WACKER

CREATING TOMORROW'S SOLUTIONS

SILPURAN®

HEALTHCARE I MEDICAL DEVICES

SILICONES FOR MEDICAL DEVICES

SILPURAN® – ENSURING SUCCESS IN THE FUTURE

The average age of the population is increasing progressively. More and more people gain access to modern healthcare and statutory requirements for medical products and services are becoming stricter. As a result, the healthcare industry faces ever-increasing demands with regard to the safety and efficiency of its solutions. WACKER's contribution to this development is SILPURAN®: the future-proof, pure silicone elastomer.

Ensuring Success in the Future

With SILPURAN®, you are assured of reliable and consistent product quality:

- Highly backward-integrated production for traceable quality
- Investment in research and development, far exceeding the global chemical-industry average
- Safety guaranteed by biocompatibility certification
- Safe application characteristics, such as biodurability, sterilizability and chemical inertness
- Assurance of long-term, consistent product specification and prior notification of changes upon request

Ultra-High Purity to Meet the Most Exacting Demands

SILPURAN® contains only precisely defined ingredients such as siloxanes, silica, curing agents and catalysts. No organic plasticizers are added.

The WACKER CLEAN OPERATIONS standard ensures that no contaminants are introduced during production:

- Selected GMP criteria are applied
- Fine filtering (50 µm, as far as technically possible)
- Filling / packaging in cleanrooms (class 8 as per DIN EN ISO 14644)

Much More Than Just a Product

SILPURAN® makes the best service available to you, ensuring your success. Our teams of experts at Application Technology, Technical Center and Regulatory Support are always at hand to meet your individual needs, thus creating customized product solutions which contribute to your long-term business success.

SILPURAN® – SILICONES FOR MEDICAL DEVICES

Medically Relevant Properties

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

- Available in a wide range of hardnesses (Shore A)
- Excellent heat resistance as well as chemical and physical resistance without additional stabilizers
- High level of transparency and colorability
- 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)
- Conformance with specifications in European Pharmacopoeia 3.1.9. as regards tests for substances soluble in hexane and volatile matter
- Device Master Files listed at FDA

Resistance in Standard Sterilization Procedures

All potential hygienic hazards must be ruled out for medical products. To this purpose, various sterilization procedures based on heat (dry heat / steam), chemical substances (ethylene oxide) or radiation (γ, β radiation) are implemented. Single-use articles are usually sterilized in their packaging using γ / β radiation, or ethylene oxide. Medical products intended for repeated use in hospitals are generally steam-sterilized.

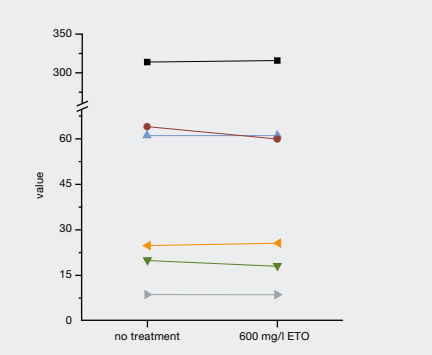
Ideally, product properties should not be influenced by these procedures.

The mechanical properties are not influenced significantly by ethylene-oxide sterilization, see Fig. 1. Only very slight changes occur with respect to the mechanical properties during steam sterilization at 134 °C and up to 500 cycles (Fig. 2).

There may be changes to the polymer network when ionizing radiation methods are used. Tests have shown that sterilization procedures using γ / β radiation cause moderate embrittlement of soft materials (5 to 50 Shore A); the other mechanical properties are also influenced. Only minor changes occur with harder materials (Fig. 3). However, the deterioration of the mechanical properties is not critical for most applications: the application specifications are usually not compromised and the functionality of the end product remains intact.

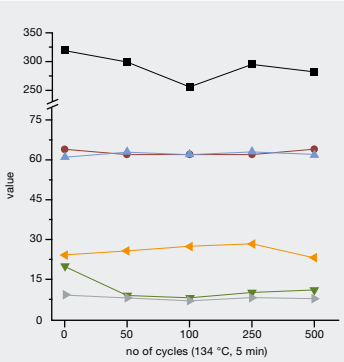
SILPURAN®'s durability when subjected to various sterilization procedures

Fig.1: Sterilization of SILPURAN® 6000 / 60 using Ethylene oxide (ETO)*



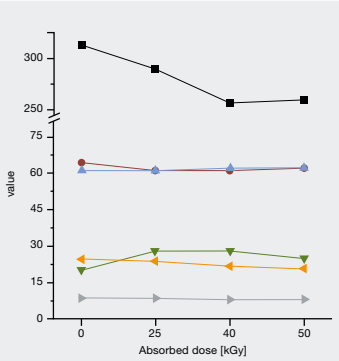
*according to DIN EN ISO 11135: 1h, 54 °C, 600 mg/l ETO

Fig. 2: Sterilization of SILPURAN® 6000 / 60 using steam**



**according to DIN EN ISO 17665 – ageing test according to DIN EN 868-8

Fig. 3: Sterilization of SILPURAN® 6000 / 60 using γ radiation***



***according to DIN EN ISO 11137-2, 2007

—■— Elongation at break [%]; DIN 53504-S1
—●— Rebound resilience [%]; DIN 53512
—▲— Hardness Shore A; DIN 53505
—▼— Compression set [%] (22 h / 175 °C); DIN ISO 815-B
—◀— Tear strength [N / mm]; ASTM D 624 B
—▶— Tensile strength [N / mm²]; DIN 53504-S1

PROCESSING OF HTV / LSR RUBBER

SILPURAN® 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 gives the extrudate its shape. The necessary pressure is produced via a conveying screw, in which the material is homogenized, compressed and deventilated. Tubes for the medical and pharmaceutical industries are manufactured in this manner.

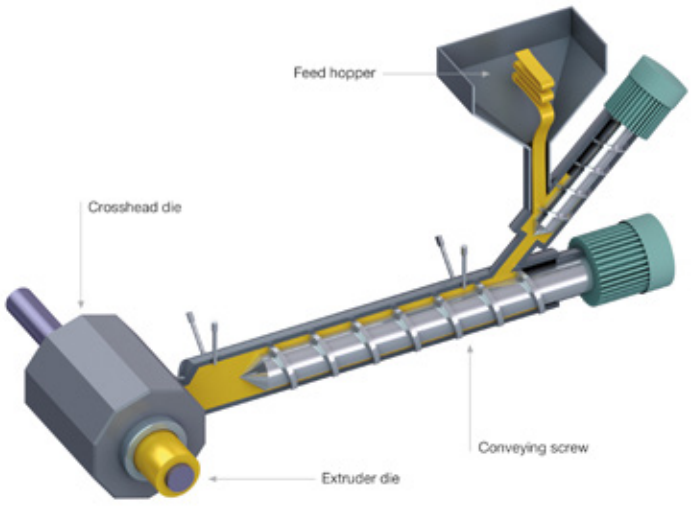
SILPURAN® solid silicone rubber is supplied in bars (profile diameter approx. 90 x 100 mm), wrapped in antistatic foil, and sealed in a bag, thus ensuring that the material reaches the customers' cleanroom without contamination.

Injection Molding

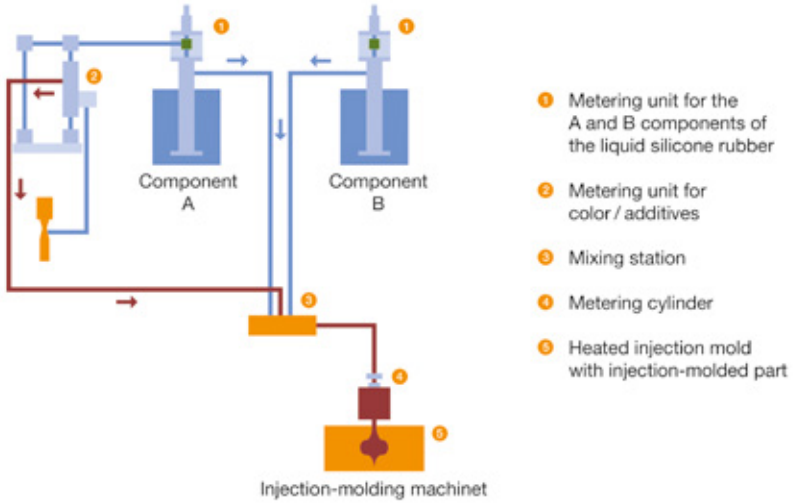
Injection molding is currently the most popular and efficient method of producing large item quantities with strict demands for consistently high product quality. Both SILPURAN® liquid and solid silicone rubbers can thus be used to produce seals, membranes and valves – the process is fully automated and secondary finishing is not required, even for the most complex geometries.

SILPURAN® liquid silicone rubber is supplied as a two-part system (A/B) in 20 kg pails or 200 kg drums.

Schematic diagram of an extruder with crosshead die



Schematic diagram of injection molding with metering unit and mixing station



*HTV (= high-temperature-vulcanizing; solid silicone rubber) / LSR (= liquid silicone rubber)

Cooling cap for chemotherapy

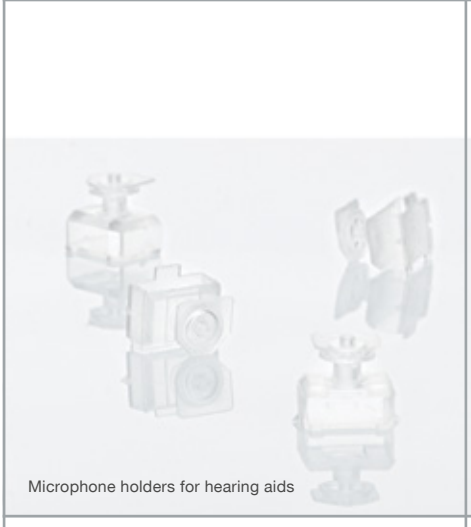
Ventilation mask

Ventilation bag

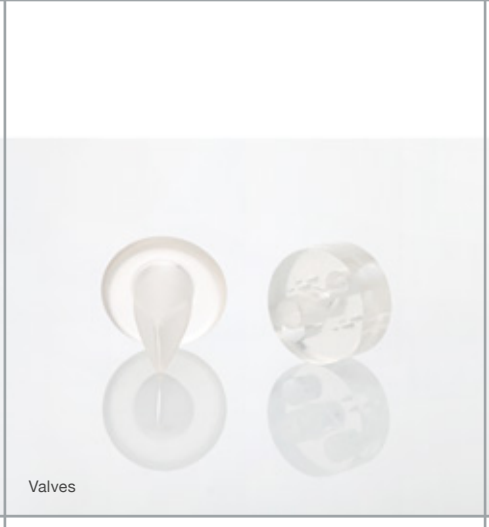
Handles for surgical instruments

Breathing tube

Syringe seals



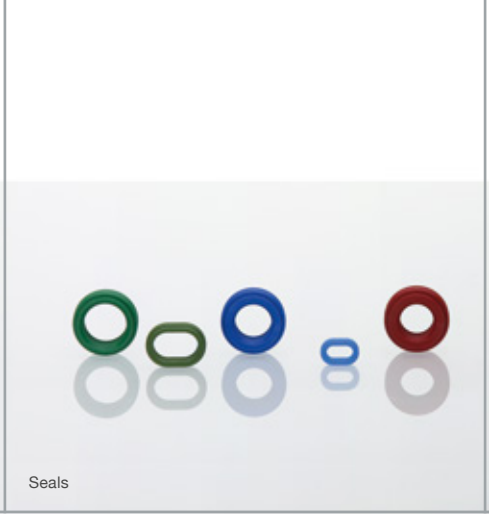
Microphone holders for hearing aids



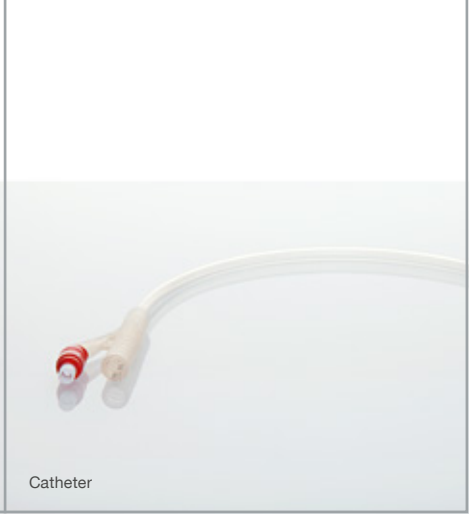
Valves

Tube connectors

Valves



Seals



Catheter

SILPURAN® MEETS MOST EXACTING DEMANDS

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

- Extrudable SILPURAN® solid silicone rubbers are used in numerous tubes in the pharmaceutical and medical industries, e.g. tubes for drainage or peristaltic pumps, breathing and feeding tubes; urinary catheters and tubes for fluid transfer.
- SILPURAN® liquid and solid silicone rubbers are injection or compression molded to produce seals, valves, septa, filters and membranes. Other applications include breathing / ventilation masks, respiratory bellows, instrument handles and mats for sterilization trays.

For further information, please contact your local WACKER SILICONES sales manager regarding SILPURAN® medical device applications.

www.wacker.com/silpuran

SILPURAN® – suitable for hose extrusion

SILPURAN® – suitable for production of ventilation masks

SILPURAN® – suitable for highly transparent molded parts

Designation	Properties	Typical Applications
SILPURAN® 4200	1-part condensation-curing silicone adhesive (tin-free)	Bonding of vulcanized silicone parts Highly elastic adhesion of silicone to textiles
SILPURAN® 6000	2-part liquid silicone rubber	Seals, gaskets, valves, connectors, bellows
SILPURAN® 6400	2-part liquid silicone rubber, high tear resistance	Seals, gaskets, valves, bellows, masks
SILPURAN® 6600	2-part liquid silicone rubber, low coefficient of friction	Seals, gaskets, valves
SILPURAN® 6610	2-part liquid silicone rubber, non-healing	Slit membranes, needle-free valves
SILPURAN® 6700	2-part liquid silicone rubber, self-adhesive	Seals, gaskets, valves, membranes, bellows
SILPURAN® 6740	2-part liquid silicone rubber, self-adhesive, high tear	Seals, gaskets, valves, membranes, masks
SILPURAN® 8020	2-part, platinum cure solid silicone rubber for molding	Molding, e.g. highly transparent molded parts
SILPURAN® 8030	2-part, platinum cure solid silicone rubber for extrusion	Extrusion, e.g. highly transparent catheters and tubes
SILPURAN® 8060	Peroxide cure solid silicone rubber for molding and extrusion	Extrusion and molding, e.g. seals, tubing
SILPURAN® AUX 8250 RO	Barium sulfat batch (75%) für HTV compounds	Radioopaque medical tubing
SILPURAN® 8461	Peroxide cure solid silicone rubber for extrusion	Extrusion, e.g. tear-resistant tubing
SILPURAN® 8630	2-part, platinum cure solid silicone rubber for extrusion, low coefficient of friction	Extrusion, e.g. catheters and tubing with low surface friction

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

COLORS FOR YOUR MEDICAL PRODUCTS

Add color to your applications with our color masterbatches for the medical device market! Biocompatibility has been demonstrated according to selected tests of ISO 10993 and USP Class VI for ten base colors. These colors and their possible blends allow you to cover a large part of the color space.

Biocompatible Pigment Pastes for Liquid Silicone Rubber: ELASTOSIL® AUX Color Paste FL[1]							
Color name	**Similar to RAL[2]**	**Affix**	**BfR[3],[4],[6]**	**FDA[5],[6]**	**ISO 10993[7]**	**USP Class VI[8]**	**Color**
EL FL Yellow	RAL 1016[9]		x	x	x	x	
EL FL Yellow	RAL 1026[10]	F	x	x	x	x	
EL FL Orange	RAL 2004[9]	F	x	x	x	x	
EL FL Red violet	RAL 4002		x	x	x	x	
EL FL Dark blue	RAL 5010		x	x	x	x	
EL FL Blue	RAL 5022		x	x	x	x	
EL FL Helio green	RAL 6004		x	x	x	x	
EL FL Green	RAL 6010		x	x	x	x	
EL FL White	RAL 9010		x	x	x	x	
EL FL Deep black	RAL 9011		x	x	x	x	

(1) Re. biocompatibility of our PT color pastes for solid silicone rubber, we kindly ask you to contact our technical service.
(2) The RAL values in the table are guide figures only.
(3) To meet the requirements as indicated in Title 21 of the Code of Federal Regulations (CFR) § 177.2600 “Rubber Articles Intended for Repeated Use”, it is important to closely observe the respective existing dosing limits and limitation on conditions of use relating to § 178.3297 “Colorants for Polymers”. Our technical service will be pleased to advise you.
(4) BfR recommendation “XV. Silicone” (BfR = Bundesinstitut für Risikobewertung)
(5) FDA 21 CFR § 177.2600 “Rubber articles intended for repeated use” (FDA = Food and Drug Administration)
(6) BfR and FDA compliance is contingent on the observation of specified dosing limits. We will be glad to assist you.
(7) Cytotoxicity, sensitization LLNA, pyrogenicity
(8) Systemic / Intracutaneous toxicity, implantation test (5 days)
(9) Please consider the defined time-temperature use conditions (B-H) acc. to table 2 under 21 CFR § 176.170
(10) Please consider the defined time-temperature use conditions (C-H) acc. to table 2 under 21 CFR § 176.170

SILPURAN® Liquid Silicone Rubber

Product	Properties	Product Description	Typical Applications
SILPURAN® 6000	High mechanical strength	• Paste-like, easily pigmentable 2-part silicone rubber with short curing times (1 : 1 A / B system) • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical applications • Economical mass production of injection-molded parts • E.g. seals, connectors, valves, bellows
SILPURAN® 6400	Excellent tear resistance	• Paste-like, easily pigmentable 2-part silicone rubber with short curing times (1 : 1 A / B system) • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical applications • Economical mass production of injection-molded parts • For articles under high mechanical stress, e.g. masks, seals, bellows
SILPURAN® 6600	Low coefficient of friction	• Paste-like, easily pigmentable 2-part silicone rubber with short curing times (1 : 1 A / B system) • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical applications • Economical mass production of injection-molded parts • Low coefficient of friction enables easy assembly, e.g. seals, valves
SILPURAN® 6610	Non-healing	• Paste-like, 2-part silicone rubber (white) with short curing times (1 : 1 A / B system) • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Needle-free valves, slit membranes • Significantly reduced tendency toward free-radical-induced healing of slit valves during sterilization with γ-rays or high-speed electrons (β-radiation; ≤ 75 kGy)
SILPURAN® 6700	Primerless self-adhesion to various substrates	• Paste-like, easily pigmentable 2-part silicone rubber with short curing times (1 : 1 A / B system) • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical applications • Economical mass production of injection-molded parts • Self-adhesion enables 2k injection molding e.g. seals, membranes, bellows, masks
SILPURAN® 6740	Primerless self-adhesion to various substrates, high tear	• Paste-like, easily pigmentable 2-part silicone rubber with short curing times (1 : 1 A / B system) • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical applications • Economical mass production of injection-molded parts • Self-adhesion enables 2k injection molding e.g. seals, membranes, bellows, masks

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"
Device Master Files listed at FDA

Hardness, Shore A	Tensile strength (DIN 53 504-S1) [N/mm²]	Elongation at break (DIN 53 504-S1) [%]	Tear strength (ASTM D 624 B) [N/mm]	USP Class VI[1]	ISO 10993[2]	BfR[3]	FDA[4]
06	2.4	680	7.8	x	x	x	
12	4.2	720	16	x	x	x	
20	6.5	760	28	x	x	x	x
32	8.5	670	33	x	x	x	x
41	9.3	590	35	x	x	x	x
50	10.2	490	32	x	x	x	x
60	10.0	370	29	x	x	x	x
69	9.3	300	23	x	x	x	x
40	9.1	630	37	x	x	x	x
50	9.1	460	42	x	x	x	x
60	9.1	380	43	x	x	x	x
41	8.8	570	35	x	x	x	x
48	8.6	440	32	x	x	x	x
59	8.6	330	27	x	x	x	x
40	6.5	470	23	x	x	x	x
50	7.4	450	27	x	x	x	x
59	6.8	280	20	x	x	x	x
70	6.9	220	19	x	x	x	x
77	6.2	140	15	x	x	x	x
39	8.0	620	23	x	x	x	x
51	8.0	580	27	x	x	x	x
60	8.2	470	27	x	x	x	x
37	8.7	700	30	x	x	x	x

(1) Systemic / intracutaneous toxicity, implantation test (5 days)
(2) Cytotoxicity, sensitation LLNA, pyrogenicity
(3) BfR recommendation “XV. Silicone” (BfR = Bundesinstitut für Risikobewertung)
(4) FDA 21 CFR § 177.2600 “Rubber articles intended for repeated use” (FDA = Food and Drug Administration)

SILPURAN® – Platinum-Curing Solid Silicone Rubber

Product	Properties	Product Description	Typical Applications
SILPURAN® 8020	Very good mechanical properties	• Platinum cure 2-part solid silicone rubber for injection molding and molding, (100 : 1.5 base / SILPURAN® curing agent M) • Easily pigmentable • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical molding applications • E.g. highly transparent and highly stressable articles • Compression, transfer or injection molding
SILPURAN® 8030	High tear resistance	• Platinum cure 2-part solid silicone rubber for extrusion (100 : 1.5 base / SILPURAN® curing agent X) • Easily pigmentable • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical extrusion applications • E.g. highly transparent and highly stressable tubes or catheters
SILPURAN® 8630	Low frictional resistance, 50-70 % lower coefficient of friction than SILPURAN® 8030	• Platinum cure 2-part solid silicone rubber for extrusion (100 : 1.5 base / SILPURAN® curing agent X) • Easily pigmentable • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical extrusion applications • E.g. catheters or tubes with reduced surface friction

SILPURAN® – Peroxide-Curing Solid Silicone Rubber

SILPURAN® 8060	High flexibility, high transparency and good mechanical properties	• Peroxide cure 2-part solid silicone rubber (base + curing agent) • Easily pigmentable • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical extrusion and molding applications • E.g. seals, tubes
SILPURAN® 8461	High tear resistance, high transparency	• Peroxide cure 2-part solid silicone rubber (base + curing agent) • Easily pigmentable • Produced in accordance with the WACKER CLEAN OPERATIONS standard	• Medical / pharmaceutical extrusion applications • E.g. tear-resistant tubes • High extrusion speeds possible

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"
Device Master Files listed at FDA

Hardness, Shore A	Curing agent	Tensile strength (DIN 53 504-S1) [N/mm²]	Elongation at break (DIN 53 504-S1) [%]	Tear strength (ASTM D 624 B) [N/mm]	USP Class VI[1]	ISO 10993[2]	BfR[3]	FDA[4]
44	M	11.6	835	38	x	x	x	x
51	M	11.8	770	40	x	x	x	x
61	M	11.6	690	31	x	x	x	x
71	M	10.3	650	38	x	x	x	x
39	X	10.1	865	32	x	x	x	x
51	X	9.1	781	36	x	x	x	x
58	X	10.3	660	41	x	x	x	x
68	X	9.1	650	44	x	x	x	x
62	X	8.1	520	42	x	x	x	x
39	E[5]	9.5	590	22	x	x	x	x
41	C1[6]	11.5	770	26	x	x	x	x
51	E	11.0	540	25	x	x	x	x
51	C1	12.0	650	30	x	x	x	x
59	E	11.0	500	26	x	x	x	x
58	C1	10.0	450	26	x	x	x	x
68	E	11.5	480	29	x	x	x	x
69	C1	11.5	560	32	x	x	x	x
61	E	10.8	510	36	x	x	x	x

(1) Systemic / intracutaneous toxicity, implantation test (5 days)
(2) Cytotoxicity, sensitation LLNA, pyrogenicity
(3) BfR recommendation “XV. Silicone” (BfR = Bundesinstitut für Risikobewertung)
(4) FDA 21 CFR § 177.2600 „Rubber articles intended for repeated use” (FDA = Food and Drug Administration)
(5) ELASTOSIL® AUX Curing Agent E
(6) ELASTOSIL® AUX Curing Agent C1

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6365C e/04.16 supersedes 6365C e/01.15