

## ABSENCE DECLARATION (SVHC)

---

Date: 29 July 2022 (1)

Version 8.0

Products: the **Mitsubishi Chemical Advanced Materials stock shapes** mentioned below:

Ketron® CLASSIX™ LSG PEEK white  
Ketron® LSG PEEK natural, blue, green, yellow, red and black  
Ketron® LSG PEEK Food Grade natural and black  
Ketron® LSG CA30 PEEK  
Sultron™ LSG R5100 PPSU natural NT15 and black BK937  
Sultron™ LSG R5500 blue BU1027, brown BN1164, green GN1007,  
grey GY1037, natural NT15, orange OR1145, red RD1018  
and yellow YL1337  
Duratron® LSG PEI natural  
Sultron™ LSG PSU natural  
Altron™ LSG PC natural  
Proteus® LSG H PP natural  
Proteus® LSG H PP HP natural

---

To the best of our knowledge, we herewith confirm that the substances mentioned on the **Candidate List of Substances of Very High Concern as published by ECHA on 28 October 2008 and updated up to and including 10 June 2022**, are neither intentionally introduced<sup>2</sup> during the production of the raw materials nor during the manufacture of the above mentioned **Mitsubishi Chemical Advanced Materials stock shapes**, or that the maximum concentration of 0.1% (w/w) mentioned by ECHA has not been exceeded, with the exceptions as mentioned below.

However, since the presence of the above mentioned substances cannot reasonably be expected, with the exceptions as mentioned below, Mitsubishi Chemical Advanced Materials does not systematically check their absence in its stock shapes by testing.

Bisphenol A (CAS Nr. 80-05-7) is a monomer that is used in the production of the resins that are used for the extrusion of **Duratron LSG PEI natural**, **Altron LSG PC natural** and **Sultron LSG PSU natural** stock shapes respectively and so it will be present in the end products in very small quantities. According to the resin suppliers these quantities are below 0.1% (w/w)

---

<sup>1</sup> 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.

<sup>2</sup> “Intentionally introduced” means “deliberately utilised in the formulation of a material to facilitate manufacture or to provide a specific characteristic, appearance or quality”.

**Acetron®**, **Duratron®**, **Ketron®** and **Proteus®** are registered trademarks of the **Mitsubishi Chemical Advanced Materials Group**.  
**Altron™** and **Sultron™** are trademarks of the **Mitsubishi Chemical Advanced Materials Group**.  
**PEEK-CLASSIX™** is a trademark of **Invivio Ltd**.

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.

M C A M . C O M