## **Regulatory Status (tubing) Tubing** Selected 3-A Sanitary Standards USP (661) Physiochemical Tests - Plastics USP (381) Elastomeric Closures for Injection To assure consistent quality for medical device Ph. Eur. (EP) Monograph 3.1.9. Silicone Elastomer for Closures and Tubing and pharmaceutical applications, Dow Corning® FDA Regulation 21 CFR 177.2600 (Food Grade) and Silastic® brand tubing products are manufactured, packaged, and tested utilizing principles of Biocompatibility Tests (base elastomer) GMP guidelines for both Active Pharmaceutical Cytotoxicity Ingredients (APIs) and Medical Devices. Mutagenicity/Genotoxicity Hemolysis Typical Properties<sup>†</sup> Skin Sensitization Burst Pressure (for 0.375 in. ID x 0.625 in. OD) Pyrogenicity (USP) Barium Sulfate Content 90-day Implant (exceeds USP Class VI) Tensile Strength at Break USP Class V and VI Modulus at 200% Elongation Elongation **Biopharmaceutical and** % **Pharmaceutical Tubing** MPa (psi) w/w% Description **Typical Applications** MPa (psi) Bar (psi) Silicone tubing · Ultra-pure fluid transfer 795 Dow Corning® Pharma-50 Tubing 2.1 (310) 8.7 (1265) 4.1 (59) Filling machines produced from 2.8 (415) 6.8 (990) Dow Corning® Pharma-65 Tubing 775 7.7 (112) platinum-catalyzed · Steam or gas transfer silicone elastomer Cleanroom 570 3.9 (570) 7.0 (1025) 13.2 (192) Dow Corning® Pharma-80 Tubing Veterinary for transfer Silastic® Laboratory Tubing, 7-5224 applications in 616 8.1 (1177) pharmaceutical and (cat. # 508) biotechnological Silastic® Laboratory Tubing, 7-5225 507 7.6 (1109) manufacturing (cat. # 515) · Extended peristaltic pump Dow Corning® Pharma Advanced 590 3.0 (435) 8.9 (1290) 3.4 (50) delivery **Pump Tubing** Dow Corning® Pharma-65 Reinforced • High/low pressure 890¹ 2.82 (409)1 7.94 (1151)<sup>1</sup> 41.2 (597) applications Tubing · Kink-resistant **Molded Tubing Assemblies** Custom-molded Biopharmaceutical and Dow Corning® Pharma Fabricated Tubing Assembly (HCR-based) pharmaceutical fluid transfer assemblies for critical fluid transfer Dow Corning® Pharma Fabricated applications Tubing Assembly (LSR-based) **Medical Grade Tubing** Silastic® Rx-50 Medical Grade Tubing 815 2.1 (302) 9.6 (1388) Silicone tubing · Infusion therapy produced from - Drug delivery Silastic® Rx-65 Medical Grade Tubing 613 2.7 (391) 9.0 (1301) platinum-catalyzed - Nutritional therapy silicone elastomer feeding tubes • Silastic® Rx-80 Medical Grade Tubing 4.0 (581) 831 7.1 (1030) for critical medical Medical catheters . . . Silastic® Rx 50R Medical Grade 805 2.2 (312) 9.6 (1395) 13 device applications - Urology catheters **Tubing Radiopaque Special** - Respiratory catheters Shunts Silastic® Rx 65R Medical Grade 600 2.6 (375) 9.1 (1320) 13 Cardiac pacing leads Tubing Radiopaque Special Silastic® Rx 80R Medical Grade • 825 2.6 (380) 7.3 (1060) 13 **Tubing Radiopaque Special** Cardio-pulmonary bypass Silastic® Rx Pump Tubing 815 2.1 (302) 9.6 (1388) • Drug delivery • High/low pressure 930<sup>1</sup> 10.0 (1450)<sup>1</sup> Silastic® Rx-50 Reinforced Medical applications Grade Tubing

· Kink-resistant

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<sup>&</sup>lt;sup>1</sup> Based on elastomer

<sup>&</sup>lt;sup>†</sup> Specifications Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office prior to writing specifications on these products.