COMPANY STATEMENT	**Non-intentionally added substances (NIAS) Statement**
SUPPLIER	Invibio Ltd
PRODUCT NAME	**PEEK-OPTIMA™ Natural grades:** LT1, LT2, LT3 Granules, stockshapes and fine powder; **PEEK-OPTIMA™ Reinforced grades:** LT1CA30, LT1DA30 Granules and Stock shapes; **PEEK-OPTIMA™ Ultra-Reinforced grades:** LT3PPT unidirectional tape **PEEK-OPTIMA™ Image Contrast grades:** LT16BA, LT120BA, LT215BA, LT320BA Granules and Stock shapes **PEEK-OPTIMA™ HA Enhanced grades:** LT120HA Granules and Stock shapes **PEEK-CLASSIX™ grades**: BC1, BC2, BC3, BC1-WH, BC2-WH, BC3-WH

This document is to confirm that the substances listed below have not been intentionally added or used in the manufacturing processes of the Invibio products detailed above and to the best of our knowledge at this time, have not been intentionally added or used in the manufacturing processes of any included additives.

1. the substance group “Asbestos”; which includes amosite, chrysotile, crocidolite, plus the fibrous varieties of tremolite, actinolite, and anthophyllite

2. Benzenesulfonamide, 4-methyl-, polymer with formaldehyde, CAS# 25035-71-6

3. Benzoyl Peroxide, CAS# 94-36-0

4. Beryllium, CAS# 7440-41-7, and its compounds

Invibio Ltd
Victrex Technology Centre, Hillhouse International, Thornton-Cleveleys, Lancashire, FY5 4QD, United Kingdom
Tel: +44 (0)1253 898 000 Fax: +44 (0)1253 898 001 Email: info@invibio.com
Registered in England and Wales No. 4088050 at address above
www.invibio.com

5. Bisphenol-A (BPA), CAS# 80-05-7 as described in EU REACH Regulation (EC) No 1907/2006Substances of Very High Concern (SVHC) https://echa.europa.eu/candidate-list-table and entry 66 in Annex XVII "The Restricted List"https://echa.europa.eu/substances-restricted-under-reach and EU plastics food contact regulation (EU) No 10/2011 (as amended by EU 2024/3190).
   Note: Reference to primary packaging spools for PEEK-OPTIMA™ LT1 FIL and PEEK-OPTIMA™ HA Enhanced LT120HA FIL, there are trace amounts of BPA below the 0.1% w/w threshold (EU MDR Annex I clause 10.4).

6. Bisphenol-S (BPS), CAS# 80-09-1 as described in EU REACH Regulation (EC) No 1907/2006 Substances of Very High Concern (SVHC) https://echa.europa.eu/candidate-list-table

7. Substances classed under the general heading of "Brominated Flame Retardants – BFR's" including those related to the substance groups listed below:

   a. Polybrominated biphenyl (PBB)
   b. Polybrominated diphenyl ether (PBDE), OctaBDE, PentaBDE
   c. Brominated Cyclohydrocarbons
   d. Hexabromocyclododecane (HBCD or HBCDD)
   e. Tetrabromobisphenol A (TBBPA or TBBP-A)
   f. Decabromodiphenyl ethane (DBDPE), CAS# 84852-53-9
   g. Decabromodiphenyl Ether (DecaBDE), CAS# 1163-19-5

8. Chitosan, CAS# 9012-76-4

9. Chromate, CAS# 12381-48-5

10. Hexavalent Chromium [Chromium VI], CAS# 18540-29-9 and Chromium Compounds

11. Cyanuric Acid, CAS# 108-80-5

12. Chlorine based flame retardants as listed below:

    a. Dechlorane Plus (DP or DDC-CO) CAS# 13560-89-9
    b. Anti-Dechlorane plus (anti-DP), CAS# 135821-74-8
    c. Syn-Dechlorane plus, (syn-DP), CAS# 135821-03-3

13. N,N-dimethylformamide (DFMA) CAS# 68-12-2

14. Substances considered as “Dioxins and Dioxin-like”

15. Diisooctyl phthalate (DIOP), CAS# 27554-26-3, as identified in the Annex in the Order of 20 August 2023 on the identification of harzardous substances in waste-generating products

16. 2,6 Diisopropyl Naphtalene (DIPN), CAS# 24157-81-1

17. Epoxy derivatives Bisphenol A diglycidyl ether (BADGE), CAS# 1675-54-3, Bisphenol F diglycidyl ether (BFDGE), CAS# 2095-03-6 and NOGE as described in Directive 1895-2005

18. Genetically Modified Organisms

19. The following metals and their compounds:
    a. Antimony,Sb
    b. Arsenic, As
    c. Berylium, Be
    d. Bismuth, Bi
    e. Cadmium, Cd
    f. Cerium, Ce
    g. Chromium, Cr
    h. Cobalt, Co
    i. Copper, Cu
    j. Gallium, Ga
    k. Germanium, Ge
    l. Gold, Au
    m. Iron, Fe
    n. Lead, Pb
    o. Manganese, Mn
    p. Mercury, Hg
    q. Nickel, Ni
    r. Platinum, Pt
    s. Silver, Ag
    t. Tellurium, Te
    u. Thallium, Tl
    v. Tin, Sn

w. Uranium, U
x. Vanadium, V
y. Zinc, Zn

20. Latex – Natural and Synthetic, including derivatives

21. Medium-chain chlorinated paraffins (MCCP), including

    a. Di, tri and tetrachlorodecane
    b. B. Alkanes, C14-C17, chloro, CAS# 85535-85-9
    c. Tetradecane, chloro derivs., CAS# 198840-65-2
    d. Alkanes, C14-C16, chloro, CAS#1372804-76-6

22. Medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC

23. Melamine, CAS# 108-78-1

24. Methyl acrylate, CAS# 96-33-3

25. Methyl methacylate, CAS#80-62-6

26. Mineral Oil, CAS# 8042-47-5

27. Mineral Oil Aromatic Hydrocarbons (MOAH) and Mineral Oil Saturated Hydrocarbons (MOSH) as defined in the European Food Safety Authority (EFSA) Scientific Opinion on Mineral Oil Hydrocarbons in Foods (2012)

28. Nitrosamines and potential sources of nitrosamine impurities ("Information on nitrosamines for marketing authorisation holders" published September 2019 by the European Medicines Agency (EMA))

    a. Nitrite (e.g. $NaNO_2$)
    b. Nitrogen Oxides (N_2O_3/N_2O_4)
    c. Nitrosyl Chloride (NOCl)
    d. Nitrosyl Thiocyanate(NO-SCN)
    e. S-Nitrosothiols (RS-NO)
    f. Nitrosonium Tetrafluoroborate (BF_4-NO^+)

g. Alkyl Nitrites (R-ONO)
h. 1,1-Disubstituted Hydrazines ($R^1R^2N\text{-}NH_2$)
i. N-Nitrosoamine or other nitroso bearing compounds ($R^1R^2N\text{-}NO$ or X-NO)

29. Ozone depleting substances – substance groups as listed within the annexes of European Regulation 2024/590 on substances that deplete the ozone layer, and repealing Regulation (EC) No 1005/2009 and substances listed in the China State Council promulgated the Regulations on the Administration of Ozone-Depleting Substances, based on the 'UN Montreal Protocol of Ozone depleting substances'

30. Fluorinated Greenhouse gases – substance groups as listed in European Regulation 517/2014 (applicable from 16th April 2014) on fluorinated greenhouse gases and repealing the European Regulation 842/2006

31. Perchlorates

32. Phosphorous and its allotropes

33. Phthalocyanine Green, CAS# 1328-53-6

34. Polychlorinated Bisphenyls (PCBs), CAS# 1336-36-3

35. Polychlorinated Terphenylys (PCTs), CAS# 61788-33-8

36. Polyphenyls

37. Polyvinyl Chloride (PVC)

38. Primary Aromatic Amines, including those listed under entry 43 to appendix 8 of Annex XVII to Regulation (EC) No 1907/2006

39. Radioactive substances, including those containing nuclides as detailed in European Directive 2013/59/EURATOM

40. Rare Earth Elements
    a. Scandium (Sc)
    b. Yttrium (Y)

c. Lanthanum (La)
d. Cerium (Ce)
e. Praseodymium (Pr)
f. Neodymium (Nd)
g. Promethium (Pm)
h. Samarium (Sm)
i. Europium (Eu)
j. Gadolinium (Gd)
k. Terbium (Tb)
l. Dysprosium (Dy)
m. Holmium (Ho)
n. Erbium (Er)
o. Thulium (Tm)
p. Ytterbium (Yb)
q. Lutetium (Lu)

41. Selenium, CAS# 7782-49-2, and its compounds

42. Sources of Secondary Amines as listed below:

a. Dimethylformamide (DMF)
b. Dimethylacetamide (DMA or DMAc)
c. NEt_3 (TEA)
d. $NEt(iPr)_2$ (Hünig's base)
e. N-Methyl-2-pyrrolidone (NMP)
f. $H\text{-}NR^1R^2$ (usage of any secondary amine)
g. $X\text{-}NR^1R^2$ (usage of any secondary amine-liberating compound)

43. Polysiloxanes; Siloxanes and Silicones

44. Steel

45. Sulfonic acid, with general formula R-S(=O)2-OH (where R is an organic alkyl or aryl group)

46. Tin and its compounds, including organotin compounds (also referred to as organostannic compounds)

47. Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (TOTM), CAS # 3319-31-1

48. Dioctyl terephthalate (bis(2-ethylhexyl) benzene-1,4-dicarboxylate (DEHT), CAS # 6422-86-2

49. Tris(2,4-ditert-butylphenyl) phosphite (UV-328), CAS# 25973-55-1

This information is provided "as is". It is not intended to amount to advice. Use of the product is at the customer's/user's risk. It is the customer's/user's responsibility to thoroughly test the product in each specific application to determine its performance, efficacy and safety for each end-use product, device or other application and compliance with applicable laws, regulations and standards. Mention of a product is no guarantee of availability. Victrex reserves the right to modify products, data sheets, specifications and packaging. **Victrex makes no warranties, express or implied (including, without limitation, any warranty of fitness for a particular purpose or of intellectual property non-infringement) and will not be liable for any loss or damage of any nature (however arising) in connection with customer's/user's use or reliance on this information, except for any liability which cannot be excluded or limited by law.** This document may be modified or retracted at any time without notice to the customer/user.

Signed: .....

Caroline Prisk
Director of Regulatory and Quality

Date: 21-May-2025