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. Antimony, CAS# 7440-36-0, and its compounds
2. Arsenic, CAS# 7440-38-2, and its compounds
3. the substance group “Asbestos”; which includes amosite, chrysotile, crocidolite, plus the fibrous varieties of tremolite, actinolite, and anthophyllite
4. Benzenesulfonamide, 4-methyl-, polymer with formaldehyde, CAS# 25035-71-6
5. Benzoyl Peroxide, CAS# 94-36-0
6. Beryllium, CAS# 7440-41-7, and its compounds
7. Bisphenol-A (BPA), CAS# 80-05-7 as described in EU REACH Regulation (EC) No 1907/2006 and

EU plastics food contact Regulation (EU) No 10/2011 (as amended by EU 2018/213)

8. Bisphenol-S (BPS), CAS# 80-09-1

9. 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

10. Chitosan, CAS# 9012-76-4

11. Chromate, CAS# 12381-48-5

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

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

14. 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

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

16. Substances considered as "Dioxins and Dioxin-like"

17. 2,6 Diisopropyl Naphtalene (DIPN), CAS# 24157-81-1

18. 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

19. Gallium, CAS# 7440-55-3

20. Germanium, CAS# 7440-56-4

21. Genetically Modified Organisms

22. Iron

23. Latex – Natural and Synthetic, including derivatives

24. 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

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

26. Melamine, CAS# 108-78-1

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

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

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

30. 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)

31. Nickel, CAS# 7440-02-0

32. 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-NH_2)
i. N-Nitrosoamine or other nitroso bearing compounds (R^1R^2N-NO or X-NO)

33. Organotin compounds

34. 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'

35. 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

36. Perchlorates

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

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

39. Polyphenyls

40. Polyvinyl Chloride (PVC)

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

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

43. 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)

44. Polysiloxanes; Siloxanes and Silicones

45. Steel

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

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

Signed: ..... **Date:** 23-May-2024

Caroline Prisk
Head of Regulatory Affairs and Product Stewardship

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