

August 25, 2022

HOSTAFORM® C 9021 NATURAL

Declaration on Polycyclic Aromatic Hydrocarbons (PAH) EU Regulation 1272/2013/EU

The above listed Celanese, Engineered Materials products by constitution do not contain polycyclic aromatic hydrocarbons (PAH) as defined in Commission Regulation (EU) No. 1272/2013.

Please note that the manufacturer or seller of parts and articles made out of the above mentioned products have to take the full responsibility regarding applicable legal requirements.

Celanese, Engineered Materials Product Safety.

Important:

This information relates only to the above mentioned materials as delivered in their original packaging. It does not relate to any product made of these materials with or without the inclusion of further additives, such as processing aids or colorants. To the extent that any hazards may have been mentioned in this publication, we neither suggest nor guarantee that such hazards are the only ones that exist. This information should not be construed as a promise or guarantee of specific properties of the products described or their suitability for a particular application. Any existing intellectual property rights must be observed.

It is the responsibility of any manufacturer of medical devices containing Celanese Engineered Materials resins to determine the necessary steps to ensure the safe and efficacious use of their products/devices and to obtain the necessary regulatory approvals for the intended applications. Insofar as this information relates to sterilization for medical purposes, the data contained herein show the typical effects of sterilization procedures on the nominal physical properties (using standardized test specimens) of the Celanese Engineered Materials resins. The actual sterility of the parts has not been evaluated for either single or multiple use applications. The products mentioned herein are not intended for use in medical or dental implant.