

**MATERIAL AND REGULATORY INFORMATION SUMMARY**

**APAF-BP - AdvantaFlex® Biopharmaceutical Grade TPE Tubing (P50102-64) - Product Series A750**

| Legislation  | Compliant  | Note  | Date     |
|--|------------|---|----------|
| REACH  | Y          |   | 7/28/21  |
| RoHS   | Y          |   | 4/4/19   |
| (EU) No. 1935/2004   | Y          | Applicable to the raw material only   | 9/9/14   |
| (EU) No. 10/2011   | Y          | Applicable to the raw material only   | 9/9/14   |
| Conflict Minerals  | Y          |   | 8/5/14   |
| TCSA Section 6(h) - PBT Chemicals  | Y          |   | 7/26/21  |
| Substances of Concern  | Absent     | Note  | Date     |
| 1,2,4-Trichlorobenzene   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| 2,4,6-Tribromoanisole  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/26/21  |
| Aflatoxins   | Y          | Not used in the manufacturing process or formulation of raw materials   | 9/19/17  |
| Alkanes, C10-C13, chloro   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| Allergens (detailed lists available upon request)  | Y          | Not used in the manufacturing process or formulation of raw materials   | 4/7/17   |
| Animal content and BSE/TSE (EMEA 410)  | Y          | Not used in the manufacturing process or formulation of raw materials   | 11/21/14 |
| Antimony Compounds   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| Antioxidants   | N          | Compliant for food contact plastics applications; derived from synthetic sources. Used to ensure thermal and processing stability       | 3/20/14  |
| Aromatic Amines or precursors  | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Asbestos   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| Azo Dyes   | Y          | Not used in the manufacturing process or formulation of raw materials   | 4/16/08  |
| BADGE (Bisphenol A diglycidyl ether)   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/24/15  |
| Benzene  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| Benzo(a)pyrene   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| Benzophenone   | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/30/16  |
| Beryllium and Beryllium Compounds  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| BHA or BHT   | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Biocides   | Y          | Not used in the manufacturing process or formulation of raw materials   | 4/10/17  |
| Bis-DMA  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/24/15  |
| Bis-GMA  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/24/15  |
| BPA (BisPhenol A)  | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Brominated Organic Compounds   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/24/15  |
| Butyl-4-Hydroxybenzoate  | Y          | Not used in the manufacturing process or formulation of raw materials   | 11/11/20 |
| Chlorinated Organic Compounds  | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Dioxin   | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| DMF  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| Epoxy Compounds  | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Ethanol  | Y          | Not used in the manufacturing process or formulation of raw materials   | 1/5/15   |
| Ethoxylated BisPhenol A Diacrylate   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/24/15  |
| Flame retardants - Brominated (including PBB, PBDE, HBCDD, TBBPA)                                  | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Formaldehyde   | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Genetically Modified Organisms (GMOs)  | Y          | Not used in the manufacturing process or formulation of raw materials   | 1/2/19   |
| Genotoxic Impurities   | Y          | Not used in the manufacturing process or formulation of raw materials   | 1/28/15  |
| Gluten   | Y          | Not used in the manufacturing process or formulation of raw materials   | 9/15/14  |
| Hormones   | Y          | Not used in the manufacturing process or formulation of raw materials   | 4/16/18  |
| Human Derivatives  | Y          | Not used in the manufacturing process or formulation of raw materials   | 10/27/14 |
| Lactose  | Y          | Not used in the manufacturing process or formulation of raw materials   | 1/5/15   |
| Latex  | Y          | Not used in the manufacturing process or formulation of raw materials   | 4/16/08  |
| Magnesium Phosphate  | Y          | Not used in the manufacturing process or formulation of raw materials   | 2/11/15  |
| Melamine   | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Mercury  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/17/14  |
| Microbials   | Y          | Not used in the manufacturing process or formulation of raw materials   | 10/27/14 |
| Mycotoxins (e.g. aflatoxins, citrinin, fusarium, ochratoxin, patulin, trichothecenes, zearalenone) | Y          | Not used in the manufacturing process or formulation of raw materials   | 9/19/17  |
| Nickel and nickel alloys   | See Note - | Extruded bulk tubing does not contain Nickel; however molded parts may contain residual Nickel due to the manufacturing/molding process | 1/3/20   |
| Nitrates   | Y          | Not used in the manufacturing process or formulation of raw materials   | 9/19/17  |
| Nitrosamine or precursors  | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Nonylphenol and nonylphenol ethoxylates  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| Octamethylcyclotetrasiloxane   | Y          | Not used in the manufacturing process or formulation of raw materials   | 1/5/15   |
| Organophosphates   | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/24/15  |
| Organotin compounds  | Y          | Not used in the manufacturing process or formulation of raw materials   | 3/18/14  |
| Ozone Depleting Substances (ODS), Class I or Class II ODS as listed in the Clean Air Act of 1990   | Y          | Not used in the manufacturing process or formulation of raw materials   | 8/15/19  |
| PCBs   | Y          | Not used in the manufacturing process or formulation of raw materials   | 4/16/08  |
| Perfluorinated Carboxylic Acids (PFCAs) or precursors  | Y          | Not used in the manufacturing process or formulation of raw materials   | 1/5/15   |
| Perfluorinated Compounds (PFCs)  | Y          | Not used in the manufacturing process or formulation of raw materials   | 8/15/19  |
| Perfluorooctanesulfonic Acid (PFOS)  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |
| Pesticide Residues   | Y          | Not used in the manufacturing process or formulation of raw materials   | 9/19/17  |
| Phenols  | Y          | Not used in the manufacturing process or formulation of raw materials   | 7/23/14  |

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| Phthalates  | Y | Not used in the manufacturing process or formulation of raw materials  | 4/16/08  |
| Plant Origin Materials, including Jatropa Plant Derivatives | Y | Not used in the manufacturing process or formulation of raw materials  | 7/23/14  |
| Polyaromatic hydrocarbons (PAHs)                            | Y | Not used in the manufacturing process or formulation of raw materials  | 3/18/14  |
| Polycarbonate   | Y | Not used in the manufacturing process or formulation of raw materials  | 7/24/15  |
| Polychlorinated Biphenyls (PCBs)                            | Y | Not used in the manufacturing process or formulation of raw materials  | 8/15/19  |
| Polychloronaphthalenes                                      | Y | Not used in the manufacturing process or formulation of raw materials  | 7/23/14  |
| Polyether Sulfone   | Y | Not used in the manufacturing process or formulation of raw materials  | 7/24/15  |
| Polyurethanes, Biostable                                    | Y | Not used in the manufacturing process or formulation of raw materials  | 7/24/15  |
| Preservatives   | Y | Not used in the manufacturing process or formulation of raw materials  | 3/18/14  |
| PVC or PVDC   | Y | Not used in the manufacturing process or formulation of raw materials  | 3/18/14  |
| Radioactive isotopes  | Y | Not used in the manufacturing process or formulation of raw materials  | 3/18/14  |
| Recycled Materials  | Y | Not used in the manufacturing process or formulation of raw materials  | 3/18/14  |
| Residual Metals   | Y | Not used in the manufacturing process or formulation of raw materials  | 1/28/15  |
| Residual Monomer  | Y | Not used in the manufacturing process or formulation of raw materials  | 11/21/14 |
| Residual Solvents   | N | Cyclohexane (Class 2 solvent per ICH Q3C) may be present in the raw material at less than 0.8 ppb (<0.0008%) | 4/19/17  |
| Slip Agents   | Y | Not used in the manufacturing process or formulation of raw materials  | 3/23/21  |
| Sulfur Hexafluoride   | Y | Not used in the manufacturing process or formulation of raw materials  | 7/23/14  |
| Tar Oils and Creosotes                                      | Y | Not used in the manufacturing process or formulation of raw materials  | 7/23/14  |
| TNPP (Trisnonylphenylphosphite)                             | Y | Not used in the manufacturing process or formulation of raw materials  | 4/16/08  |
| Tri (2,3-dibromo-propyl) phosphate                          | Y | Not used in the manufacturing process or formulation of raw materials  | 7/23/14  |
| Tris (aziridinyl) phosphin oxide                            | Y | Not used in the manufacturing process or formulation of raw materials  | 7/23/14  |
| Vegetable Origin Materials                                  | Y | Not used in the manufacturing process or formulation of raw materials  | 7/23/14  |
| Vinyl Chloride  | Y | Not used in the manufacturing process or formulation of raw materials  | 3/18/14  |
| Vinylidene Chloride   | Y | Not used in the manufacturing process or formulation of raw materials  | 3/18/14  |

| Regulations                       | Available | Note  |
|-----------------------------------|-----------|---|
| USP Testing                       | Y         | 85; 87; 88 (Class VI) 70 C for 24 Hrs; 381; 643; 661; 788 |
| ISO Testing                       | Y         | 10993   |
| NSF LISTING                       | N         |   |
| 3-A Sanitary Procedure            | N         |   |
| FDA Testing                       | Y         | 21 CFR 177.2600   |
| European Pharmacopeia Testing     | Y         | 3.2.2.1   |
| Animal Ingredient Derivative Free | Y         | Yes   |



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