MULTISORB Technologies | The World Leader in Active Packaging Technology®

October 11, 2017

MiniPax® / StripPax® Food Contact Compliance Statement

Multisorb Technologies MiniPax® and StripPax® are suitable for their intended use within the meaning of section 409 of Federal Food, Drug and Cosmetics Act, as amended.

The silica gel contained in the Multisorb Technologies MiniPax® and StripPax® products meets the United States Pharmacopeia/National Formulary (USP/NF) requirements under the official monograph for Silicon dioxide. Silicon dioxide is listed under Title 21 of the Code of Federal Regulations (CFR) Part 172 “Food Additives Permitted for Direct Addition to Food for Human Consumption”.

The active ingredient, consisting of silica gel, is contained in a Tyvek® sachet. DuPont Tyvek® spunbonded polyolefin is a high density polyethylene fiber product with no binders or fillers. Tyvek® meets the requirements of Title 21 of the United States Code of Federal Regulations for olefin polymers (21 CFR 177.1520) where temperatures do not exceed 212^{o}F.

The components of the ink used to print on the surface of the MiniPax® and StripPax® sachets are acceptable for direct contact with food products under the appropriate sections of Title 21 of the Code of Federal Regulations, Parts 170-186.

These components are manufactured at the Multisorb Technologies facility under a Quality Management System designed and operated in accordance with 21 CFR parts 210 and 211current Good Manufacturing Practices and certified to meet ISO 9001:2008 guidelines.

Multisorb Technologies has established a US Drug Master File (DMF #7092) and Canadian Drug Master File (DMF #1990-013) that includes detailed information on its MiniPax® and StripPax® products. 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.

Sincerely,

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Holly Namiotko
Regulatory Affairs Coordinator