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Control of Microbiological Contaminants in Mineral Oil and Petrolatum

It is well known that mineral oil 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, we take great measures to exclude water from our finished products, including in storage tanks and bulk and packaged shipments. A specification of 50 ppm maximum water content exists for mineral oil and petrolatum. Routine tests on finished products consistently show water contents below 20 ppm.

Processing Conditions

Several processing steps involved in mineral 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 mineral oil and petrolatum. In addition to hydrotreating, some mineral oil 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 tank 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 tank trucks are confirmed suitable for loading. Approximately 25 gallons of mineral oil is flushed through the outlet value to be sure that any residual moisture in the outlet leg is removed before the tank truck is 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 mineral oil 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 mineral oil 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 exposure of our products to water and to maintain the cleanest possible environment. Calumet does not use disinfectants or sterilization procedures. This eliminates the possibility that residual quantities of these agents end up in our finished products.

Calumet Refining routinely tests USP/NF grade mineral oil and petrolatum per USP/ NF <61> Microbial Limit Tests and they routinely test within acceptable parameters. 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