

2780 Waterfront Pkwy. E. Dr. Indianapolis, IN 46214 Phone: 317-328-5660 Fax: 317-328-5668 Sales: 1-800-437-3188 www.calumetspecialty.com

01 January 2024

Control of Microbiological Contaminants in Mineral Oils and Petrolatum

It is well known that mineral oils and petrolatum do not support the growth of microorganisms since they are completely hydrocarbon systems. Therefore, Calumet Refining, LLC does not have a microbiological testing program in place, although we have occasionally used the services of an outside lab.

There are circumstances under which microorganisms develop and thrive. Given sufficient time, organisms will grow at a water-oil interface. Therefore, Calumet Refining takes great measures to exclude water from our products. This includes storage tanks for finished products, tank trucks for bulk shipments, as well as drums and pails. A specification of 50 ppm maximum water content exists for white oils and petrolatum. Routine tests on finished products consistently show water contents below 20 ppm.

Processing Conditions

Several processing steps involved in white oil and petrolatum production are severe enough to destroy nearly all viable organisms. Hydrotreating, for example, occurs at temperatures more than 600°F (315°C) and at high hydrogen pressures. This processing step is used for both white oils and petrolatum. In addition to hydrotreating, some white oils are also subjected to contact with fuming sulfuric acid. This strong acidic environment is sufficient to destroy proteins and nucleic acids in any biological system.

Storage Tanks

Products from the processes described above are pumped into storage tanks that are closed to the atmosphere except for vents at the tops of tanks. The vents are equipped with desiccant that only allow dry air to reenter the tanks as they are drawn down during pumping.

Shipping Containers

Bulk shipments are made in stainless steel tanks trucks. Each tank truck is washed and dried before it comes into Calumet Refining's facility. A typical cleaning solution used at a tank truck wash consist of a sodium or potassium hydroxide solution. Following washing, the tank trucks are flushed with hot water until the effluent is clear. The vessel is then dried with ambient air that is blown through the trailer.

When tank trucks arrive at Calumet they are thoroughly inspected inside and outside. In addition, the exterior valve is dismantled and inspected before it is reassembled and wrapped in plastic. The inspectors pay particular attention to locate residual moisture or odors before the tanks truck are suitable for loading. Approximately 25 gallons of white oil is flushed through the outlet value to be sure that any residual moisture in the outlet leg is removed before the tank trucks are sealed for shipment. Unfortunately, petrolatum cannot be flushed since such a procedure would plug the outlet valve and leg and make it very difficult for customers to off load petrolatum.



Drums and pails used for white oils and petrolatum are manufactured to Calumet Refining specifications. During fabrication they are subjected to curing temperatures in excess of 250°F (122°C) for at least 15 minutes.

Filters

Bag filters of five (5) micron (micrometer) pore size are used to filter white oils and petrolatum prior to loading into tank trucks, railcars, drums, and pails. Unfortunately, this size is not small enough to filter out microorganisms, but it is effective in eliminating miscellaneous particulate matter.

Conclusions

Calumet Refining's emphasis on controlling microorganisms is to limit our products exposure to water and to maintain the cleanest possible environment. No attempt is made to use specific disinfectants or sterilization procedures. This precludes the possibility that residual quantities of these agents may end up in our finished products.

Calumet Refining guarantees that USP/NF grade white mineral oils and petrolatum are free of contaminants (when loaded at our plant) whether they are particulates, water, or viable microorganisms as described in USP/ NF (61) Microbial Limit Tests. From a practical point of view our products are shipped in commercial transports that are not maintained in sterile conditions. Therefore, it is important that customers take whatever precautions they feel necessary to reduce the possibility of contamination with microorganisms.

Please contact Calumet's Product Support Team at <u>technical@clmt.com</u> should you have further questions.

Sincerely,

Lynn Massad Technical Market Development Manager