

FOOD CONTACT COMPLIANCE STATEMENT (FDA)

Date: 19 August 2022 ⁽¹⁾

Version 3.0

Product: **Proteus[®] LSG H PP natural stock shapes**

We hereby provide the following information based on the compliance status of materials used at present by Mitsubishi Chemical Advanced Materials for the manufacture of the stock shapes mentioned above, 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:

- **Proteus LSG H PP natural** complies with the requirements of the FDA regulations 21 CFR § 177.1520 “Olefin polymers” and 21 CFR § 178.3297 “Colorants for polymers”, as well as with those of other applicable FDA regulations.
Proteus LSG H PP natural may basically be used for the manufacture of articles or components of articles intended for food-contact, except for articles used for packing or holding food during cooking. The material can be used with food types II, III, IV, V, VII-A and IX under conditions of use C to G as defined in tables 1 and 2 in 21 CFR 176.170(c), respectively.

Proteus[®] is a registered trademark of the **Mitsubishi Chemical Advanced Materials Group**.

NOTE: The above information, based on raw material supplier data, 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. .

¹ 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.

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.

The products of Mitsubishi Chemical Advanced Materials should not be used for applications involving medical devices that are intended to remain implanted in the human body continuously for a period exceeding 24 hours (30 days*), or are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days*), or as critical components of medical devices that are essential to the continuation of human life.

*: "30 days" applies to Ketron® PEEK-CLASSIX™ LSG white only.

Mitsubishi Chemical Advanced Materials is not a medical device manufacturer and the information herein does not constitute any express or implied warranties or representations whatsoever, including, but not limited to, all warranties provided for by any applicable law, any implied warranty of merchantability, of fitness for a particular purpose, any warranty against hidden defects or redhibitory defects or vices, or that the products of Mitsubishi Chemical Advanced Materials are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in implantable medical device applications and in applications that are essential to the restoration of or continuation of a bodily function important to the continuation of human life.

PEEK-CLASSIX™ is a trademark of Invivio Ltd.