

ABSENCE DECLARATION REACH (SVHC)

Date.: 24.07.2023 ⁽¹⁾

Version 10.0

Products: stock shapes

PEEK Classix white

PEEK LSG natural, black, green, blue, yellow, red

PEEK LSG und FG natural, black

PEEK CA30 LSG

PPSU LSG all colors

PEI LSG natural, black, colors

PSU LSG natural

PC LSG natural

PP-H LSG 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 14 June 2023**, are neither intentionally introduced² during the production of the raw materials nor during the manufacture of the above mentioned 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, Cellpack AG BBC Cellpack Technology 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 **PEI natural**, **PC LSG natural** and **PSU LSG 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).

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 BBC Cellpack Technology / Cellpack AG 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 in any given application or for use in a finished device.

The products of BBC Cellpack Technology / Cellpack AG 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 PEEK Classix white only.

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- 1) This statement expires in case of regulatory or compositional changes.
 - 2) "Intentionally introduced" means "deliberately utilised in the formulation of a material to facilitate manufacture or to provide a specific characteristic, appearance or quality".