

FDA Food Contact

March 2025, Version 3.0
Previous version obsolete

Applicable to: Sultron™ LSG PSU natural 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 (MCAM) for the manufacture of the product mentioned above, 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:

The product complies with 21 CFR 177.1655 for use as articles or components of articles intended for repeated use in contact with food, with all food types and under conditions of use A through H as described in Tables 1 and 2 of 21 CFR 176.170(c). When used for single-service food-contact, the product may be used only under condition of use H described 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

The product is not manufactured nor tested according to Regulation (EU) No 10/2011.

NSF

The product is 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, 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.

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.

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

PEEK-CLASSIX™ is a trademark of Invibio Ltd., Technology Centre, Hillhouse International, Thornton Cleveleys, Lancashire FY5 4QD, United Kingdom.

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