Biocompatibility, Food Contact and Pharmacopeia Testing*

March 12, 2015

DUPONT Tyvek®

Cytotoxicity (ISO 10993-5)	PASS: • Pre-sterilization • Post-sterilization and 5-year accelerated aging (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)	In progress: 10-year accelerated aging
Endotoxins (USP ‹85›)	PASS (pre-sterilization)	COMPLETED
Skin irritation and sensitization (ISO 10993-10)	PASS (pre-sterilization)	COMPLETED
Bioburden (ISO 11737-1)	Similar performance to current Tyvek® (pre-sterilization)	COMPLETED
Extractables and leachables (ISO 10993-18: Infrared spectroscopy; ICP-MS; GC-MS; UPLC-MS)	Pre-sterilization: • No major bands of interest (Infrared spectroscopy) • Met all requirements (ICP-MS; GC-MS; UPLC-MS) Post-sterilization (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam): • No major bands of interest (Infrared spectroscopy) • Met all requirements (ICP-MS; GC-MS) • UPLC-MS testing—see**	COMPLETED
U.S. Food Contact		
21 CFR 177.1520	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)	COMPLETED
U.S. Pharmacopeia		
USP ‹88› Class VI	PASS (pre-sterilization)	COMPLETED
USP ‹661›	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)	COMPLETED
European Food Contact		
EC Reg. 10/2011	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, steam)	COMPLETED
European Pharmacopeia		
EP 3.1.5 and EP 3.1.3	Meets the compositional and extractable requirements (pre-sterilization)	COMPLETED
EP 3.1.5 Selected Testing: (1) Identification A: IR Spectrometry (2) Hexane Solubility	PASS (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)	COMPLETED

NOTES: * Generated for 1073B and/or 1059B Transition Protocol material and Tyvek® 1073B and/or 1059B current material.

** Under extraction conditions of 70°C for 24 hours in purified water, a compound tentatively identified as an "oxygenated unsaturated hydrocarbon" was found to exceed the 0.1 µg/mL concentration allowance by ~0.01-0.25 µg/mL.