

ABSENCE DECLARATION REACH (SVHC)

Date.: 16 February 2024 ⁽¹⁾

Version 11.0

Products: stock shapes

PEEK Classix white
PEEK LSG natural, black, green
PEEK LSG und FG natural, black
PPSU LSG all colors
PEI LSG natural, black, blue
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 23 January 2024**, 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, BBC Cellpack Technology AG 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 LSG**, **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 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 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.

BBC Cellpack Technology AG 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 BBC Cellpack Technology AG 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.

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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".