



About Dow Corning® Brand Tubing

Frequently Asked Questions

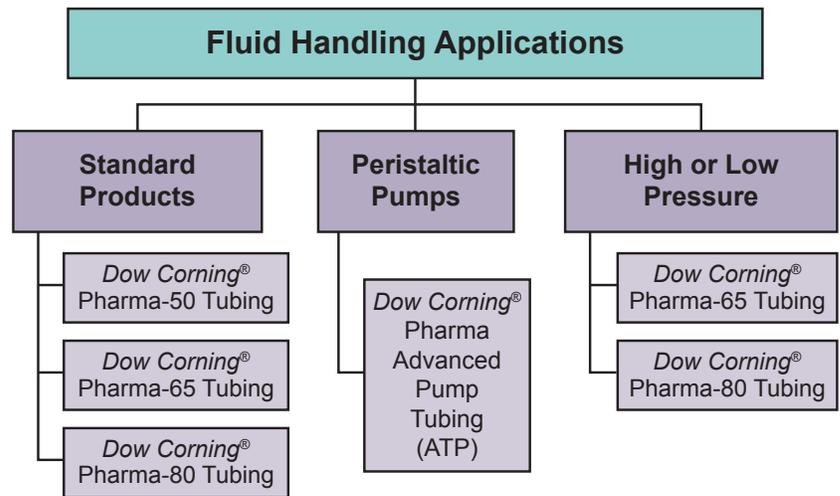
Please Read Carefully

Information contained in this publication is an accurate description of the typical characteristics for the product, and it is intended only to provide guidelines for use of the product. It is the responsibility of the users to thoroughly test the product in their specific applications to determine its performance, efficacy and safety.

Product Offering

1. What tubing products are available from Dow Corning for pharmaceutical fluid handling applications?

The following chart provides our recommended product offering for pharmaceutical fluid handling applications:



2. What are the intended applications for Dow Corning® brand Pharma tubing?

We offer Dow Corning® brand Pharma tubing for pharmaceutical and biotechnology fluid handling applications (e.g.: drug production, sterile processing, fill-finish, peristaltic fluid transfer, and part of single-use assemblies). We also offer Silastic® brand Laboratory Tubing for general applications in the laboratory.

3. For what types of applications is Dow Corning® brand Pharma Advanced Pump Tubing recommended?

Dow Corning brand Pharma Advanced Pump Tubing is a platinum-catalyzed tubing designed for use in peristaltic pump applications. It was designed to give longer pump life in peristaltic (roller) pumps than observed with standard platinum-cured silicone tubing. Our data indicates that, on average, the pump life of Dow Corning® brand Advanced Pump Tubing is five to six times that of standard 50 durometer silicone tubing.

4. Is sterile tubing available from Dow Corning?

Silicone tubing, as purchased from Dow Corning, is not pre-sterilized. It has been produced in a controlled environment, but it is the responsibility of the user to sterilize and clean the tubing if sterilization is an application requirement.

5. From which distributors can I purchase *Dow Corning*[®] brand tubing?

Dow Corning brand Pharma Tubing may be purchased from any of the following distributors. For contact information, please refer to:

Healthcare site on the Dow Corning Web site:
dowcorning.com/healthcare

Examples of distributors from whom *Dow Corning* brand Pharma Tubing may be purchased include the following. This is not an all inclusive list.

North America:

- Cole Parmer Instrument Company (800 323 4340)
- VWR Scientific International (800 932 5000)

Europe:

- Biesterfeld Spezial Chemie GmbH (+49 403 200 8278)
- Azelis (+44 1992 825 555)

6. Can Dow Corning produce “custom” tubing, such as special sizes, to meet a customer’s specific requirements?

Yes, customization options include special dimensions, shapes, tolerances, cut lengths, bulk packaging, spooling, and marking to meet customers’ unique requirements.

7. Can I purchase the elastomers from which *Dow Corning*[®] brand tubing products are manufactured?

No, the elastomers used to produce *Dow Corning* tubing products are available for internal Dow Corning extrusion use only and are not commercially available. Dow Corning does have commercially available elastomers for healthcare applications, but the formulations of these products are different from the specially formulated proprietary elastomers used to extrude *Dow Corning* tubing.

Composition

8. What are the differences among *Dow Corning*[®] Pharma-50 Tubing, *Dow Corning*[®] Pharma-65 Tubing, and *Dow Corning*[®] Pharma-80 Tubing?

These three products differ in their hardness, or Shore A durometer. *Dow Corning* Pharma-50 Tubing is the softest, most pliable tubing while *Dow Corning* Pharma-80 Tubing is harder and more rigid. *Dow Corning* Pharma-65 Tubing and *Dow Corning* Pharma-80 Tubing offer greater pressure and kink resistance relative to *Dow Corning* Pharma-50 Tubing. Translucency also increases with increasing hardness.

9. What is the composition of the silicone tubing produced by Dow Corning?

The silicone elastomers used to make silicone tubing are composed of a silicone (polydimethyl siloxane polymer) base, a silicone cross-linker, an inhibitor and a catalyst. No other additives or organic plasticizers are added to the silicone formulation. Silicone elastomers cure irreversibly (thermoset polymers) and are stable at high temperature. In addition, *Dow Corning*[®] brand silicone elastomers do not contain latex. In contrast, plasticizers and other additives are often added to organic (non-silicone) tubing.

10. Can you tell me what *Dow Corning*[®] brand elastomer is used to produce *Dow Corning*[®] brand Pharma Tubing?

No. We do not disclose product formulations. The elastomers used to produce our tubing are biomedical grade, but commercially not available and are produced exclusively for our internal extrusion use. We can provide general composition and extractable data to our customers.

11. What catalyst systems are used in the manufacture of *Dow Corning*[®] brand tubing?

Dow Corning offers customers platinum-catalyzed tubing.

12. How do platinum-catalyzed and peroxide-catalyzed tubing products differ and which one is appropriate for my application?

The appropriate product depends upon the customer’s application and is the customer’s decision. Platinum-catalyzed tubing is recommended for ultra-pure fluid transfer applications as platinum catalysts are used at very low concentrations, and they become an integral part of the elastomer. In contrast, peroxide catalysts are used in much higher concentrations and are degraded by the heat of the curing process. The peroxide degradation products are driven off by a post-cure step that is not required for platinum-cured products.

13. What is the general appearance of the platinum-cured silicone tubing?

Silicone tubing is usually not completely transparent as it is made of two materials, silica and silicone polymer, of different refractive indexes. It most often has a translucent appearance and may have a whitish-gray to pale yellow or slightly blue tint. Tubing color is dependent upon tubing dimensions and the lighting under which the tubing is observed. This color range should not be perceived as a quality concern as it is actually a natural result of the platinum catalyst colloid size.

14. How does *Dow Corning*[®] brand Pharma Tubing differ from alternative suppliers' silicone tubing?

In addition to producing *Dow Corning*[®] brand tubing under strict manufacturing controls, the elastomer used to produce the tubing is produced at our Healthcare Industry Materials Site under principles of Good Manufacturing Practices (GMPs). Our unique vertically-integrated supply chain allows every step of the manufacturing process to be accounted for – from silicon metal to silicone polymer, to silicone elastomer, to silicone tubing. To our knowledge, no other tubing producer has this level of control over the ENTIRE manufacturing process, from raw materials through finished tubing. Tubing quality is contingent upon not only the final extrusion step, but upon the entire manufacturing process, from polymer synthesis through final extrusion.

that the tubing retains no cleaning agents that may be potentially leached into subsequent products. If the tubing must be cleaned, it is advisable to use a water solution of mild soap that can be easily rinsed from the tubing surface. Because silicone tubing is very hydrophobic, Dow Corning does not recommend the use of oleophilic (oil-loving) cleaning materials as these materials may be absorbed into the silicone tubing.

Application Information

15. Within what temperature ranges can silicone tubing withstand and remain useable?

Silicone tubing remains usable over a very wide temperature range, from -50°C to 250°C. At temperatures above 150°C, formaldehyde may be generated due to the cleavage of methyl groups on the silicone polymer. As indicated on product labeling, adequate ventilation is therefore recommended if the tubing is used at elevated temperatures. Exposure to extreme heat, especially above 300°C, may result in additional cross-linking of the silicone elastomer, which leads to an increase in hardness (durometer) of the tubing. If this condition is carried to an extreme (high temperature for an extended period of time), the tubing may become brittle.

16. What conditions may affect the compatibility of silicone tubing?

Silicone tubing is compatible with numerous chemicals including acids, bases, and a variety of solvents. However, some solvents such as hydrocarbons and silicone fluids swell the silicone tubing, depending on the duration of exposure. Swelling results in the loss of some physical properties of the tubing. The physical properties return to normal once the solvent has evaporated from the tubing. Dow Corning highly recommends that the customer complete preliminary feasibility studies to determine the fitness for use under conditions encountered in the application. Detailed compatibility data is available upon request.

17. Can silicone tubing be cleaned for re-use?

In most fluid handling applications, it is now standard practice to change tubing between uses for different drugs or other liquid products. This practice eliminates the need to validate the cleaning process in most cases, and it ensures

18. What methods can be used to sterilize silicone tubing?

Silicone tubing can be sterilized by any of the common methods, including autoclaving, dry heat, ethylene oxide, and gamma radiation. Studies have shown that the tubing can be sterilized by autoclaving for at least 25 cycles (121°C, 15 psi, 30 minutes) without any significant changes in physical properties. For gamma radiation sterilization, Dow Corning recommends that a single cycle of no more than or 50 kGy be used. Higher doses of radiation or repeated cycles may cause further cross-linking of the silicone elastomer, which results in slight changes in physical properties. Changes will depend upon exposure duration and the dose level of radiation. Because the hardness of the elastomer may increase, these changes will likely be manifested as stiffer tubing.

Note: Silicone tubing, as purchased from Dow Corning, is not pre-sterilized. It has been produced in a clean environment, but it is the responsibility of the user to sterilize the tubing, if sterilization is an application requirement.

19. Can silicone tubing be used in an application requiring pressure?

Because of its extreme flexibility, silicone tubing expands under pressure before bursting. Burst pressure of Pharma tubing depends upon several factors, including hardness of the elastomer, the inside diameter (I.D.) and outside diameter (O.D.) of the tubing, and the wall thickness. Tubing made from higher hardness elastomer (e.g.: 65 and 80 durometer) better withstands higher pressures due to the increased modulus of the elastomer. In addition, Dow Corning offers Dacron[®]- reinforced tubing for high-pressure applications. For additional information regarding burst pressure, please refer to Dow Corning's white paper on this subject which can be found on our Web site (dowcorning.com/content/healthcare/healthtube) or by requesting literature form number 52-1047 from Dow Corning.

Quality & Regulatory Information

20. Is each batch of tubing tested before release?

Yes, each batch of each product undergoes final lot acceptance testing prior to shipment. The data are entered into the Quality Assurance database. The database is also used to generate Certificates of Analysis and for statistical process control. Hardcopy data is currently retained for ten (10) years.

21. How is the tubing's Use By date (expiry date) established?

The Use By date is based on the date of extrusion of the tubing. Expiration date is indicated on Certificate of Analysis and product labeling. Tubing products are part of the Dow Corning Healthcare Industries Materials Site Stability Program, in which compliance to lot acceptance requirements are monitored on selected batches of tubing.

22. What constitutes the definition of a batch?

Each individual batch is assigned a unique ten-digit batch number. Each batch is produced from a single elastomer batch. The material is homogeneous both physically and chemically, thus making a random sample withdrawn from any coil representative of all of the all coils from the batch.

23. What assessment of toxicity or health impacts has Dow Corning performed on tubing?

Dow Corning can provide Product Regulatory Information and Summaries of Health Data for each of our tubing products upon request. These documents summarize the qualification testing performed on each of our tubing products.

24. Can Dow Corning provide extractables data on your tubing?

An extraction "white paper" is available on our Web site (dowcorning.com/content/healthcare/healthtube) or requesting form number 52-1046. Additional information may be available upon request.

25. Are customers notified of changes to the product or process?

Yes, a formal change notification policy applies to tubing from Dow Corning. Customers are informed of changes such as deliberate substitution or modification of the formulation, sampling, testing, process or equipment that could likely impact the chemical or physical properties, impurity profile, identity, strength, quality, purity, or functionality of our tubing.

Contact Dow Corning

When you need innovation, Dow Corning can help. *Dow Corning*[®] brand solutions are dedicated to meeting your needs for speciality materials, collaborative problem-solving and innovation support. Learn how we can help you at dowcorning.com/healthcare.

Your Global Connection

Dow Corning has sales offices and manufacturing facilities worldwide, as well as full-service, global technical support. Contact us today by visiting dowcorning.com/ContactUs.

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Dow Corning's sole warranty is that our products will meet the sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

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Form No: 52-1074B-01



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