

TECHNICAL BULLETIN

Silicone Gel for HEPA Filters



What Generated this Piece

Over the past six years, several incidents involving the use of silicone gel in HEPA filters, where oil aerosols such as Polyalphaolefin (PAO) are routinely used to test filter integrity, have resulted in the formation of a liquid droplet on the downstream frame of the filter. The purpose of this Technical Bulletin is to inform the reader of the known facts surrounding this abnormality.

Recently, a major HEPA filter manufacturer (not Camfil Farr) released a quality control alert on the subject of gel or fluid seal issues relating to HEPA filters in pharmaceutical facilities.

That publication contains several misleading statements that run counter to the results of many scientific investigations conducted by a number of qualified researchers directly associated with the manufacture and use of HEPA filters.

These statements also run counter to nearly a decade of experience and observations conducted on HEPA filters manufactured by Camfil Farr and installed in Pharmaceutical and related clean rooms around the world.

The Facts

Facilities using Camfil Farr filters have not reported a single incident related to the use of silicone gel in connection with filter integrity testing with (PAO).

Not one Camfil Farr product has been identified as the culprit, when gel has been found dripping from an installed HEPA filter.



A competitor has published a bulletin noting that there may be possible industry-wide failures with regard to gel performance on HEPA filters.

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Camfil Farr products undergo continuous rigorous testing, including gel components, to ensure product performance, testing material compatibility and suitability to purpose.



Camfil Farr has a policy of rigorous testing of all filter component materials prior to incorporating them in any product.

Research

Between 2004 and 2006, Camfil Farr conducted a series of tests with the purpose of fully understanding the compatibility of our silicone gel with other materials and agents, including PAO. At the same time, Camfil Farr collaborated with a principle investigator and polymer chemist of a major domestic pharmaceutical manufacturer, who was conducting similar tests and evaluations. The results of these trials and the conclusions were in general agreement.

Owing to the extremely stable, and relatively inert chemistry, characterizing the cured silicone gel used by Camfil Farr, and PAO, no chemical reaction occurs when the two materials come into contact. When a vast excess of PAO is applied over a surface of cured silicone gel, some PAO may diffuse into the gel and cause minor swelling. Laboratory observations, and field experience in many facilities, shows that this physical effect is minor and in no way compromises the integrity of the gel system, or the effectiveness of the filter seal. Degradation of Camfil Farr silicone gel in contact with PAO does not occur.

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Camfil Farr, and the aforementioned chemist, independently studied other commercially available gel systems in an effort to understand the mechanism of downstream droplet formation related to field issues associated with one particular HEPA filter manufacturer. The conclusion was that a single root cause did not exist and that a number of factors needed to be present for the issue to occur.

The issue has not affected filters manufactured by Camfil Farr because a number of contributing factors, other than the interaction of PAO and silicone gel, do not exist in the design of the Camfil Farr filters and component materials. These experimental results and conclusions were presented at a number of high level industry conferences including CETA, ISPE and NEBB in 2007.

Silicone Gel Chemistry

The silicone gel that Camfil Farr uses in our HEPA filter manufacturing utilizes unique and specifically formulated chemistry to offer superior cured strength and physical characteristics. It is ideally suited to meet the demands of HEPA filter applications, compared to other conventional and commercially available silicone gel systems. The chemistry utilized, results in a higher molecular weight of unbound polymer, a higher cross link density and superior structure of the gel cross link network. As a result, the Camfil Farr gel is tougher and resists degradation and exudation. Additionally, our state-of-the-art automated production equipment ensures precise mixing of components during filter manufacturing.

Collaborative Design

Camfil Farr employs a system of best practices as a form of quality control. We engage in technical collaboration with our colleagues, including our suppliers and end-users. Finally, we implement and audit manufacturing and quality control procedures to ensure a high quality product suitable for the intended use.



Camfil Farr is very concerned that the pharmaceutical community is presented the facts related to this issue and all subjects related to air filtration so that end users can make informed decisions.

We engage in continuous proactive research in an effort to anticipate customer needs and to avoid performance problems as noted herein. We also participate in industry conferences, and serve on committees to share our air filtration and industry knowledge for the benefit of the community.

Questions? Call us.

If you have questions related to this subject, Camfil Farr has additional resources and information available.

If you have additional questions or concerns please contact us at info@camfilfarr.com.

References:

Bio-Pharma HEPA Specification (gel spec included)

NEBB Presentation, Steve Devine, Vice-President of Research & Development, Camfil Farr, 2007

Brief discussion of Gel, Steve Devine, Vice-President of Research & Development, Camfil Farr, 2007

Decon/PAO/Cleaning Agent Study, Steve Devine, Vice-President of Research & Development, Camfil Farr, 2007



Comments or suggestions for revisions may be directed to literature@camfilfarr.com or info@camfilfarr.com. Camfil Farr reserves the right to continually update materials. Contact your Camfil Farr Representative or Distributor for the latest information.