

FDA Food Contact

February 2025, Version 3.0
Previous version obsolete



Applicable to: **Ketron™ TX PEEK stock shapes**

FDA

We hereby provide the following information based on the compliance status of the raw materials used at present by Mitsubishi Chemical Advanced Materials for the manufacture of the stock shapes mentioned above, with respect to their composition, 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 stock shapes comply with FDA 21 CFR 177.2415, 21 CFR § 178.3297, as well as with those of other applicable FDA regulations for repeated use food contact applications in contact with all food types I to IX, except for infant formula and breast milk, and under all conditions of use A to H as defined in tables 1 and 2 in 21 CFR 176.170(c), respectively.

USDA

USDA does not approve materials. USDA requires that finished articles are made of FDA food contact compliant materials.

EU 10/2011

Ketron™ TX PEEK stock shapes have not been manufactured or tested as EU 10/2011 requirements. For EU 10/2011 compliance, specific “Food Grade” items are available to purchase as manufactured and tested according to the regulations. These specific items will have “...FG...” in the item’s description, be labelled with the “fork and glass” logo and will arrive with declarations of compliance.

NSF

Ketron™ TX PEEK stock shapes are not NSF listed or NSF approved products. NSF 51 compliance is based on the FDA compliance of the raw materials.

If NSF 51 compliance is needed for **Ketron™ TX PEEK** the farthest end user will need to contact NSF to begin the process. NSF will then send Mitsubishi Chemical Advanced Materials a “Request for Formulation” form, which will be filled out and returned to NSF.

Mitsubishi Chemical Advanced Materials (“MCAM”) is a specialist in the production, processing, and application of engineering plastics and innovative composite materials (“products”).

All statements, technical information, recommendations, and advice are for informational purposes only and do not constitute any express or implied warranties or representations whatsoever. This includes, but is not limited to, all warranties provided for by any applicable law, any implied warranty of merchantability, of fitness for a particular purpose, or any warranty against hidden defects or redhibitory defects or vices, or that the products are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in invasive or implantable medical devices or medical devices essential to the restoration of or continuation of a body function or structure important to the continuation of human life. The customer, however, is cautioned that nothing herein shall be construed as guarantee of the accuracy or completeness and it is the customer’s sole responsibility to test and assess the suitability of our products in any given or intended application, process or for use in a finished or non-finished device.

This statement is subject to change without notice and becomes obsolete in case of any changes to the regulation referenced, or in case of any changes to the product’s composition, or in case a new version is issued. New versions of this statement will either be published on our website or are provided to you upon request. Please always consult either our website or contact your MCAM sales representative to request the current version of this statement. MCAM undertakes no express or implied obligation to communicate the expire of previous versions nor the issue of new versions of this statement.

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

Mitsubishi Chemical Advanced Materials

Compliance Department – Americas
Mitsubishi Chemical Advanced Materials Inc.
2120 Fairmont Avenue
Reading, PA, 19605-3041
United States of America

tel: +1 610 320 66 00
mail: regulatorysupport.mcam@mccg.com
web: mcam.com

Compliance Department – Europe
Mitsubishi Chemical Advanced Materials NV
I.P. Noord – Galgenveldstraat 12
8700 Tielt
Belgium

tel: +32 51 23545
mail: regulatorysupport.mcam@mccg.com
web: mcam.com