

Material expertise accelerates device biological risk assessment



A medical device OEM was developing a long-term implantable product using one of Lubrizol's thermoplastic polyurethanes (TPU). It had been working with a testing lab for its chemical and biological assessment of the device including extractables/leachables. After conducting its analysis, the OEM and the lab realized that specialized expertise would be helpful to interpreting the results. Together the lab and the OEM reached out to Lubrizol for help to identify TPU-related extractable substances and to keep the project timeline on track.



CUSTOMER TYPE

Medical device OEM developing a long-term implantable product using one of Lubrizol's medical-grade TPUs.

CUSTOMER CHALLENGE

The testing lab that the OEM had selected to conduct the chemical and biological assessment of the device was new to analyzing devices made of TPU, so they reached out for help with the interpretation of the test results. Specifically, the lab selected did not understand how to identify TPU-related extractable substances, how to differentiate them from extractable substances coming from other adhesives and/or thermoplastics, or how to interpret the test results.

SOLUTION

The OEM called the experts at Lubrizol for help. After setting up a confidentiality agreement that included the lab, Lubrizol educated the lab on how to identify TPU-related extractable substances and supported them in differentiating those substances from extractable substances coming from other materials of construction in the device. In addition, the team at Lubrizol assisted the lab in providing potential sources where other extractables could have come from.

"When considering the large amount of information obtained from an extractable/leachable analysis of a medical device, it can be helpful to understand the source of the extracted substances. Our material expertise can help OEM toxicologists with assessment of the device-specific risk associated with certain extracted substances, especially when established toxicology data does not exist for all identified compounds."

Jennifer Green, Technical Marketing Manager,
Medical Polymers, Lubrizol Life Science Health

OUTCOME

With Lubrizol's guidance, the test lab was able to correctly interpret the test results for the OEM. We worked together with the OEM and the test lab to share our knowledge on interpretation of the data based on our material expertise. This result led to the test lab being able to complete its analysis of the OEM's device and allowed the OEM to confidently include this information in the submission.

To discuss a specific inquiry or project need, please [contact us](#) to be connected with one of our regulatory experts.



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