Healthcare Solutions

Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™ 366, 35% Dimethicone NF Emulsion

Frequently Asked Questions

Please Read Carefully

The information contained in this publication is an accurate description of the products' typical characteristics and is designed to supplement the Product Data Sheets and Safety Data Sheets.

However, these are only guidelines for use; it is the user's responsibility to thoroughly test the product(s) in any specific application to determine their performance, efficacy and safety. Statements regarding other aspects, such as emerging regulations, are believed to be accurate at the time this FAQ is being written. Regulations can change from time to time. It is the user's responsibility to understand and comply with all current germane laws and regulations; as well as to determine the safety and efficacy for use of the materials in their application.

Product Offering

1. How are these two products, Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™ 366, 35% Dimethicone NF Emulsion similar?

Both emulsion products are composed of 35% dimethicone dispersed in water with non-ionic surfactants and preservatives. Typically, the comparable emulsions have been considered for similar applications and product nomenclature (although Liveo™ no longer uses a comma "," in new product names). Typical mechanical **oil-in-water** emulsions of this type have a particle size of around 100 nanometers (nm) to 1 micron (µm).

2. Why does DuPont™ Liveo™ offer two emulsions of similar composiCon?

Liveo™ 365, 35% Dimethicone NF Emulsion contains the non-ionic surfactant polyethylene glycol tert-octylphenyl ether (CAS 9036-19-5). Polyethylene glycol tert-octylphenyl ether is in the octylphenyl ethoxylates (OPE) family.

The OPE family of surfactants have been added to the REACh (Registration, Evaluation, Authorisation and Restriction of Chemicals) Authorisation List administered by the EChA (European Chemical Agency).

Liveo™ developed a new material, Liveo™ 366 35% Dimethicone NF Emulsion, which is similar to Liveo™ 365, 35% Dimethicone NF Emulsion, however with the polyethylene glycol tert-octylphenyl ether replaced by a different surfactant which is not currently a listed substance of very high concern under REACH. An additional difference is that the Liveo™ 366 35% Dimethicone NF Emulsion formulation does not contain parabens.

3. For a new application, which dimethicone emulsion should I use?

Liveo™ 366 35% Dimethicone NF Emulsion has been formulated in recent years using ingredients which are not listed as REACH substance of very high concern candidates. This emulsion has also been formulated to avoid the use of paraben preservatives. For these regulatory reasons, Liveo™ 366 35% Dimethicone NF Emulsion may be preferred for new applications in which you find it is suitable.

4. Are these dimethicone emulsions suitable for food contact applications?

Both Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™ 366 35% Dimethicone NF Emulsion contain preservatives which are not affirmatively listed as preservatives by the EFSA (European Food Safety Authority) and/or some other EU Member State Authorities and consequently are not represented as suitable for food contact. Similarly, a preservative in Liveo™ 366 35% Dimethicone NF Emulsion is not affirmatively listed by US FDA as suitable for food contact. Coatings of Liveo™ 365, 35% Dimethicone NF Emulsion are not currently precluded under US regulation for indirect food contact situations in the USA. The customer should confirm suitability for its particular food contact application.

5. Are there additional notable regulatory considerations for Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™ 366 35% Dimethicone NF Emulsion?

While there are no USP/NF (United States Pharmacopeia/ National Formulary) or Ph. Eur. (European Pharmacopoeia) monographs for dimethicone emulsion compositions per se, the silicone (polydimethylsiloxane) fluid used as the active material in Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™ 366 35% Dimethicone NF Emulsion has been qualified to meet the Dimethicone NF and Dimeticone Ph. Eur. monograph requirements. Furthermore, Liveo™ holds a Certificate of Suitability for the Dimeticone Ph. Eur. Monograph, and a Drug Master File is maintained with the United States FDA.

6. What important factors should be considered with respect to the manufacturing and testing of Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™

The emulsions are manufactured at the Liveo™ Healthcare Industries Materials Site using a quality system based on bulk pharmaceutical cGMPs. The materials are manufactured using USP purified (but not sterilized) water and are not packaged in an ultra-clean-room environment – although they are filtered through a 25 micron (µm) filter. They are not manufactured to be pyrogen-free. Liveo™ does not test this emulsion for pyrogen levels due to the difficulties associated with testing of any material that uses surfactants in the formulation.

7. Does Liveo™ perform microbiological testing on Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™ 366 35% Dimethicone NF Emulsion?

One of the Lot Acceptance Requirements is microbial testing with a specification of less than 100 Colony Forming Units (CFU) per mL. Liveo™ also has control measures in place which require any colonies found to be identified in order to ensure that they are not among those listed in USP <61> ("Microbial Limit Test"). Any lot showing these organisms will be immediately rejected and destroyed. Typically, this material does not show any CFUs in the microbial count test.

8. Are there any known toxicology concerns with Liveo™ 365, 35% Dimethicone NF Emulsion or Liveo™ 366 35% Dimethicone NF Emulsion?

Liveo™ has a wealth of toxicological information and 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 DuPont's Environmental Health & Safety Department.

9. What is the fate in the body of the additives used in Liveo™ 365, 35% Dimethicone NF Emulsion or Liveo™ 366 35% Dimethicone NF Emulsion if they are introduced from siliconized articles such as needles or syringes?

The surfactants and preservatives are present at low levels in the product as sold. Typically, the product is diluted from 35% to 1–5% silicone prior to application, which reduces the concentration of these ingredients further. As a result, any still present on the articles are at extremely low levels and unlikely to cause any adverse effects. Furthermore, these additives are commonly used in other industries that produce materials that come into human contact, for example food and cosmetic applications.

However, it is recommended that users determine by their own testing that these additives will not cause a problem in their specific application.

10. What are the principal applications and considerations for using Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™ 366 35% Dimethicone NF Emulsion?

Since the product is a water-based method of delivering silicone fluid, it may be employed in siliconization applications where it is not possible to use an organic solvent as a diluting agent for the fluid. The product is also widely used for siliconization of glass syringe barrels, which are often ultimately sterilized and depyrogenated with dry heat. In the case of articles such as rubber stoppers, for which it may not be possible to perform depyrogenation, it is very important to consider diluting the material with USP Water for Injection (WFI) grade water in a clean-room environment to help control bioburden.

11. What are the principal methods for applying Liveo™ 365, 35% Dimethicone NF Emulsion or Liveo™ 366 35% Dimethicone NF Emulsion to an article?

Application equipment often consists of washing/rinsing/drying machines; another application method is to spray a diluted solution of the emulsion and equipment for this process has been developed by Spraymation Inc. (spraymation.com). Liveo™ recommends the use of appropriate controls in order to limit operator exposure to silicone in aerosol spray form. Some articles may be dip-coated in a diluted solution of the emulsion while others may be wipe-treated via 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.

12. Should Liveo™ 365, 35% Dimethicone NF Emulsion or Liveo™ 366 35% Dimethicone NF Emulsion be diluted before use?

As the products' nomenclature indicates, Liveo™ 365, 35% Dimethicone NF Emulsion and Liveo™ 366 35% Dimethicone NF Emulsion have 35% silicone fluid in their formulations as sold. It is recommended that the emulsion you intend to treat articles with be diluted with sterile, pyrogen-controlled (WFI) water to a concentration of 1–5% silicone in the final treatment solution. As stated above, delivery to the surface of just enough silicone to achieve the desired lubrication is sufficient.

13. Are there any special considerations to keep in mind regarding the use of Liveo™ 365, 35% Dimethicone NF Emulsion or Liveo™ 366 35% Dimethicone NF Emulsion?

Each product is a silicone-in-water emulsion and therefore has a high tendency to phase-separate but can be easily mixed to return the material to its optimum useable form. Labels and product information sheets recommend that the material be thoroughly mixed before each sampling or use to ensure good uniformity. This has been a common cause of problems related to PDMS assays of the product. All original containers or extracted samples must be thoroughly mixed before use or testing. If PDMS values are out of specification, it is highly recommended to try more extensive mixing before rejecting the material.

14. Can the silicone fluid delivered by Liveo™ 365, 35% Dimethicone NF Emulsion or Liveo™ 366 35% Dimethicone NF Emulsion be "cured" on an article?

Linear polydimethylsiloxane fluids do not have 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 the polydimethyl siloxane delivered by these dimethicone NF emulsions as a fluid with the capability of spreading from its point of application, especially if applied in excess. Some studies (e.g., 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 becoming "bound" to the surface, but it is usual to consider it as non-curable and able to be mostly removed from the surface of an article.

15. 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 usually advantageous to "bake" it after treatment. This will help ensure complete removal of the water 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 to 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. As stated above, no bulk chemical bonding results, rather a strong physical attraction occurs 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 (302°F) 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.

16. 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. More sophisticated, equipment-dependent but non-destructive methods have been developed including the application of reflectometry and FTIR (Fourier-Transform Infrared) Spectroscopy assays.

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

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 that 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) which 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.

18. Can articles treated with Liveo™ 365, 35% Dimethicone NF Emulsion or Liveo™ 366 35% Dimethicone NF Emulsion 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 substantial effect on the fluid with doses up to 2.5 Mrad (25 kGy). However, higher doses have the potential to affect polydimethylsiloxane fluid by causing some cross-linking that will result in an increase in molecular weight and viscosity. This may affect the lubrication properties of the article, so it is recommended that articles be tested for proper lubrication after the sterilization process.

19. How can Liveo™ 365, 35% Dimethicone NF Emulsion or Liveo™ 366 35% Dimethicone NF Emulsion be removed from surfaces that may have been accidentally 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, you might wish to consider contacting Steris Corporation 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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Form Number: 001-20493-CDP-REV0-0921