Dow Corning® 365, 35% Dimethicone NF Emulsion

Frequently Asked Questions

DOW CORNING

PLEASE READ CAREFULLY:

The information contained in this publication is an accurate description of the product's typical characteristics and is designed to supplement the Product Data Sheet and Material Safety Data Sheet.

However, these are only guidelines for its use and it is the user's responsibility to thoroughly test the product in any specific application to determine its performance, efficacy and safety.

1. What is the formulation of *Dow Corning* 365, 35% Dimethicone NF Emulsion?

The emulsion is composed of 35% *Dow Corning*® 360 Medical Fluid, 350 cSt in water with non-ionic surfactants, Tween® 20 and Triton® X-100 and the preservatives, sodium benzoate and parabens (propyl and methyl p-hydroxy-benzoates).

Typical mechanical emulsions of this type have a particle size of 0.1 – 1 micron.

2. What are the most important factors to consider with respect to the manufacturing and testing of *Dow Corning* 365, 35% Dimethicone NF Emulsion?

The emulsion is manufactured at the Dow Corning Healthcare Industries Materials Site using a quality system based on bulk pharmaceutical cGMPs. The material is manufactured using USP purified (but not sterilized) water and is not packaged in an ultra clean-room environment – although it is filtered through a 25 micron filter. It is therefore labeled "**NOT MANUFACTURED OR TESTED TO BE PYROGEN-FREE**". Dow Corning does not test this emulsion for pyrogen levels due to the difficulties associated with testing of any material that uses surfactants in the formulation. It is the user's responsibility to determine the safety and efficacy for use of the material in their application and this will be addressed further in the sections to follow.

3. Does Dow Corning perform any microbiological testing on *Dow Corning* 365, 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. Dow Corning 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 Limits 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.

4. What are the important regulatory considerations for *Dow Corning* 365, 35% Dimethicone NF Emulsion?

There are no guideline USP/NF or Ph. Eur. ("EP") monographs for compositions such as *Dow Corning* 365, 35% Dimethicone NF Emulsion. However, the silicone fluid used as the active material in the emulsion (Dow Corning 360 Medical Fluid, 350 cSt) has been qualified to meet the Dimethicone NF and Dimeticone EP monograph requirements. Furthermore, Dow Corning 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 with *Dow Corning* 365, 35% Dimethicone NF Emulsion?

Dow Corning 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 Dow Corning's Environmental Health & Safety Department.

6. What is the fate in the body of the additives used in *Dow Corning* 365, 35% Dimethicone NF Emulsion if they are introduced from siliconized articles such as needles or syringes?

The components of the surfactant and preservative package used in the emulsion are present at levels of fractions of a percent. Typically, the product is diluted to 2-3% silicone prior to application, which reduces these ingredients to ppm quantities. As a result, any still present on the articles are at extremely low levels and unlikely to cause any adverse effects (none have ever been reported). Further, these additives are commonly used in other industries that produce materials that come into human contact, for example food applications.

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

7. If applicable, will the additives used in *Dow Corning* 365, 35% Dimethicone NF Emulsion interfere with the customer's drug components?

There have been no reported negative interactions between the emulsion components and any particular type of drug or drug component (e.g. proteins). As stated above, it is important to remember that the recommended application procedure requires that the emulsion be diluted with water and this effectively dilutes all the emulsifier and preservative components to very low levels. It is therefore unlikely that they will interfere with anything in the customer's solutions although of course this must be verified by the customer's own development work. (It is of interest to note that this emulsion has been successfully used to treat drug vials to prevent protein adsorption onto the vial surface).

8. What are the principal applications and considerations for using *Dow Corning* 365, 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 a 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 control any bio-burden.

9. What are the principal methods for applying *Dow Corning* 365, 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. of Florida. (Dow Corning 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.

10. Should *Dow Corning* 365, 35% Dimethicone NF Emulsion be diluted before use?

Dow Corning 365, 35% Dimethicone NF Emulsion is manufactured with 35% silicone fluid in the formulation and it is recommended that the emulsion 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.

11. Are there any special considerations to keep in mind regarding the use of *Dow Corning* 365, 35% Dimethicone NF Emulsion?

The product is an emulsion and therefore has a high tendency to 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 the most 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.

12. Can the silicone fluid delivered by *Dow Corning* 365, 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 *Dow Corning* 360 Medical Fluid delivered by *Dow Corning* 365, 35% Dimethicone NF Emulsion 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.

13. 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 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 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. As stated above, no significant 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.

14. 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.

15. 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) 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.

16. Can articles treated with dow corning 365, 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 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 affect especially the higher viscosity fluids by causing some cross-linking that will result 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.

17. How can *Dow Corning* 365, 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. Dow Corning® Q7-9180 Silicone Fluids (or industrial grade Dow Corning® 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 clean-room 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. Dow Corning uses CIP 100 in its emulsion processing units that see extensive exposure to PDMS.

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Form no. 52-1040-01

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