

1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
tel. 202.434.4100
fax 202.434.4646

Writer's Direct Access
Catherine R. Nielsen
(202) 434-4140
nielsen@khlaw.com

July 31, 2009

Via Electronic Mail and U.S. Mail

David Lundberg, Ph.D.
General Manager
Higher Dimension Materials Inc.
570 Hale Avenue
Oakdale, Minnesota 55128

**Re: FDA Status of SuperFabric[®] EP Resin Coating for HDPE Fabric
Food-Contact Gloves Intended for Use with Vinyl, Nitrile Rubber, or Latex
Outer Gloves in Food Processing Facilities and Restaurants; Our File No.
HI11982-2**

Dear Dr. Lundberg:

The purpose of this letter is to respond to your request for our opinion regarding the status, under the laws and regulations administered by the U.S. Food and Drug Administration (FDA), of Higher Dimension Material Inc.'s (HDM) SuperFabric[®] EP resin for use as a coating on HexArmor high density polyethylene (HDPE) fabric gloves. The coated HexArmor gloves are intended for use in handling and cutting food in meat, poultry, and other food processing facilities, including restaurants. We understand that the coated HDPE gloves are intended for repeated use in these facilities, and will be worn with a disposable outer vinyl, nitrile rubber, or latex glove¹ with a thickness of 2.5 mil or greater.

Based on the information that you have provided to us, we have no hesitation in advising that the coated gloves may be used as intended, and that such use may be said to comply fully with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable food additive

¹ "Nitrile rubber" is a commonly used name for acrylonitrile-butadiene copolymers and "vinyl" is a commonly used name for vinyl chloride polymers (PVC). Similarly, "latex" is a commonly used name for polyisoprene or synthetic polyisoprene in the case of "latex free" gloves.

Please note that our opinion is limited to the HDM SuperFabric[®] EP resin alone, and does not address the FDA status of the HDPE gloves, or the FDA status of the vinyl, nitrile, or latex outer glove. We understand from you that these materials will have a suitable FDA status; you have only inquired about your product, the SuperFabric[®] EP Resin.

KELLER AND HECKMAN LLP

David Lundberg, Ph.D.

July 31, 2009

Page 2

regulations, provided that the coated gloves are used with vinyl, nitrile rubber, or latex outer gloves of 2.5 mils or greater thickness.

We trust that you will find this letter to be fully responsive to your request for our opinion. Should you have any further questions, or if we may be of assistance in any other way, please do not hesitate to contact us.

Cordially yours,

A handwritten signature in black ink, appearing to read "Catherine R. Nielsen". The signature is fluid and cursive, with a large initial "C" and "N".

Catherine R. Nielsen