U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh St., S.W.
Washington, D.C. 20590

OCT 3 2000

Ref. No. 00-0229

Ms. Cathy VanDerVeer
Artegraft, Inc.
P.O. Box 7305
North Brunswick, NJ 08902

Dear Ms. VanDerVeer:

I am responding to your August 11, 2000 letter regarding the definition of a consumer commodity under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) as it applies to Artegraft's alcohol based "Sterilizing Solution."

You stated that your company's sterilizing solution is an alcohol based sterilant utilized in the manufacturing process of an Artegraft. An Artegraft is an all collagen vascular access graft used by physicians. The sterilizing solution is 50% ethyl alcohol with the remaining balance being water. The product is a Class 3 (flammable liquid) in Packing Group III, in accordance with §§ 173.120 and 173.121, and described as "Ethyl alcohol solutions."

The product is packaged in 500-milliliter inner containers, placed in a Styrofoam box, and then packaged in an outer fiberboard box. The boxes are overpacked in a fiberboard box with a higher burst/edge crush strength. The outer packaging contains from 1 to 10 units depending upon the quantities ordered. The total weight of the packages range from 4 pounds to 34 pounds. Specifically, because the components of Artegraft's sterilant are similar to many alcohol based household sterilants, you believe that the alcohol based sterilizing solution meets the definition of "Consumer commodity, ORM-D."

The definition of a consumer commodity in § 171.8 includes a material that is packaged and distributed in a form suitable for retail sale for consumption by individuals for purposes of personal use or household use even if not specifically so intended. We agree that the Artegraft alcohol based sterilizing solution described in your letter is suitable for household use and qualifies to be described and classed as a "Consumer commodity, ORM-D."

I hope this satisfies your inquiry. If we can be of further assistance, please contact us.

Sincerely,

Delmer F. Billings
Chief, Regulations Development
Office of Hazardous Materials Standards

000229

171.8

Artegraft™

Engrum
§ 171.8
Consummer
Commodity

August 11, 2000

VIA US MAIL AND FACSIMILE

Mr. Edward Mazzullo, Director
Office of Hazardous Materials Standards
U.S. Department of Transportation
Research and Special Programs Administration
400 7th Street, S.W.
Washington, DC 20590

Dear Mr. Mazzullo:

I am requesting formal written confirmation that the product known as the Artegraft Sterilizing Solution is a consumer commodity within the meaning of 49 C.F.R. 171.8 (pg 76 in the 10-01-99 edition).

The Artegraft Sterilizing Solution is an alcohol based sterilant utilized in the manufacturing process of an Artegraft. An Artegraft is an all collagen vascular access graft. This graft is utilized by physicians. The Sterilizing Solution is 50% ethyl alcohol with the remaining balance being water. The MSDS for the alcohol is attached.

The product is packaged in 500-milliliter containers. The containers are packaged in a Styrofoam box and labeled appropriately. These packages are then packaged inside a fibreboard box. These boxes are then packaged inside of another fibreboard box with a higher burst/edge crush strength. (Outer packaging varies from 1 to 10 units dependent upon order quantity) The total weight of the packages range from 4 pounds to 34 pounds.

I understand that because the packages contain 50% of ethyl alcohol, the Artegraft product is considered hazardous material under Title 49. The Artegraft is classified as "ethyl alcohol solution and is assigned a packing group III. These classifications are determined under 49 CFR 173.120 and 173.121. The flash point of the solution is 78°F (Closed Cup). (see attached)

Based on the form and quantities that the Artegraft is shipped, the shipments qualify for the limited quantity exemption. As stated above, Artegraft is packaged in a new-strong outer package with 1 – 10 containers of 500 ml of solution each with a maximum weight not exceeding 34 pounds. As a result of this, the Artegraft is shipped under the limited quantity exemption under 49 CFR 173.150.

We feel that because the steriliant solution resembles many alcohol-based consumer products, Artegraft can be considered a consumer commodity under 49 CFR 171.8. As such, if shipped in limited quantities, Artegraft can lawfully be labeled "ORM-D" and shipped as a consumer commodity under 49 CFR 173.150 (c). Shipments of ORM-D materials are not subject to the shipping paper requirements (unless transported by air).

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The term consumer commodity is defined under the Department of Transportation regulations as "a material that is packaged and distributed in a form intended or suitable for sale through retail sales agencies or instrumentality's for consumption by individuals for purposes of personal care or household use. This term also includes drugs and medicines." 49 CFR 171.8. I was advised that this definition might include a product like Artegraft. In terms of the components of the steritant, Artegraft is very similar to rubbing alcohol or other alcohol based household sterilants. I therefore believe that this product can properly be considered a consumer commodity.

For example, the Office of Hazardous Materials Standards issued an explanation of a sterilant called Vapo-Steril that it could be shipped consumer commodity, Ref No. 99-0108. (see attached).

Your response to the above inquiry has very significant impact on us, as the manufacturer, as well as, our distributors. I would like to request a written response, as soon as possible, as to whether the Artegraft steriliant would qualify as a consumer commodity.

Sincerely,

Cathy VanDerVeer
Office Manager

Attachments (3)