



March 09, 2017

**Re: Regulatory Information on Legacy Tyvek® 1059B and 1073B**

To Whom It May Concern;

Below are statements concerning Legacy Tyvek® styles 1059B and 1073B:

1. FDA Food Contact Regulation (21 CFR 177.1520)
2. European Food Contact Regulation (EU N° 10/2011 and EC N° 2023/2006)
3. USP <661.1> Plastic Materials of Construction
4. European Pharmacopoeia 3.1.3 and 3.1.5
5. Cytotoxicity (ISO 10993-5, USP <87>)
6. USP <88> Class VI
7. Skin Irritation and Sensitization (ISO 10993-10)
8. Extractables and Leachables (ISO 10993-18)
9. Endotoxins (USP <85>)
10. Bioburden (ISO 11737-1)
11. Animal Origin
12. Heavy Metals (RoHS (Directive 2015/863/EU), WEEE (Directive 2012/19/EU), EU Packaging Waste (Directive 94/62/EC) and US CONEG)
13. California Proposition 65
14. REACH
15. Chemical Substances

The information and certifications provided herein are based on data we believe to be reliable, to the best of our knowledge. The information and certifications apply only to the specific material and styles designated in the applicable paragraph herein as sold by DuPont and do not apply to use in any process or in combination with any other material. They are provided at the request of and without charge to our customers. Accordingly, DuPont cannot guarantee or warrant such certifications or information and assumes no liability for their use.

Please feel free to contact me if additional information is needed.

Sincerely,

A handwritten signature in black ink that reads "Hannah Suh".

Hannah Suh, Ph.D.  
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### **1. FDA Food Contact Regulation (21 CFR 177.1520)**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont meet the Federal Food, Drug and Cosmetic Act (FDA) requirements of Title 21 of the United States Code of Regulations for olefin polymers (21 CFR 177.1520) and additives (21 CFR 178.2010).

### **2. European Food Contact Regulation (EU N° 10/2011 and EC N° 2023/2006)**

All monomers and additives used in the composition of DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont are listed in Annex I, the Union List of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids of the Commission Regulation (EU) N° 10/2011 and its amendments.

Tests carried out according to the rules for migration testing set out in Article 18 of Regulation (EU) No 10/2011, and in accordance to the rules of the series of standards EN 1186, EN 13130 and CEN/TS 14234, "Materials and articles in contact with foodstuffs - Plastics", on DuPont Tyvek® styles 1059B and 1073B manufactured by DuPont have shown that the OML (Overall Migration Limit) restriction of 10 mg/dm<sup>2</sup> is met with acetic acid 3% (w/w) and ethanol 20% (v/v) simulants at the test conditions of 10 days at 40 °C, as well as isooctane at the test conditions of 2 days at 20 °C.

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont do not contain any substance with a Specific Migration Limit (SML) and any dual use additive.

Trace of substances authorized as food additives can be present. If present, the migration to food stuff is not reasonably expected to exceed the limits specified in relevant food additive legislation.

DuPont Tyvek® styles 1059B and 1073B manufactured by DuPont are produced according to our quality management systems which meet the requirements of the Good Manufacturing Practices of Commission Regulation (EC) N° 2023/2006.

Presuming appropriate further processing following the Commission Regulation (EC) N° 2023/2006, the product can be used in the countries of the European Community for the manufacturing of food contact materials or articles according to article 3 of the Regulation (EC) N° 1935/2004.

As such, DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont may be used safely in the field of food plastic packaging intended to come into contact with foodstuffs at room temperature or below for an unspecified period. They may stand in direct contact with dry, moist and fatty foodstuffs.

### **3. USP <661.1> Plastic Materials of Construction**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont meet the testing requirements of USP 39, <661.1> Plastic Materials of Construction.

### **4. European Pharmacopoeia 3.1.3 and 3.1.5**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont meet the compositional and testing requirements of Section 3.1.3., "Polyolefins", as well as the requirements of Section 3.1.5., "Polyethylene with Additives for Containers for Preparations for Parenteral Use and for Ophthalmic Preparations", in the 8<sup>th</sup> edition of European Pharmacopoeia.

**5. Cytotoxicity (ISO 10993-5, USP <87>)**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont meet the testing requirements of USP 36, <87> Biological Reactivity Tests, *in vitro* and ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity.

**6. USP <88> Class VI**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont meet the testing requirements of USP 36, <88> Class VI Biological Reactivity Tests, *in vivo*.

**7. Skin Irritation and Sensitization (ISO 10993-10)**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont meet the testing requirements of ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

**8. Extractables and Leachables (ISO 10993-18)**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont meet the testing requirements of ISO 10993-18:2005 Biological evaluation of medical devices - Part 18: Chemical characterization of materials. DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont do not contain quantifiable extractables detected by FTIR, GC/MS, ICP/MS or UPLC/MS.

**9. Endotoxins (USP <85>)**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont meet the testing requirements of USP 36, <85> Bacterial Endotoxins Test.

**10. Bioburden (ISO 11737-1)**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont have shown the average values less than 100 CFU/ft<sup>2</sup> per ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.

**11. Animal Origin**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont do not contain animal products. DuPont neither adds any of the substances to Tyvek® styles 1059B and 1073B, nor uses any in the process to manufacture Tyvek® styles 1059B and 1073B.

**12. Heavy Metals (RoHS (Directive 2015/863/EU), WEEE (Directive 2012/19/EU), EU Packaging Waste (Directive 94/62/EC) and US CONEG)**

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont do not contain heavy metals such as lead, mercury, cadmium and chromium and the substances identified in the RoHS (Directive 2015/863/EU), WEEE (Directive 2012/19/EU), EU Packaging Waste (Directive 94/62/EC) and US CONEG. DuPont neither adds any of the substances to Tyvek® styles 1059B and 1073B, nor uses any in the process to manufacture Tyvek® styles 1059B and 1073B.

### 13. California Proposition 65

DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont do not contain any substances identified under the California Proposition 65 list of hazardous chemicals.

### 14. REACH

Information regarding REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) for our Tyvek® products can be found in different languages on our DuPont and REACH website (<http://reach.dupont.com>).

### 15. Chemical Substances

The following substances are neither intentionally added during the manufacturing process nor do incoming raw materials contain them for DuPont Tyvek® styles 1059B and 1073B as manufactured by DuPont:

- |   |   |
|---|---|
| 1) Antibiotics  | 16) Mercury   |
| 2) Asbestos   | 17) Nanoparticles   |
| 3) Azo compounds  | 18) Organic tin compounds   |
| 4) Bisphenol A  | 19) Perfluorooctane acid (PFOA)                                       |
| 5) Cadmium  | 20) Perfluorooctane sulfonate (PFOS)                                  |
| 6) Chlorine based bleaching agents  | 21) Phthalates  |
| 7) Chromium VI  | 22) Plasticizers as ESBO<br>(EC Regulation N° 372/2007)               |
| 8) Dimethyl fumarate  | 23) Polybrominated biphenyl (PBB)<br>(EC Directive 2002/95/EC)        |
| 9) Dioxins  | 24) Polybrominated diphenyl ether (PBDE)<br>(EC Directive 2002/95/EC) |
| 10) Epoxy derivatives as BADGE, BFDGE and<br>NOGE (EC Regulation N° 1895/2005)        | 25) Polychlorinated biphenyls (PCB)                                   |
| 11) Food allergens<br>(Food Allergen Labeling and Consumer<br>Protection Act of 2004) | 26) Polychlorinated naphthalenes (PCN)                                |
| 12) Formaldehyde  | 27) Rubber/latex  |
| 13) Gluten  | 28) Silicones   |
| 14) Lead  | 29) Toluene   |
| 15) Melamine  | 30) Vinyl Chloride and polyvinyl chloride                             |