

Regulatory Compliance Certificate

FreshPax[®] Packets

Issued November 30, 2018

Quality System

Multisorb Technologies Quality Management System is designed and operated in a manner that combines its registration to the ISO 9000:2015 quality standard with compliance to 21 CFR Parts 117, 210 and 211 (U.S. FDA Current Good Manufacturing Practices [CGMP]).

US FDA Food Contact Status

FreshPax[®] is suitable for its intended use within the meaning of section 409 of Federal Food, Drug and Cosmetics Act, as amended.

The product complies with the following Code of Federal Regulation (CFR) Title 21 paragraphs:

Part 177 "Indirect Food Additives: Polymers," paragraph 177.1630 "Polyethylene Polymers." Part 175 "Indirect Food Additives: Adhesives and Components of Coatings," including paragraph 300 "resinous and polymeric coatings." Part 176 "Indirect Food Additives: Paper and Paperboard Components." Paragraph 170 "components of paper and paperboard in contact with aqueous and fatty foods." Part 177, paragraph 1350 "Ethylene-vinyl acetate copolymers." Part 177, paragraph 1520 "Olefin polymers," Part 175 "Indirect Food Additives: Adhesives and Components of Coatings," Part 178 "Indirect Food Additives: Adjuvants, Production Aids and Sanitizers", Part 182 "Substances Generally Recognized as Safe" and Part 184 "Direct Food Substances Affirmed as Generally Recognized as Safe."

The ink is contained between the layers of the packet film, so does not come into contact with food. The components of the ink used to print the FreshPax[®] packets are acceptable for indirect contact with food products under the appropriate sections of Title 21 of the Code of Federal Regulations, Part 175.300 resinous and polymeric coatings.

Drug Master File (DMF), US FDA

Multisorb Technologies has established a US FDA Drug Master File (DMF #15416) that includes detailed information on this product. Upon request, a DMF access letter can be provided to support an Investigational New Drug Application, a New Drug Application, an Abbreviated New Drug Application, another DMF, an Export Application or amendments and supplements to any of these.

Health Canada – Food Directorate

Health Canada – Food Directorate issued a Letter Of Non-Objection (LONO) to Multisorb Technologies FreshPax[®] products. Per the letter, "no objection is taken to the use of this packaging product for direct contact with packaged foods stored in ambient, refrigerated or frozen temperatures."

EU Food Contact Status

All monomers used in the composition of the packet are listed in Annex I, Substances (the Union List of authorized monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids) of the Commission Regulation EU No. 10/2011 and its amendments 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213 and 2018/831. The product may be used in direct contact with dry, moist and fatty foodstuffs.

The product is manufactured at Multisorb Technologies facilities under a Quality Management System designed and operated in accordance with Good Manufacturing Practices/ EC Regulation 2023/2006 and it meets the requirements of EC Regulation 1935/2004 and its amendments on materials and articles intended to come into contact with food. In addition, they are manufactured at the Multisorb Technologies facility under a Quality Management System designed and operated in accordance with EC Regulation 2023/2006.

REACH Substances of Very High Concern (SVHC)

This product does not contain any SVHC, per the candidate list that was current as of the date of this certificate, as identified in European Regulation 1907/2006 Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) above the 0.1% limit. These products do not contain any of the substances as described in REACH Article 67 or Annex XVII with amendments that are in force prior to the issue date of this document.

Restriction of Hazardous Substances (RoHS)

This product meets the applicable parts of RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment. These products do not contain lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers, bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP) above the maximum limits required by the RoHS Directive.

California Proposition 65 Compliance

This product does not have intentionally added chemicals (substances classified as carcinogens, mutagens or reproductive toxins) listed on the State of California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) as of the issue date of this document and there should not be the potential for these chemicals within the product.

GMO/GME

This product does not contain any Genetically Modified Organisms as defined in European Directive 2001/18/EC or Genetically Engineered Organisms.

Heavy Metals

This product is in compliance with all statutes (CONEG, Toxic Packaging Reduction Act and Article 11 of Council Directive 94/62/EC) that govern the presence of heavy metals in packaging, or packaging components in the United States and the European Union. This product does not contain any lead, cadmium, mercury or hexavalent chromium which has been intentionally introduced, and the sum of the concentration of all lead, cadmium, mercury or hexavalent chromium incidentally present, does not exceed 100 ppm by weight.

BSE/TSE

This product does not contain material directly from animals. However, there are ingredients that may be used in the components of the products that contain animal-derived substances. The processing of these animal-derived substances complies with USDA/APHIS Title 9 Code of Federal Regulations (CFR) and/or European Regulation EC 1774/2002, *laying down health rules concerning animal by-products not intended for human consumption*. These animal-derived substances meet exemption 1 of Commission Regulation (EU) No 722/2012 Annex I Section 3 and the requirements of EC Notice 2011/C 73/01, European Medicines Agency guidance on “Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products” (EMA 410/01 Rev 3).

Conflict Minerals

This product does not contain Cassiterite (tin), Columbite-tantalite (coltan or tantalum), Wolframite (tungsten) or gold. In addition, materials used in these products are not sourced from the Democratic Republic of Congo (DRC) or adjoining countries or the Central/East African Republic (Sudan, Uganda, Rwanda, Burundi, Angola, Tanzania, and Zambia). Therefore, Multisorb Technologies is in compliance with the applicable sections of the Dodd–Frank Wall Street Reform and Consumer Protection Act. A current Conflict Minerals Reporting Template (CMRT) is available upon request.

Dimethyl Fumarate

This product does not contain Dimethyl Fumarate (DMF). DMF is not a natural component of any of the materials and is not added to any of the materials used to manufacture these products and DMF is not used during the manufacturing process.

Nanoparticles

This product does not contain Nanoparticles (intentionally manufactured materials at nanoparticle sizes of 1-100nm) as defined in 2011/696EU Recommendation 18 October 2011 *on the definition of nanomaterial* and EC Regulation 1907/2006 *Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)* Article 3. Multisorb Technologies products are not subject to registration according to the French Republic Decree No. 2012-232 of 17 Feb 2012.

Residual Solvents

This product does not have residual solvents used in the manufacture of the packet or during manufacturing at Multisorb Technologies facilities as defined in USP <467>, CPMP/ICH/283/95 Class I, Class II, Class III, or other Solvents.

4-Methyl Benzophenone and Benzophenone

This product does not utilize 4-methyl benzophenone or benzophenone as part of the manufacturing process and to the best of our knowledge, none of the components used to make the products contain 4-methyl benzophenone or benzophenone. This statement is based on information provided by our suppliers.

Food Allergen

This product does not contain food allergens as listed in Annex IIIa of European Directive 2000/13/EC as amended by Directive 2007/68/EC and as listed in the US Food Allergen and Labeling Consumer Protection Act of 2004:

- Milk and milk by-products (including butter, buttermilk, casein, cheese, cottage cheese, curds, whey, lactose, caseinate, nougat and " natural flavor"),
- Eggs (including mayonnaise, meringue and ovabumin),
- Legumes (including peanut butter, mixed nuts, nut pieces, peanut flour, peanut protein, hydrolyzed peanut protein; soybeans - including soy-derived vegetable protein and textured vegetable protein),
- Tree nuts (including almonds, walnuts, hazelnuts, pecan, cashew, etc.),
- Wheat (including bran, bread crumbs, farina, malt wheat germ, wheat gluten, wheat starch and semolina),
- Crustacean (including shrimp, lobster and crab),
- Fish (including fresh or saltwater fin fish),
- Mollusks (including oysters, clams, mussels and scallops),
- Cereals containing gluten and products thereof,
- Peanuts and products thereof,
- Celery and products thereof,
- Mustard and products thereof,
- Sesame seeds and products thereof,
- Lupin and products thereof,
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂
- Peach and products thereof,
- Pork and products thereof,
- Tomato and products thereof.

Benzyl phenol

This product does not utilize benzyl phenol as part of the manufacturing process and to the best of our knowledge, none of the components used to make these products contain benzyl phenol. This statement is based on information provided by our suppliers.

Bisphenol A (BPA) Compliance

This product is in compliance with EU regulation 321/2011 that governs the presence of BPA in materials in the European Union. The product does not have intentionally added BPA as part of the manufacturing process and there should not be the potential for BPA.

Latex/Rubber

This product does not contain natural rubber latex or dry natural rubber as defined in 21 CFR 801.437 and no latex or dry natural rubber is used in the manufacturing process.

Melamine

This product is not made using melamine and to the best of our knowledge none of the components used to make this product contain any melamine.

Nitrosamine

This product does not have nitrosamines or nitrosatable substances added to the product as part of the manufacturing process and there should not be the potential for these substances in the products. The product complies with the European Directive 93/11/EEC.

Epoxy

This product does not utilize epoxy adhesives as part of the manufacturing process and there should not be the potential for BADGE, NOGE, BFDGE or related epoxy derivatives in the products. These products comply with the EC Regulation 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

Polyvinyl Chloride (PVC)

This product does not have PVC added as part of the manufacturing process and there should not be the potential for PVC in the product. This product complies with the European Directive 78/142/EEC and EP 3.1.11 Materials Based on Non-Plasticized Poly (Vinyl Chloride) for Containers for Dry Dosage Forms for Oral Administration.

Ozone Depleting Chemicals/Chlorinated fluorocarbons Compliance

This product does not contain and are not manufactured with any Class I and Class II Ozone depleting chemicals within the meaning of Title IV of the Clean Air Act and U.S. EPA regulation 40 CFR Part 82 and/or Ozone Depleting Chemicals listed in Annex I and Annex II of EC Regulation 1005/2009 on substances that deplete the ozone layer.

Phthalate and DEHP

This product does not have phthalates, as listed in EC regulation 2005/84/EC, added to the product as part of the manufacturing process and there is no DEHP or PBT in the components.

Miscellaneous Materials Compliance

This product does not have the following materials added to the product as part of the manufacturing process and there should not be the potential for these materials in the product:

- Perfluorooctane sulfonate (PFOS)
- Perfluorooctanoate (PFOA)
- Polystyrene (PS)
- BHT/BHA
- rBGH
- Bromated Vegetable Oils
- Synthetic Astaxanthin
- Potassium bromate
- Ractopamine
- Phenols and phenol derivatives
- Recycled materials