January 29, 2020

Marina Palmisano

PolyOne
1275 Windham Parkway
Romeoville IL USA 60446

PLEXIGLAS® DR®-101 ACRYLIC RESIN (200014186)

To whom it may concern:

Thank you for your interest in the referenced product. This letter is provided in response to your request for regulatory compliance information. Please note that this letter is effective on the date created and supersedes any prior documents received.

REACH AND INVENTORY STATUS

Substance of Very High Concern (SVHC)

This paragraph concerns substances listed in the Candidate List of Substances of Very High Concern, in accordance with Article 59 of the European Regulation 1907/2006 effective: 01/16/2020

Based on the final product composition this product is not a Substance of Very High Concern and does not contain any SVHC substance(s) above the declaration threshold.

Please note that we do not routinely analyze for additional substances that are not listed in the SDS. Unless otherwise indicated, the information provided herein is based upon information from raw material suppliers, product composition and knowledge of our manufacturing process. If a questionnaire was submitted we note that, as global regulatory requirements expand, we are receiving increasing numbers of requests from customers regarding the regulatory status of our products. Given this, it is no longer possible for us to individually complete each company's specific form. To respond to each customer in a timely and efficient manner, our company has developed a system to store and report the requested information. Use of this standardized system will allow us to properly track requests and responses and notify your company of changes when appropriate.

Sandy Schmidt

Sandy Schmidt

Sr. Product Safety Specialist

Arkema Inc.
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Arkema has implemented a Medical Policy regarding the use of Arkema products in medical device applications that are in contact with the body or circulating bodily fluids (http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices , and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies) It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.