

## MATERIAL AND REGULATORY INFORMATION SUMMARY

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

Legislation	Compliant	Note	Date
REACH	Y		2/1/21
RoHS	Y		7/17/14
(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

  

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
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 (EMA 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
Phthalates	Y	Not used in the manufacturing process or formulation of raw materials	4/16/08
Plant Origin Materials, including Jatropha 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
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) phosphinoxide	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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