

March 25, 2024

Ms. Kelly Murphy
Nexeo Plastics
5200 Blazer Parkway
Dublin, OH 43017

Dear Kelly:

This letter provides regulatory information for the following Alphagary product as requested:

Nexeo Plastics (Customer ID # 55207, 55208, 55209, 55210, 55211, 55212)		
Nexeo P/N	AG P/N	Product
703713	956683	SK/2223C-70 Clear 0003

Biocompatibility

Thermoplastic compounds such as our SK/2223C-70 Clear 0003 can be demonstrated to be biocompatible through testing according to nationally and globally recognized standards such as USP and ISO 10993. Alphagary maintains certificates for many of its medical products, although not all products have been tested. A test certificate is included with this letter showing that SUPERKLEEN products can meet the requirements for USP Class VI plastics. The similarity in base structures indicates that SK/2223C-70 Clear 0003 should also meet Class VI requirements.

As to leachable and extractables testing, we have not submitted this series for testing. The test procedure for USP Class VI testing does include extractables testing, however, we do not have standalone test data. None of the components in SK/2223C-70 Clear 0003 are themselves known to display cytotoxic behavior.

Sincerely,



Christopher Ptak
Regulatory Compliance

Cc: Ms. Joyce Jones (Alphagary)
Mr. Troy Brantley (Alphagary)