



August 13, 2013

RE: Tyvek® 1051B and 1071B Inquiry on Food Contact Regulations

To Whom This May Concern:

I am responding to your request regarding whether Tyvek® styles 1051B and 1071B are in compliance with Commission Regulation (EU) No 10/2011 as amended, Commission Regulation (EC) No 2023/2006 and Federal Food, Drug and Cosmetic Act (FDA) requirements of Title 21.

Commission Regulation (EU) No 10/2011, as amended and Commission Regulation (EC) No 2023/2006

All monomers and additives used in the composition of the Tyvek® styles 1051B and 1071B 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) No 10/2011, as amended.

Tests carried out according 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 a representative sample have shown that for the Tyvek® styles 1051B and 1071B manufactured by DuPont the OML (Overall Migration Limit) restriction of 10 mg/dm² 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. We do the tests at specialized and well known institutes (e.g. Isega).

To the best of our knowledge, the Tyvek® styles 1051B and 1071B manufactured by DuPont do not contain any additive with a Specific Migration Limit (SML) and any dual use additive.

The Tyvek® styles 1051B and 1071B as manufactured by DuPont are produced according to our quality management systems which meet the requirements of Commission Regulation (EC) No 2023/2006.

Presuming appropriate further processing following the Good Manufacturing Practices of the Commission Regulation (EC) No 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) No 1935/2004.

As such, the Tyvek® styles 1051B and 1071B 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, including a heating to 70°C up to 2 hours or a heating to 100°C up to 15 minutes. They may stand in direct contact with dry, moist and fatty foodstuffs.

Federal Food, Drug and Cosmetic Act (FDA) requirements of Title 21

DuPont Tyvek® styles 1051B and 1071B 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).

The information provided herein corresponds to our knowledge on the subject at the date of its publication. This information may be subject to revision as new knowledge and experience becomes available. The data provided fall within the normal range of product properties and relate only to the specific materials designated; these data may not be valid for such materials used in combination with any other materials or additives or in any process, unless expressly indicated otherwise. The data provided should not be used to establish specification limits or used alone as the basis of design; they are not intended to substitute for any testing you may need to conduct to determine for yourself the suitability of a specific material for your particular purposes. Since DuPont cannot anticipate all variations in actual end-use conditions DuPont makes no warranties and assumes no liability in connection with any use of this information. Nothing in this publication is to be considered as a license to operate under or a recommendation to infringe any patent rights.

I hope that this satisfies your request. Please feel free to contact me if additional information is needed.

Sincerely,



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