

Difference Between Food Grade and Medical Grade Silicone

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Key Difference – Food Grade vs Medical Grade Silicone

The demand for [silicone](#) rubber has been increasing very rapidly over the past few decades because of its excellent properties. These properties are due to the unusual molecular structure of the [polymer](#) backbone with silicon atoms alternating with oxygen atoms. The silicon oxygen linkage is similar to the linkage in [quartz](#) and glass. Because of these linkages, silicon shows excellent heat resistant properties when compared to other [elastomers](#). Another reason for this high heat resistance is the high bond energy of silicon-oxygen bonds when compared to carbon-carbon single bonds. Another advantage of having inorganic silicon-oxygen double bonds is the fungal resistance and rodent repellent properties, which makes silicon rubber suitable for the usage in many food-grade applications. Silicon also has high permeability to gasses and high compressibility. Moreover, Silicon rubber is highly resistant to oxidative attacks by [ozone](#) and ultraviolet, especially at higher temperatures. This property ultimately enhances its service life even at elevated temperatures. Moreover, silicon rubber shows good tensile properties and has a low glass-transition temperature. Because of these excellent properties, silicone rubber can be used in a wide temperature range from -100 °C to 200 °C. Since silicone rubber is odorless, tasteless, and nontoxic, it is used to manufacture many food-products and medical-grade products. The key difference between food grade and medical grade silicone is their use; **Food-grade silicone is used for manufacturing of food-contact products while medical-grade silicon is used for manufacturing of pharmaceutical products and implant devices.**

What is Food Grade Silicone?

Silicone rubber has been widely applied as a food-grade material in many applications, unlike any other elastomer in the world because of its exceptional purity, odorless, non-toxic, non-corrosive and inert properties. Usually, all food-contact silicon products must meet any of the available food standard regulations introduced by several countries/ regions. Such regulations include the existing EU legislation and guidelines, Council of Europe Resolution on silicones, German recommendation XV from the BfR, and the US Food and Drug Administration (FDA) regulations.



Figure 01: Silicon Kitchen Utensils

The assessment of the safety of silicone materials and articles for food applications can be done by fingerprinting potential migrants from silicone products, multi-element semi-quantitative inductively coupled plasma scan, identification of migrants, FDA regulations for Rubbers, determination of specific elements and [formaldehyde](#), and determination of low molecular weight species using GC-MS and LC-MS instrumentation. Usually, for food-contact applications, it is recommended to use platinum-catalyzed curing systems for silicone rubbers. In addition, post curing is also recommended for food-contact articles in order to improve the mechanical properties and most importantly, to remove the volatile by-products derived from crosslinking chemicals and low-molecular components. Some applications of food-grade silicone include baking molds, ice cube trays, grips of kitchen knives, whisks, spoons, and other kitchen utensils, and seals and o-rings in contact with foods.

What is Medical Grade Silicone?

Medical grade silicone rubbers are the most widely applied synthetic rubber of all synthetic elastomers in permanently implanted sub-dermal devices owing to their non-toxic and inert behavior. Although certain fillers and vulcanizing agents are used in silicone rubber manufacturing processes, the rubbers do not contain a wide variety of additives as compounding ingredients, which are used in organic rubber compounding processes. There are two types of medical grade silicones: room-temperature-

vulcanizing types and heat-vulcanizing types. The term ‘medical-grade’ is applied to the silicones that fulfill three requirements;

- (a) a long history of successful implantation in both animals and humans,
- (b) manufactured under good pharmaceutical manufacturing conditions,
- (c) quality controlled for medical applications.

Platinum-catalyzed curing systems are recommended for medical-grade silicon rubber products. Peroxide curing is not recommended as it leaves or blooms acid residues after the curing process. Medical grade silicones are used to make feeding tubes, catheters, implants for long and short-term use, seals and gaskets, syringe pistons, scar treatment silicon sheets, gels, condoms, menstrual cups, respiratory masks. etc. In the United States, implanted devices with medical grade silicones are regulated by the Center for Devices and Radiological Health (CDRH) under FDA regulations. In addition, there is European medical device regulatory framework for medical grade silicones.



Figure 02: Silicone Breast Implants

What is the difference between Food Grade and Medical Grade Silicone?

Food Grade vs Medical Grade Silicone

Food-grade silicone is used for manufacturing of food-contact products.

Medical-grade silicone is used for manufacturing of pharmaceutical products and implant devices.

Regulatory bodies

Food-grade silicone is regulated by FDA, BfR and EU regulations.

Medical-grade silicon is regulated by FDA and EU regulations.

Summary – Food Grade vs Medical Grade Silicone

Both food grade and medical grade silicone products are manufactured under good quality control procedures in order to meet the existing regulations such as FDA, BfR, EU, etc. The odorless, non-toxic, inert, high-temperature stability and chemical resistance are the important properties of silicone rubber that enable their use in food-contact and medical-grade applications. Platinum catalyzed curing system is recommended for both silicone grades. Both grades ensure that there is no harm to human and environment, and facilitates biocompatibility.

References:

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