Healthcare Solutions

DuPont™ Liveo™ MDX4-4159, 50% Medical Grade Dispersion

Frequently Asked Questions

Please Read Carefully

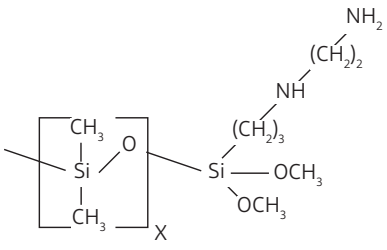
The information contained in this publication is an accurate description of the product's typical characteristics and is designed to supplement the Product Data Sheet and Material Safety Data Sheet.

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.

Product Offering

1. What is formulation and chemical composition of the silicone material in Liveo™ MDX4-4159, 50% Medical Grade Dispersion?

Liveo™ MDX4-4159, 50% Medical Grade Dispersion is 50% silicone in a co-solvent system of 70% Stoddard Solvent (mineral spirits) and 30% isopropanol (iPA). The silicone is an amine functional polymer that also incorporates reactive methoxy- groups and has the following structure:



2. What are the important regulatory considerations for Liveo™ MDX4-4159, 50% Medical Grade Dispersion?

Although it has become widely recognized as an excellent material for use as a needle lubricant, there are no guideline USP/NF or Ph. Eur. ("EP") monographs for Liveo™ MDX4-4159, 50% Medical Grade Dispersion type materials. However, a Drug Master File is maintained with the United States FDA.

3. What are the principal toxicological considerations for Liveo™ MDX4- 4159, 50% Medical Grade Dispersion?

Stainless steel, coated with a cured layer of Liveo™ MDX4-4159, 50% Medical Grade Dispersion, has been fully evaluated to meet the requirements of "Biomedical Grade" materials produced by Liveo™. No adverse effects were noted in any of the assays that met testing requirements for ISO Surface Devices, Externally Communicating Devices, and Implantation Devices categories. The tests included Systemic Toxicity, Intracutaneous Reactivity, USP Pyrogen, Cytotoxicity, Genotoxicity (Ames Test),

Short-term Implantation, Guinea Pig Sensitization and Hemocompatibility (Hemolysis). The tests are summarized in Liveo's Summary of Health Data for this product and this information forms part of the Drug Master File that is maintained with the United States FDA.

Please refer to the Material Safety Data Sheet to understand the hazards and proper handling of the uncured material. 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.

4. What are the principal healthcare applications for Liveo™ MDX4-4159, 50% Medical Grade Dispersion?

The product can be used for treatment of most substrates but is particularly useful for siliconization of reactive (metal) surfaces with which the functional groups on the silicone can bind. Indeed, it was patented principally for use to treat cutting edges such as stainless steel blades and has since become widely accepted for lubricating hypodermic needles.

5. What are the principal methods for applying Liveo™ MDX4-4159, 50% Medical Grade Dispersion?

Parts to be treated are usually dipped in a diluted solution of Liveo™ MDX4-4159, 50% Medical Grade Dispersion which are then dried with a stream of air. Spraying is not recommended because inhalation of aerosol droplets of materials similar to Liveo™ MDX4-4159, 50% Medical Grade Dispersion has been found to elicit adverse toxicological responses. Although Liveo™ MDX4-4159, 50% Medical Grade Dispersion has not been specifically evaluated, we do not recommend spray application that would generate respirable sized particles. Furthermore, since this material must be carried in a solvent system for application, a spraying process would inevitably be associated with safety hazards regarding the spraying of solvents and the possibility of explosion.

6. Should Liveo™ MDX4-4159, 50% Medical Grade Dispersion be diluted before use?

The material as received contains 50% silicone and if this is applied neat to a surface it is unlikely to cure or function properly. The material should be diluted with a suitable solvent system to a final concentration of between 1 and 5% silicone. It is strongly recommended that development work be performed to determine the lowest concentration needed to achieve suitable lubrication on the final article.

7. What solvent systems are suitable for diluting Liveo™ mdx4-4159, 50% medical grade dispersion?

Non-polar aliphatic and aromatic solvents may be used to dilute Liveo™ MDX4-4159, 50% Medical Grade Dispersion but alcohols are not suitable. However, since the material is mostly non-polar but also has some polarity in the methoxy and amino groups, it is highly recommended that a co-solvent system be used, similar to the one in which the original material is supplied (70% of non-polar Stoddard Solvent and 30% iPA). Liveo™ Q7-9180.

Silicone Fluids (volatile short chain linear polydimethylsiloxanes) can also be used successfully to dilute Liveo™ MDX4-4159, 50% Medical Grade Dispersion.

Other organic solvents that can be used are hexane and heptane but the co-solvent system will give the best solubility of the silicone material and should yield a clear solution. If the solvent system is not compatible with the silicone then the final treatment bath may contain gels or become cloudy in appearance.

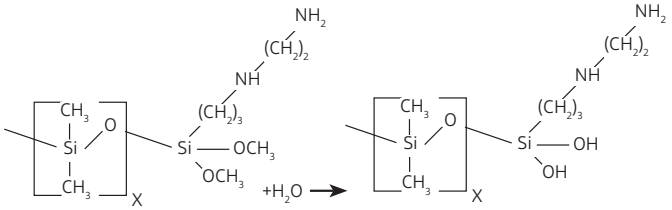
8. What is the typical life of a treatment bath of Liveo™ MDX4-4159, 50% Medical Grade Dispersion?

Since this material is very sensitive to moisture – which indeed is required for curing – any treatment bath/solution should be carefully protected from as much excess moisture and humidity as possible, although "dry" solvents need not be used. If the treatment solution becomes cloudy in appearance or begins showing signs of gel formation, this is an indication that it has become too old to be effectively used and a new bath/solution should be prepared.

9. Does Liveo™ MDX4-4159, 50% Medical Grade Dispersion "cure" on a surface?

Since the product contains reactive amine functional groups as well as methoxy- groups that become hydrolyzed to yield hydroxy- functionality, it can be "cured" on a surface that is capable of reacting with these groups. The curing process requires presence of ambient moisture in order to achieve optimum results.

The hydrolysis may be chemically described by the following reaction:



The reactivity of the hydroxy- groups is enhanced by the organic amine groups on the terminal silicon and the polymer attaches to most reactive surfaces and will polymerize with itself as well. The result is a hard, durable coating on the surface of the article being treated.

Ideally suited for siliconization of metal surfaces, the product can also be used to treat functional plastics as well. However, when used on non-reactive thermoplastics it will only react with itself to form a polymeric coating around the substrate being treated but without actually attaching to the surface. Any treated article of this type must not therefore be exposed to significant friction as small sections of the coating may be abraded from the treated surface.

10. What are the optimum curing conditions for Liveo™ MDX4-4159, 50% Medical Grade Dispersion?

The humidity level required for proper curing should be between 40% and 70%, the optimum range being 55-60%. Low humidity slows down the curing process while excess inhibits the reaction resulting in a tacky surface on the treated article. With sufficient humidity the material will cure at room temperature in about 24 hours; however, optimum lubrication properties will continue to develop over a period of several days after the initial cure. Since it is generally desired to speed up the curing process for cost-effective production the parts may be stored at room temperature with optimum humidity for 1-2 hours, then moved to a heated area to accelerate removal of solvent and the curing process. The heating time and temperature is dependent on the heat tolerated by the part but in any case it is sufficient to use only enough time to remove the solvent.

If it is not possible to place the treated parts in an area with optimum humidity for curing, then an alternative is to add a few drops of water to the treatment bath to add some moisture to the system. (Similarly, as stated above "dry" solvents need not be used for diluting Liveo™ MDX4-4159, 50% Medical Grade Dispersion).

After treatment, it is recommended that the parts not be immediately enclosed in any kind of packaging or other closed environment as it is likely that this will delay or inhibit the curing process and optimum lubrication may not be achieved.

11. Can the cured polymer of Liveo™ MDX4-4159, 50% Medical Grade Dispersion be detected on a treated surface?

If Liveo™ MDX4-4159, 50% Medical Grade Dispersion has been properly applied and cured, it is a challenge to detect the treatment on the surface. It is possible that the contact angle of a siliconized surface has changed compared to an untreated one, so goniometry can be attempted. Also, 2D microscopic Fourier-Transform Infrared Spectroscopy (FTIR) may be used to produce a map of the treatment on the surface with reference to an untreated control. Quantification of the amount of treatment or coating thickness on an article will require that the polymer be destroyed in order to remove it from a surface.

12. Can articles treated with Liveo™ MDX4-4159, 50% Medical Grade Dispersion be sterilized, and by what methods?

Siliconized articles may be sterilized by the usual methods such as 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. Sterilization should only be done on fully cured articles as excess moisture in such processes as autoclaving may inhibit the curing process if it is not complete.

Radiation may increase the rubbery nature of the coating and lubricity may change so users are encouraged to validate their treatment and sterilization conditions relative to their intended application(s).

13. Can the cured polymer of Liveo™ MDX4-4159, 50% Medical Grade Dispersion be removed from a treated surface?

If the product has not been cured then it can be removed with a typical non-polar organic solvent. If the material has cured then the polymer becomes a hard resinous coating that is very difficult to remove and must be degraded using a powerful alkaline solution such as concentrated potassium hydroxide. Typical solvents will not remove the coating.

14. What are the most important factors to consider with regard to the shelf-life of Liveo™ MDX4-4159, 50% Medical Grade Dispersion?

Liveo™ MDX4-4159, 50% Medical Grade Dispersion has a shelf-life of 18 months from the date of manufacture but it should be noted that precautions must be taken to protect the contents of the opened original container from moisture of any kind. It is recommended that material be poured from the original container in an area with low humidity, replacing the cap quickly preferably after a nitrogen purge of the container head-space. Formation of gels and/or a cloudy appearance are both indications that moisture is present and polymerization is taking place. In this case, the material should be discarded and a fresh container used.

The typical (normal or approved) color range for the product is clear to a light yellow or straw-color. The yellow color is indicative of the presence of an amino-functional polymer and this can sometimes be affected by the amount of light that the material has been exposed to during its preparation and packaging. Color does not indicate age; a yellow product is within specification and may be successfully used for siliconization processes.

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