

COMPANY STATEMENT	REACH - (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SUPPLIER	Invibio Ltd
PRODUCT NAME	<p>PEEK-OPTIMA™ Natural grades: LT1, LT2, LT3 Granules, stockshapes and fine powder;</p> <p>PEEK-OPTIMA™ Reinforced grades: LT1CA30, LT1DA30 Granules and Stock shapes;</p> <p>PEEK-OPTIMA™ Ultra-Reinforced grades: LT3PPT unidirectional tape</p> <p>PEEK-OPTIMA™ Image Contrast grades: LT16BA, LT120BA, LT215BA, LT320BA Granules and Stock shapes</p> <p>PEEK-OPTIMA™ HA Enhanced grades: LT120HA Granules and Stock shapes</p> <p>PEEK-CLASSIX™ grades: BC1, BC2, BC3, BC1-WH, BC2-WH, BC3-WH</p>
<ul style="list-style-type: none"> • Invibio Ltd is committed to ensuring full REACH⁽¹⁾ compliance for all its current and future products. • Victrex (the parent company of Invibio Ltd) has registered all required substances manufactured in or which it imports into the EU. In addition, Invibio works closely with suppliers to ensure key substances, that support its supply chain and are manufactured in or imported into the EU, are registered. • Invibio Ltd polymer grades are exempt from the REACH registration requirements. However, the monomers used in the polymer manufacture are in scope and have been registered in accordance with the requirements of REACH⁽²⁾. • Invibio Ltd does not intentionally add or use, any Substance of Very High Concern (SVHC) >0.1%w/w https://echa.europa.eu/candidate-list-table (latest version as published 23-January-2024), or any substances listed in Annex XVII "The Restricted List" https://echa.europa.eu/substances-restricted-under-reach (See note on exemption for synthetic polymer microparticles) ⁽³⁾ or any substances listed in Annex XIV "The Authorisation List" https://echa.europa.eu/authorisation-list, in its products. Invibio Ltd monitors the above lists on a regular basis to identify and manage any changes that may have an impact on its raw materials and products. 	

- If any substances / chemicals used by Invibio to manufacture its products become 'chemicals of concern' i.e. are officially listed within the REACH regulation under 'Substances of Very High Concern' (SVHC), or listed in REACH Annex XVII 'The Restricted List', or listed in REACH Annex XIV 'The Authorisation List' and accompanying conditions are met, Invibio would seek to phase-out affected products in line with sunset clauses or reformulate to ensure we maintain our compliance to REACH.
- Invibio Ltd product classifications per the EU CLP regulation⁽⁵⁾ are available via the Material Safety Data Sheets (MSDS) through our website www.invibio.com.
- As a downstream user, Invibio Ltd continues to work with suppliers to ensure all raw materials will be supported and Invibio's manufacturing processes are not affected.

Notes

1. Registration, Evaluation, Authorisation and Restriction of Chemicals Regulations - (EC) No 1907/2006
2. Article 6.3 of Regulation (EC) No 1907/2006

3a. Regarding synthetic polymer microparticles⁽⁴⁾ as listed in Annex XVII "The Restricted List", the definition per Regulation (EU) 2023/2055 Entry '78 applies to powder and granule forms of INVIBO products. The conditions for restriction for the placing of synthetic polymer microparticles⁽⁴⁾ on the EU market does not apply to INVIBIO products as the following exemptions are met:

Section 4 (a) *synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites.*

Section 5 (a) *synthetic polymer microparticles are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use;*

(b) *synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry;*

(c) *synthetic polymer microparticles permanently incorporated into a solid matrix during intended end use.*

3b. The microparticles⁽⁴⁾ definition per Regulation (EU) 2023/2055 Entry '78 does not apply to PEEK-OPTIMA™ stock shape products.

4. Synthetic polymer microparticles as defined within (EU) 2023/2055 amending Annex XVII to REACH(1)

5. Classification, Labelling and Packaging (CLP) Regulation - (EC) No 1272/2008

Signed:

Caroline Prisk

Head of Regulatory Affairs and Product Stewardship

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