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## FOOD CONTACT COMPLIANCE STATEMENT (FDA)

Date: 19 August 2022 (1) Version 2.0

Product: Ketron® TX PEEK stock shapes

We hereby provide the following information based on the compliance status of <u>the raw</u> <u>materials</u> used at present by Mitsubishi Chemical Advanced Materials for the manufacture of the stock shapes mentioned above, <u>with respect to their composition</u>, as set out in the regulations that apply in the United States of America (FDA) for plastic materials and articles intended to come into contact with foodstuffs:

• Ketron TX PEEK complies with the compositional requirements of the FDA regulations 21 CFR § 177.2415 "Poly(aryletherketone) resins", 21 CFR § 178.3297 "Colorants for polymers", as well as with those of other applicable FDA regulations. Based on their composition, Ketron TX PEEK stock shapes may basically be used for the manufacture of articles or components of articles intended for repeated food-contact use with all food types I to IX, except with infant formula and breast milk, under all conditions of use A to H as defined in tables 1 and 2 in 21 CFR 176.170(c), respectively.

Ketron® is a registered trademark of the Mitsubishi Chemical Advanced Materials Group.

NOTE: The above information, <u>based on raw material supplier data</u>, corresponds with our actual knowledge and is believed to be a valuable help in the choice of a Mitsubishi Chemical Advanced Materials product. However, Mitsubishi Chemical Advanced Materials makes no guarantees as to the suitability of its materials for any given application, and thus assumes no obligation or liability whatsoever in connection with the information provided above.

It remains the customer's sole responsibility to assess the final suitability of the chosen Mitsubishi Chemical Advanced Materials product for the intended food contact application; i.e. checking if the physical properties of the plastics material make it suitable for the intended application, checking compliance of the finished plastics article with the relevant extraction limits, checking possible influence of the plastics material on colour, odour or taste of the contacting foodstuffs, etc. .

All statements, technical information, recommendations, and advice are for informational purposes only and are not intended and should not be construed as a warranty of any type or term of sale. The reader, however, is cautioned that Mitsubishi Chemical Advanced Materials does not guarantee the accuracy or completeness of this information and it is the customer's responsibility to test and assess the suitability of the products of Mitsubishi Chemical Advanced Materials in any given application or for use in a finished device.

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<sup>&</sup>lt;sup>1</sup> This statement expires in case of regulatory or compositional changes. New statements are published on our website in case of alterations; previous statements then automatically become void. Please always consult our website for the latest version.