DECLARATION

FDA Food Contact

January 2025, Version 4.0
Previous version obsolete

Applicable to: **Proteus™ LSG HP PP-H 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 FDA regulations that apply in the United States of America, for plastic materials and articles intended to come in contact with foodstuffs:

> **Proteus™ LSG HP PP-H** stock shapes comply with FDA 21 CFR 177.1520 for use as articles or components of articles intended for repeated use in contact with food except for articles used for packing or holding food during cooking, for food types II, III, IV, V, VII-A, and IX as described in Table 1 of 21 CFR 176.170(c), and under conditions of use C through G as defined in Table 2 of 21 CFR 176.170(c).

USDA

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

EU 10/2011

Proteus™ LSG HP PP-H 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

Proteus™ LSG HP PP-H 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 **Proteus™ LSG HP PP-H** 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.

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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.

The products should neither be used in invasive or implantable medical devices that are intended to be introduced in and remain inside the human body or replace an epithelial surface or the surface of the eye for more than 24 hours (or 30 days for Ketron™ LSG PEEK-CLASSIX™ white respectively), nor should they be used as critical components of medical devices that are essential to the continuation of human life.

The products do not fall within the applicable regulations of a medical 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.

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