- Batch documentation and tracking
- Change control management
- When it comes to maintenance, packaging and storage, we guarantee the highest product safety standards by letting exceptional attention to detail rule the day
- We check the cleanliness of shipping units individually, before they leave the cleanroom
- Visual inspection during the manufacturing process

**Consistent Quality**
- Production management is responsible for implementing WACKER CLEAN OPERATIONS production standards
- Integrated process control system
- Cleanroom classification qualified on an annual basis
- Failure mode and effects analysis (FMEA) conducted and actions implemented annually
- Customers are informed in advance anytime changes are to be made that impact product specifications
Highly transparent molded parts

A VARIETY OF APPLICATIONS

Further products and specific product characteristics can be found in the tables below and in our technical data sheets.

Products and specific product characteristics can be found in the tables below and in our technical data sheets.

More information on the uses of SILPURAN® and ELASTOSIL® in medical technology can be found at www.wacker.com/healthcare

12

Further products and specific product characteristics can be found in the tables below and in our technical data sheets.

More information on the uses of SILPURAN® and ELASTOSIL® in medical technology can be found at www.wacker.com/healthcare

SILPURAN® AND ELASTOSIL® FOR A VARIETY OF APPLICATIONS

SILPURAN® silicone elastomers from WACKER are ideal for use in the complex and highly sensitive field of medical technology.

Extrudable SILPURAN® ELASTOSIL® solid silicone rubber grades are used in numerous tubes in the pharmaceutical and medical industries, such as drains, peristalsis, breathing and feeding tubes, urinary catheters and tubes for fluid transfer. SILPURAN® ELASTOSIL® liquid and solid silicone rubber products are injection or compression molded to produce seals, valves, septa, filters and membranes.

Other applications include respirators, respiratory bellows, instrument handles and mats for sterilization trays.

ADD COLOR TO YOUR MEDICAL TECHNOLOGY PRODUCTS

Add color to your applications with our color master batches for the medical technology market. Select tests described in ISO 10993 and USP Class VI were used for verifying biocompatibility of a large number of base colors. You can cover a great deal of the color space by using or blending these colors.

<table>
<thead>
<tr>
<th>Product name</th>
<th>Properties</th>
<th>Typical Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>SILPURAN® 4200</td>
<td>1-part condensation-curing silicone adhesive (room-temperature vulcanization)</td>
<td>Binding cured silicone parts, highly elastic bonding between silicone and textiles</td>
</tr>
<tr>
<td>SILPURAN® 6000</td>
<td>2-part liquid silicone rubber</td>
<td>Seals, valves, connectors, bellows</td>
</tr>
<tr>
<td>SILPURAN® 6400</td>
<td>2-part liquid silicone rubber, high tear resistance</td>
<td>Seals, valves, bellows, masks</td>
</tr>
<tr>
<td>SILPURAN® 6600</td>
<td>2-part liquid silicone rubber, low coefficient of dynamic friction</td>
<td>Seals, valves</td>
</tr>
<tr>
<td>SILPURAN® 6610</td>
<td>2-part liquid silicone rubber, non-healing</td>
<td>Stuffed membranes, needle-free valves</td>
</tr>
<tr>
<td>SILPURAN® 6700</td>
<td>2-part liquid silicone rubber, self-adhesive</td>
<td>Seals, valves, membranes, bellows</td>
</tr>
<tr>
<td>SILPURAN® 6740</td>
<td>2-part liquid silicone rubber, self-adhesive, high tear resistance</td>
<td>Seals, valves, membranes, masks</td>
</tr>
<tr>
<td>SILPURAN® 6760</td>
<td>2-part liquid silicone rubber, self-adhesive, low coefficient of dynamic friction</td>
<td>Seals, valves</td>
</tr>
<tr>
<td>SILPURAN® 8020</td>
<td>2-part, platinum-curing solid silicone rubber for molding</td>
<td>Molding, e.g. highly transparent molded parts</td>
</tr>
<tr>
<td>SILPURAN® 8030</td>
<td>2-part, platinum-curing solid silicone rubber for extrusion</td>
<td>Extrusion, e.g. highly transparent catheters and tubes</td>
</tr>
<tr>
<td>SILPURAN® 8060</td>
<td>Peroxy-curing solid silicone rubber for molding and extrusion</td>
<td>Extrusion and molding, e.g. seals, tubing</td>
</tr>
<tr>
<td>SILPURAN® AUX 8250 RO</td>
<td>Barium sulfate batch (75%) for HPV compounds</td>
<td>X-ray opaque tubing</td>
</tr>
<tr>
<td>SILPURAN® AUX 8521 RO</td>
<td>Peroxy-curing solid silicone rubber for extrusion, high tear resistance</td>
<td>Extrusion, e.g. tear-resistant tubing</td>
</tr>
<tr>
<td>SILPURAN® 8461</td>
<td>Peroxy-curing solid silicone rubber for extrusion, low coefficient of dynamic friction</td>
<td>Extrusion, e.g. catheters and tubing with low coefficients of dynamic friction</td>
</tr>
</tbody>
</table>

Further products and specific product characteristics can be found in the tables below and in our technical data sheets.

Biocompatible pigment pastes for liquid silicone rubber ELASTOSIL® FL color pastes

Color name | Similar RAL® | Affix | BfR | FDA | ISO 10993 | USP Class VI | Color
--- | --- | --- | --- | --- | --- | --- | ---
EL FL yellow | RAL 1016 | x | x | x | x
EL FL orange | RAL 2004 | F | x | x | x
EL FL red | RAL 3000 | F | x | x | x
EL FL ultramarine blue | RAL 5002 | x | x | x | x
EL FL blue | RAL 5010 | x | x | x | x
EL FL green | RAL 6010 | x | x | x | x
EL FL white | RAL 9010 | x | x | x | x
EL FL black | RAL 9005 | F | x | x | x
EL FL deep black | RAL 5011 | x | x | x

(1) For questions regarding the biocompatibility of our PT pigment pastes for solid silicone rubber, please contact our technical service department.
(2) The RAL numbers in the table are only a guide.
(3) An important aspect of meeting the requirements stipulated in the Code of Federal Regulations (CFR), Title 21, Sec. 177.600 “Rubber articles intended for repeated use” is precise compliance with concentration limits and limitations on the conditions of use in conjunction with Sec. 178.3297 “Colorants for Polymers.” Our technical service personnel will be happy to assist you.
(4) BfR recommendation “XV. Silicone” (BfR = Bundesinstitut für Risikobewertung) (German Institute for Risk Assessment)
(5) FDA 21 CFR Sec. 177.2600 “Rubber articles intended for repeated use” (FDA = Food and Drug Administration)
(6) Conformance with BfR and FDA requirements may in certain circumstances depend on compliance with the specified concentration limits. We will be glad to assist you.
(7) Cytotoxicity, pyrogenicity, sensitizing LLNA, further tests on request
(8) Systems / intracutaneous toxicity, implantation test (5 days)
(9) Please observe the conditions of use (C-H) defined for temperature and duration in table 2 under Title 21, CFR Sec. 176.170.
(10) Please observe the conditions of use (C-H) defined for temperature and duration in table 2 under Title 21, CFR Sec. 176.170.
<table>
<thead>
<tr>
<th>Product</th>
<th>Properties</th>
<th>Product Description</th>
<th>Typical Applications</th>
<th>Shore A</th>
<th>Tensile strength (DIN 53 504-31) [N/mm²]</th>
<th>Elongation at break (DIN 53 504-31) [%]</th>
<th>Tear resistance (ASTM D 454 B) [N/mm]</th>
<th>USP Class V</th>
<th>ISO 10993</th>
<th>BfR</th>
<th>FDA 21 CFR Pt. 177.2600</th>
</tr>
</thead>
<tbody>
<tr>
<td>SILPURAN® 6000</td>
<td>High mechanical strength</td>
<td>• Readily pigmentable LSR with short curing times (1:1 A/B system) &lt;br&gt; • Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td>• Medical/pharmaceutical applications &lt;br&gt; • Seals, connectors, valves, bellows, etc.</td>
<td>05</td>
<td>2.5</td>
<td>700</td>
<td>6</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10</td>
<td>4.2</td>
<td>740</td>
<td>12</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20</td>
<td>8.0</td>
<td>850</td>
<td>21</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30</td>
<td>8.6</td>
<td>650</td>
<td>25</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>40</td>
<td>9.6</td>
<td>600</td>
<td>29</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>10.0</td>
<td>480</td>
<td>30</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>10.0</td>
<td>360</td>
<td>27</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>70</td>
<td>9.5</td>
<td>290</td>
<td>22</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>SILPURAN® 6400</td>
<td>High tear resistance</td>
<td>• Readily pigmentable LSR with short curing times (1:1 A/B system) &lt;br&gt; • Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td>• Medical/pharmaceutical applications &lt;br&gt; • For molded parts subject to significant mechanical stress (masks, seals, bellows, etc.)</td>
<td>40</td>
<td>9.2</td>
<td>630</td>
<td>35</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>9.1</td>
<td>450</td>
<td>47</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>9.5</td>
<td>430</td>
<td>51</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>SILPURAN® 6600</td>
<td>Low coefficient of dynamic friction</td>
<td>• Readily pigmentable LSR with short curing times (1:1 A/B system) &lt;br&gt; • Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td>• Medical/pharmaceutical applications &lt;br&gt; • Low coefficient of dynamic friction for easy assembly (seals, valves, etc.)</td>
<td>40</td>
<td>9.4</td>
<td>550</td>
<td>35</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>8.9</td>
<td>440</td>
<td>31</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>9.0</td>
<td>310</td>
<td>26</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>SILPURAN® 6610</td>
<td>Reduced healing</td>
<td>• LSR (white) with short curing times (1:1 A/B system) &lt;br&gt; • Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td>• Needle-free valves, slotted membranes &lt;br&gt; • Significantly reduced tendency toward free-radical-induced healing of slotted valves during γ sterilization or electron radiation (≤ 75 kGy)</td>
<td>40</td>
<td>7.2</td>
<td>550</td>
<td>32</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>8.0</td>
<td>440</td>
<td>31</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>7.0</td>
<td>310</td>
<td>26</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>SILPURAN® 6700</td>
<td>Primer-free self-adhesion on wide range of substrates</td>
<td>• Readily pigmentable LSR with short curing times (1:1 A/B system) &lt;br&gt; • Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td>• Medical/pharmaceutical applications &lt;br&gt; • Self-adhesion for 2-part injection molding (seals, membranes, bellows, etc.)</td>
<td>40</td>
<td>8.5</td>
<td>640</td>
<td>23</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>8.5</td>
<td>590</td>
<td>24</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>8.2</td>
<td>490</td>
<td>26</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>SILPURAN® 6740</td>
<td>Primer-free self-adhesion on wide range of substrates, high tear resistance</td>
<td>• Readily pigmentable LSR with short curing times (1:1 A/B system) &lt;br&gt; • Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td>• Medical/pharmaceutical applications &lt;br&gt; • Self-adhesion for 2-part injection molding (seals, membranes, bellows, etc.)</td>
<td>40</td>
<td>9.2</td>
<td>710</td>
<td>25</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>8.4</td>
<td>600</td>
<td>27</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>SILPURAN® 6760</td>
<td>Primer-free self-adhesion on wide range of substrates, low coefficient of dynamic friction</td>
<td>• Readily pigmentable LSR with short curing times (1:1 A/B system) &lt;br&gt; • Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td>• Medical/pharmaceutical applications &lt;br&gt; • Self-adhesion for 2-part injection molding (seals, membranes, bellows, etc.)</td>
<td>50</td>
<td>8.4</td>
<td>600</td>
<td>27</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>ELASTOSIL® LR 34004</td>
<td>X-ray opaque</td>
<td>• LSR (white) (1:1 A/B system) &lt;br&gt; • X-ray opaque</td>
<td>• X-ray opaque injection moldings</td>
<td>50</td>
<td>7.8</td>
<td>450</td>
<td>26</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>ELASTOSIL® LR 5040</td>
<td>Low volatiles content, even without postcuring</td>
<td>• Readily pigmentable LSR with short curing times (1:1 A/B system) &lt;br&gt; • Low volatiles content and good mechanical properties, even without postcuring</td>
<td>• Cost-effective, large-scale production of injection-molded parts</td>
<td>50</td>
<td>9.0</td>
<td>580</td>
<td>38</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>9.5</td>
<td>490</td>
<td>42</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** The information provided is based on the products being suitable for medical/pharmaceutical applications. For detailed specifications and requirements, please consult the respective product information.
### SILPURAN® – Platinum-Curing Solid Silicone Rubber

<table>
<thead>
<tr>
<th>Product</th>
<th>Properties</th>
<th>Product Description</th>
<th>Typical Applications</th>
<th>Hardness, Shore A</th>
<th>Measured with a Crosslinker</th>
<th>Tensile strength (DIN 53 504-S1) [N/mm²]</th>
<th>Elongation at break (DIN 53 504-S1) [%]</th>
<th>Tear strength (ASTM D5034 B) [N/mm]</th>
<th>USP Class</th>
<th>ISO 10993?</th>
<th>BfR?</th>
<th>FDA?</th>
</tr>
</thead>
<tbody>
<tr>
<td>SILPURAN® 8020</td>
<td>Very good mechanical properties</td>
<td>Platinum-curing, two-part solid silicone rubber for molding (100:1.5 base/SILPURAN® Crosslinker M)</td>
<td>Medical/pharmaceutical injection-molding applications</td>
<td>40 M®</td>
<td>11.1</td>
<td>820</td>
<td>34</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Readily pigmentable</td>
<td>Highly transparent, durable parts, etc.</td>
<td>50 M</td>
<td>11.2</td>
<td>760</td>
<td>35</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td>Compression molding, transfer molding or injection molding</td>
<td>60 M</td>
<td>11.2</td>
<td>670</td>
<td>31</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>70 M</td>
<td>10.4</td>
<td>650</td>
<td>37</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

| SILPURAN® 8030 | High tear resistance | Platinum-curing, two-part solid silicone rubber for extrusion (100:1.5 base/SILPURAN® Crosslinker X) | Medical/pharmaceutical extrusion applications | 40 X® | 9.7 | 810 | 30 | x | x | x | x |
| | | Readily pigmentable | Highly transparent, durable tubes and catheters, etc. | 50 X | 10.5 | 850 | 35 | x | x | x | x |
| | | Produced in accordance with the WACKER CLEAN OPERATIONS Standard | | 60 X | 10.7 | 710 | 39 | x | x | x | x |
| | | | | 70 X | 9.7 | 650 | 41 | x | x | x | x |

| SILPURAN® 8630 | Low coefficient of dynamic friction; coefficient of friction is up to 70% lower than that of SILPURAN® 8030. | Platinum-curing, two-part solid silicone rubber for extrusion | Medical/pharmaceutical extrusion applications | 60 X | 5.0 | 50 | 41 | x | x | x | x |
| | | Readily pigmentable | Catheters, tubing, etc. with low coefficients of dynamic friction | | | | | | | | |
| | | Produced in accordance with the WACKER CLEAN OPERATIONS Standard | | | | | | | | | |

| SILPURAN® ALX 8251 RO | | Barium sulfate batch (75%) | X-ray opaque additive for platinum-curing silicone rubber compounds | | | | | | | | |

### SILPURAN® – Peroxide-Curing Solid Silicone Rubber

<table>
<thead>
<tr>
<th>Product</th>
<th>Properties</th>
<th>Product Description</th>
<th>Typical Applications</th>
<th>Hardness, Shore A</th>
<th>Measured with a Crosslinker</th>
<th>Tensile strength (DIN 53 504-S1) [N/mm²]</th>
<th>Elongation at break (DIN 53 504-S1) [%]</th>
<th>Tear strength (ASTM D5034 B) [N/mm]</th>
<th>USP Class</th>
<th>ISO 10993?</th>
<th>BfR?</th>
<th>FDA?</th>
</tr>
</thead>
<tbody>
<tr>
<td>SILPURAN® 8060</td>
<td>Highly flexible, highly transparent, good mechanical properties</td>
<td>Peroxide-curing, two-part solid silicone rubber (base + crosslinker)</td>
<td>Medical/pharmaceutical extrusion and injection molding applications</td>
<td>40 E®</td>
<td>9.3</td>
<td>560</td>
<td>23</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Readily pigmentable</td>
<td>Seals, tubing, etc.</td>
<td>40 C1®</td>
<td>11.4</td>
<td>780</td>
<td>29</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Produced in accordance with the WACKER CLEAN OPERATIONS Standard</td>
<td></td>
<td>50 E</td>
<td>11.0</td>
<td>520</td>
<td>25</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50 C1</td>
<td>12.0</td>
<td>640</td>
<td>28</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60 E</td>
<td>11.0</td>
<td>470</td>
<td>25</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60 C1</td>
<td>10.6</td>
<td>510</td>
<td>26</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>70 E</td>
<td>11.6</td>
<td>480</td>
<td>29</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>70 C1</td>
<td>11.0</td>
<td>520</td>
<td>31</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

| SILPURAN® 8461 | Highly tear resistant, highly transparent | Peroxide-curing, two-part solid silicone rubber (base + crosslinker) | Medical/pharmaceutical extrusion applications | 60 E | 10.5 | 480 | 33 | x | x | x | x |
| | | Readily pigmentable | Tear-resistant tubing, etc. | | | | | | | | |
| | | Produced in accordance with the WACKER CLEAN OPERATIONS Standard | High extrusion rates possible | | | | | | | | |

| SILPURAN® ALX 8252 RO | | Barium sulfate batch (75%) | X-ray opaque additive for peroxide-curing silicone rubber compounds | | | | | | x | x | x | x |

---

These figures are only intended as a guide and should not be used in preparing specifications.

Please contact us regarding our products’ conformity to the European Pharmacopoeia, section 3.1.9 “Silicone elastomers for closures and tubing”

Please contact your technical service manager to see whether ELASTOSIL® products are suitable for your projects and applications.

(1) Systemic / intracutaneous toxicity; implantation test (5 days)
(2) Cytotoxicity, sensitization LLNA, pyrogenicity, additional tests upon request
(3) Systemic / intracutaneous toxicity, implantation test (5 days)
(4) FDA 21 CFR Sec. 177.2600 “Rubber articles intended for repeated use” (FDA = Food and Drug Administration)
(5) ELASTOSIL® AUX Crosslinker E
(6) ELASTOSIL® AUX Crosslinker C1
(7) SILPURAN® Crosslinker M
(8) SILPURAN® Crosslinker X

*WACKER CLEAN OPERATIONS* base / SILPURAN® base / SILPURAN® silicone rubber for extrusion (100:1.5 silicone rubber (base + crosslinker))

*WACKER CLEAN OPERATIONS* base / SILPURAN® silicone rubber (base + crosslinker)
PERFECT SERVICE – GLOBALLY CONNECTED, LOCALLY AVAILABLE

Innovation through Dialog

Individual services play a decisive role in the healthcare industry. Hardly any other field is as dynamic or innovative. Your market success is determined by the support of a competent and experienced partner who assists you through each phase of product development.

You can tap into the full potential of WACKER’s silicone rubber compounds by consulting us on anything from materials development, to tests, pilot series and registration – all in accordance with the latest regulations. All around the world, we support you with our highly experienced specialists, state-of-the-art research labs and application expertise.

SILPURAN® and ELASTOSIL® are top-quality, extraordinarily flexible products. A broad range of these products can be customized to meet your individual requirements.

Speak with a WACKER sales manager about how you plan to use SILPURAN® and ELASTOSIL®. These individuals are well acquainted with standard production processes. They also have a profound technical understanding of your requirements, and know how best to incorporate these requirements into the properties of our silicone elastomers. Innovative and custom solutions thrive on dialog between experts.

Applications Labs

Our technical service engineers will work closely with you and tackle specific questions from actual practice. Worldwide, we offer assistance by finding the optimum product for your specific requirements and by supporting your product development from material selection through to industrial production. Because the labs’ primary focus is on medical technology, they possess outstanding expertise in this field.

Technical Centers

We maintain technical centers in all key regions to proactively assist you in any technical matters, from adjusting formulations, to meeting individual requirements, to testing the properties of rubber compounds and cured material. Our technical centers are equipped to perform all relevant analyses, lab tests and trials for you according to international and local standards and regulations.

Besides our local experts, you can also draw on our international knowledge network based on over 50 years of market experience. For example, our pilot plant in Burghausen forms the interface between product and applications expertise. It is equipped with a lab and test facilities, as well as production systems (extrusion and injection molding) for HTV and LSR silicone rubber, and 2-component composite materials.

At our pilot plant, we put our product lines through a range of practical tests as part of their development, testing, modification and optimization. At the same time, we offer extensive advice at every step in the supply chain, and put our pilot plant and all the necessary tools at your disposal. We can also offer on-site consultation at your production plant.

Regulatory Support

To ensure product safety, we of course offer you regulatory support. Our experts will respond to your questions about environmental, health and regulatory matters such as the following:

• Suitability for contact with food products (e.g. BfR, FDA)
• Pharmaceutical and medical applications (e.g. European Pharmacopeia and US Pharmacopeia)
• National and international directives and regulations (e.g. the KTW Guideline, EU–RoHS, REACH)
• Specific customer requirements (e.g. banned substance and substances avoidance lists)
• Toxicology and ecotoxicology
• Risk analysis

The WACKER ACADEMY

To transfer its own expertise and market experience, WACKER has founded a unique institution, the WACKER ACADEMY. Here, at a number of sites worldwide, you can take advantage of a versatile, industry-specific seminar program. To access the current program, please go to: www.wacker.com/wacker-academy

Infoline

• We have set up an information hotline so that you can start talking with us quickly and easily. For all questions concerning WACKER silicones and related products and services, just call us or email us. You will be redirected to a specialist who can answer your questions.
• Europe and the Middle East
  • Infoline Germany
    0800-6279-800
  • Infoline International
    +49 89 6279-1741
  • Email: info.silicones@wacker.com
• NAFTA Region – Canada, Mexico and the USA
  • Infoline
    +1 888-922-5374 (+1 888-WACKER 4 U)
  • Email: info.usa@wacker.com
EXPERTISE AND SERVICE NETWORK ON FIVE CONTINENTS

All figures are based on fiscal 2018.

WACKER is one of the world’s leading and most research-intensive chemical producers and manufacturers. Products range from silicones, binders and enzyme solutions for diverse industrial sectors to biorefinery pharmaceuticals and hyperpure silicon for semiconductor and solar applications. As a technology leader focusing on sustainability, WACKER promotes products and ideas that offer a high value-added potential to ensure that current and future generations enjoy a better quality of life, based on energy efficiency and protection of the climate and environment.

Spanning the globe with 4 business divisions, we offer our customers highly-specialized products and comprehensive service via 24 production sites, 24 technical competence centers, 13 WACKER ACADEMY training centers and 50 sales offices in Europe, North and South America, and Asia – including a presence in China.

With a workforce of some 14,000, we see ourselves as a reliable innovative partner that develops tailoring solutions fast and in collaboration with our customers. We also help them boost their own success. Our technical competence centers employ local specialists, who assist customers worldwide in the development of products tailored to regional demands, supporting them during every stage of their complex production processes, if required.

WACKER e-solutions are online services provided via our customer portal and as integrated process solutions. Our customers and business partners thus benefit from comprehensive information and reliable service to enable projects and orders to be handled fast, reliably and highly efficiently.

Visit us anywhere, anytime around the world at: www.wacker.com

Perfect Service – Globally Connected, Locally Available

Innovation through dialogue

Individual services play a decisive role in the healthcare industry. Nearly any other field is as dynamic or innovative.

Your market success is determined by the support of a competent and experienced partner who assists you through each phase of product development.

You can tap into the full potential of WACKER’s silicone rubber compounds by consulting us on anything from material development to tests, pilot series and registration – all in accordance with the latest regulations. All around the world, we support you with our highly-experienced specialists, state-of-the-art research labs and application experts.

SILPURAN® and ELASTOSIL® are top-quality, extraordinarily flexible products. A broad range of these products can be customized to meet your individual requirements.

Speak with a WACKER sales manager about how you plan to use SILPURAN® and ELASTOSIL®. These individuals are well-acquainted with standard production processes. They also have an excellent technical understanding of your requirements, and know how best to incorporate these requirements into the properties of our silicone elastomers. Innovative and custom solutions thrive on dialog between experts.

Speak with a WACKER sales manager about how you plan to use SILPURAN® and ELASTOSIL®. These individuals are well-acquainted with standard production processes. They also have an excellent technical understanding of your requirements, and know how best to incorporate these requirements into the properties of our silicone elastomers. Innovative and custom solutions thrive on dialog between experts.
ELASTOSIL ® is a registered trademark of Wacker Chemie AG.
SILPURAN ® is a registered trademark of Wacker Chemie AG.

The data presented in this brochure are in accordance with the present state of our knowledge, but do not absolve the user from carefully checking all supplies immediately on receipt. We reserve the right to alter product constants within the scope of technical progress or new developments. The recommendations made in this brochure should be checked by preliminary trials because of conditions during processing over which we have no control, especially where other companies’ raw materials are also being used.

The information provided by us does not absolve the user from the obligation of investigating the possibility of infringement of third parties’ rights and, if necessary, clarifying the position. Recommendations for use do not constitute a warranty, either express or implied, of the fitness or suitability of the product for a particular purpose.