Healthcare Solutions

DuPont™ Liveo™ 360 Medical Fluid

Frequently Asked Questions

Please Read Carefully

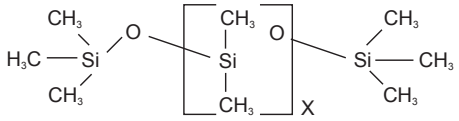
Information contained in this publication is an accurate description of the typical characteristics for the product, and it is intended only to provide guidelines for use of the product. It is the responsibility of the users to thoroughly test the product in their specific applications to determine its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

Product Offering

1. What is the chemical composition of DuPont™ Liveo™ 360 Medical Fluid?

The material is linear polydimethylsiloxane (PDMS) having the general structure:

PDMS



2. What determines the different viscosities?

The relative number of repeating siloxane units (x) in the polymer chain will determine the molecular weight and viscosity of a particular fluid. As the number of units increase the polymer obviously becomes longer and the viscosity also increases. The average molecular weight of a particular fluid can be determined by Gel Permeation Chromatography (GPC).

3. Is Liveo™ 360 Medical Fluid processed differently from the industrial fluids?

Liveo™ proposes a number of different grades of PDMS fluid but additional controls are in place for Liveo™ 360 Medical Fluid as well as further documentation for traceability. Additionally Liveo™ 360 Medical Fluid goes through a depyrogenation process in a closed process by passing it through a 3 micron depth filter, followed by a 5 micron fiber-free filter (efficiency >99.99%). It is then packaged in a Class 100 curtained area within a Class 10,000 clean-room.

4. What are the important regulatory considerations for DuPont™ Liveo™ 360 Medical Fluid?

DuPont™ Liveo™ 360 Medical Fluid is tested to meet all the requirements of the Dimethicone NF monograph and, depending on the viscosity of the fluid, the Dimeticone and Silicone Oil Used as a Lubricant Ph. Eur. (or "EP") monographs. Furthermore, Liveo™ holds a Certificate of Suitability for both Ph. Eur. Monographs and a Drug Master File is maintained with the United States FDA.

5. Are there any known toxicology concerns associated with Liveo™ 360 Medical Fluid?

Liveo™ has a wealth of toxicological information on PDMS. Specific questions on toxicology should be addressed to your Customer Service Professional or Technical Service Specialist who will direct you to the appropriate person within Liveo's Environmental Health & Safety Department.

6. What are the principal methods for applying Liveo's 360 Medical Fluid to an article?

Spraying the pure fluid is a widely used method of application (although Liveo recommends the use of appropriate controls in order to limit operator exposure to silicone in aerosol spray form). Equipment for this has been developed by Spraymation Inc. of Florida who have heated nozzles to allow the 12,500 cSt fluid to be applied by this method. The fluid can also be wiped on with a sponge or other device. Whichever method is chosen, it is very important to consider how much fluid is applied to an article. The process should be designed to deliver the minimum amount needed to achieve the desired lubrication as any excess may come off the article and become suspended in fluids delivered from siliconized articles such as syringes.

7. Can Liveo™ 360 Medical Fluid be diluted for more accurate treatments?

A common application method is to dilute Liveo™ 360 Medical Fluid to 0.1-5% (depending on requirements) and then use this solution for dipping, spraying or wiping. Since Liveo™ 360 Medical Fluid is a non-polar silicone fluid it is soluble principally in aliphatic (e.g. hexane, or preferably heptane) and aromatic (e.g. toluene or xylene) solvents. It is only very slightly soluble in alcohols such as isopropanol but not in ethanol. Certain chlorinated solvents can also be used (subject to local environmental laws) but this is becoming less common.

Liveo™ Q7-9180 Silicone Fluids (volatile short-chain linear polydimethylsiloxanes) are particularly suitable for diluting Liveo™ 360 Medical Fluid where good results can be obtained due to the superior silicone oil/silicone solvent compatibility.gain a competitive advantage.

8. Can Liveo™ 360 Medical Fluid be "cured" on an article's surface?

Linear polydimethylsiloxane fluids do not contain any (appreciable) functional groups that allow the fluid to attach to a surface or itself be polymerized and thus become "cured". It is best to think of Liveo™ 360 Medical Fluid as remaining as a fluid, with the capability of spreading from its point of application – especially if applied in excess. Some studies (Mundry, Schurreit and Surmann, *PDA Journal of Pharmaceutical Science & Technology 54: 5, 383 (2000))* have indicated that heat treatment can result in a small percentage of fluid become "bound" to the surface but it is usual to consider it as non-curable and able to be removed from the surface of an article.

9. Even if the fluid cannot be "cured", can it be made slightly more durable on a surface?

If the article being siliconized can withstand some application of heat, it is advantageous to "bake" it after treatment. This will ensure complete removal of any solvents used and, on a microscopic scale, allow the silicone fluid to become more intimately associated with the substrate. The input heat energy assists small aggregates or droplets of the fluid to spread out evenly over the surface and create a more uniform film. At the same time the "water of hydration" – a layer of moisture present on the surface of an article due to humidity from the air – is displaced. Heating or baking only needs to be done at a temperature and time sufficient to remove this water of hydration from the substrate surface. No chemical bonding results, rather a strong physical attraction between the surface and initial monolayer of fluid that is thought to be the most important for lubrication.

Again, it is very important to remember to apply only the minimum amount of silicone fluid that is required to achieve the desired level of lubrication on the article (which itself should be clean and free of contaminants before treatment).

It is suggested that the baking temperature be kept below 150°C to minimize any possibility of oxidation and the formation of formaldehyde. Additionally, the time needed for baking is related to the temperature used and can be substantially shortened at higher temperatures. It is suggested that customers perform their own time/temperature studies in order to identify their optimum conditions for the part being siliconized.

Some increase in durability or decrease in mobility can be achieved by using a fluid with a higher viscosity. Higher viscosity fluids will not flow as easily across a surface (migrate) and will not tend to be removed into suspension as easily as lower viscosity fluids.

10. Is there a simple qualitative method that can be used to determine if a surface has been siliconized and whether the treatment is uniform?

A siliconized article can be dipped into a container of a fine powder such as talc for a gross verification of whether or not the surface has been siliconized. If the treatment has been successful the powder will stick to it and the uniformity of the coating can be estimated by examining the surface for any areas where the powder did not stick.

However, in order for this method to be effective, it is important to first check that the powder does not stick to the untreated surface; furthermore, contamination of the surface can also give misleading indications so care must be taken. Items tested in this way should be discarded afterwards

11. What quantitative analytical methods may be used to determine the amount of silicone fluid applied to a surface?

Fourier-Transform Infrared Spectroscopy (FTIR) has been used to quantify the amount of silicone fluid applied to an article. However, this method generally requires that a number of articles be extracted in order to get enough PDMS to quantify from the spectrum and standards must be used. This does not therefore generally allow exact determination of the amount applied to any one article.

Another more specific method that can be applied is Flame Absorption Atomic Spectroscopy (FAAS) that quantifies Si based on a standard curve. FAAS may also require multiple articles be extracted to achieve sufficient concentration to make a determination.

Comparative testing of siliconized versus non-siliconized items is of course an obvious method of qualitative and quantitative assessment.

12. Can articles treated with Liveo™ 360 Medical Fluid be sterilized, and by what methods?

Siliconized articles may be sterilized by the usual methods such as steam autoclaving, dry heat, radiation, and ethylene oxide (ETO). If ETO is used, proper out-gassing must be completed before the article is suitable for use. It has been found that sterilization by radiation generally has no affect on the fluid with doses up to 2.5 Mrad for the appropriate amount of time. However, higher doses and times have the potential to especially affect the higher viscosity fluids by causing some cross-linking that results in an increase in molecular weights and viscosities. This may affect the lubrication properties of the article so it is recommended that articles be tested for proper lubrication after the sterilization process.

13. How can Liveo™ 360 Medical Fluid be cleaned off exposed surfaces that may accidentally have been coated?

The most effective cleaning agents for PDMS are aliphatic and aromatic organic solvents but many have hazards associated with flammability and/or toxicity. Liveo™ Q7-9180 Silicone Fluids (or industrial grade Liveo™ OS Fluid equivalents) have also been used for cleaning PDMS from surfaces but it should be noted that they are also flammable.

If a water-based detergent is desired for cleaning and use in cleanroom areas, it is recommended that Steris Corporation be contacted to obtain either CIP 100® detergent (potassium hydroxide based) or CIP 200® detergent (phosphoric acid based):

Steris Corporation
5960 Heisley Road
Mentor, OH 44060-1834

Phone: 1-800 444 9009 or +1 (440) 354 2600

Fax: +1 (440) 350 7077

These detergents are widely used in pharmaceutical facilities to remove PDMS from equipment. Liveo™ uses CIP 100 in its emulsion processing units that see extensive exposure to PDMS.

Contact Liveo

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