



U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

MAY 11 1999

Ms. Carolina L. Mederos and
Mr. Duane A. Siler
PATTON BOGGS LLP
Attorneys at Law
2550 M Street, NW
Washington, DC 20037-1350

Ref No. 99-0108

Dear Ms. Mederos and Mr. Siler:

This is in response to your letter of April 26 1999, requesting confirmation of your understanding of the definition for "consumer commodity" under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) as it applies to your client's product "Vapo-Steril."

You describe "Vapo-Steril" as an alcohol-based sterilant, consisting of 72.36% ethanol and 0.23% formaldehyde, with the balance being inert ingredients. It is classified as a Class 3 (flammable liquid) in Packing Group III and is used in a vaporizing sterilizer to sterilize instruments and other apparatus, mainly for dental and medical purposes. Vapo-Steril is packaged in one liter containers by the manufacturer. Four such four-packs, a total of 16 one liter containers, are placed in an outer packaging or box. The total weight of the entire package is approximately 35 pounds. You indicate it is similar to household sterilizing solutions whose active ingredient is alcohol and which are sold to consumers at retail.

As you are aware, 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 product Vapo-Steril, in the described formulation and quantity limits, is suitable for household use and therefore qualifies for shipment as a "Consumer commodity, ORM-D."

I hope this information is helpful. If we can be of further assistance, please contact us.

Sincerely,

Edward T. Mazzullo

Director, Office of Hazardous Materials
Standards



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April 26, 1999

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VIA US MAIL AND FACSIMILE

Mr. Edward Mazzullo – DHM-10
Director, Office of Hazardous Materials Standards
Research and Special Programs Administration
U.S. Department of Transportation
400 7th Street, S.W.
Room 8102
Washington, DC 20590

Re: Status of Alcohol-Based Vaporizer Sterilant Product Under Federal HazMat Regulations

Dear Mr. Mazzullo:

We are writing to memorialize our conversation on Thursday, April 23, 1999 and to request written confirmation that a product known as Vapo-Steril is a consumer commodity within the meaning of 49 C.F.R. 171.8.

As we explained, Vapo-Steril is an alcohol-based sterilant. The product contains 72.36% ethanol and 0.23 % formaldehyde, with the balance being inert ingredients. The material is manufactured and marketed by Barnstead/Thermolyne, a subsidiary of our client, Sybron International Corporation of Milwaukee. Vapo-Steril is designed for use in a specific type of vaporizing sterilizer, the Chemiclave EC Series Sterilizer, which is used to sterilize instruments and other apparatus, mainly in dental and medical offices. The current MSDS for Vapo-Steril is attached.

The product is packaged in one-liter containers at the point of manufacture. These containers are packaged in four-packs, which are shipped to customers in outer

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boxes containing four such four-packs, or a total of 16 one-liter containers in each box. The total weight of the entire package is approximately 35 pounds.

We understand that, because it contains 72.36% ethanol, Vapo-Steril is a "hazardous material" under the Hazardous Materials Table, 49 C.F.R. 172.10, and would be classified as "alcohol n.o.s." with UN 1987. We further understand that, due to its indicated flash point of 71-75 degrees F, Vapo-Steril would be considered a flammable liquid (Class III) and is in Packaging Group II under 49 C.F.R. 173.121.

As we discussed, based on the form in which Vapo-Steril solution is shipped, i.e., in a strong outer box containing 16 one-liter bottles, with a gross weight of less than 66 pounds, these shipments are "limited quantities" within the meaning of 49 C.F.R. 173.150(b)(2).

You indicated that, because it resembles many alcohol-based consumer products, Vapo-Steril probably can be considered a "consumer commodity" under 49 C.F.R. 171.8. As such, if shipped in "limited quantities," as at present, Vapo-Steril can lawfully be labeled "ORM-D" and shipped as "consumer commodities" under 49 C.F.R. 173.150(c) without the necessity for hazardous material shipping papers (unless transported by air).

The term "consumer commodity" is defined under Department of Transportation (DOT) regulations as "a material that is packaged and distributed in a form intended or suitable for sale through retail sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use." 49 C.F.R. 171.8. You advised that this definition can include a product like Vapo-Steril that is shipped for sale to professional end-users for more specialized applications, provided the product is substantially similar to some household product. In terms of its composition, Vapo-Steril solution is very similar to rubbing alcohol or other alcohol-based household sterilants. We therefore conclude that this product can properly be considered a "consumer commodity."

We note that your advice is consistent with that previously provided by the Office of Hazardous Materials Standards (OHMS). For example, in a letter dated May 23, 1997, and posted on DOT's website, OHMS advised the manufacturer of an aerosol product used solely for industrial applications that limited quantities of the product could be shipped as ORM-D. See letter from Delmer F. Billings, Chief, Regulations

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Development, to Ms. Karen E. Liedigk (May 23, 1997) (copy attached). As OHMS explained: "this definition [of consumer commodity] includes materials that are suitable for retail sale even if not specifically so intended and which may, in fact, be used in some other fashion." (emphasis added) The letter went on to note that the shipper's product, a type of marking fluid, "is for industrial use only and not suitable for household use." Nevertheless, because of the product's similarities to spray paint, some of which may have household applications, OHMS concluded it met the definition of a consumer commodity.

Like the industrial marking fluid at issue in the foregoing interpretation, Vapo-Steril is not generally suitable or cost-effective for household use, primarily because it is designed for use in a vapor sterilizer device by health care professionals. However, the product contains predominantly ethanol and therefore is substantially similar to household sterilizing solutions whose active ingredient is alcohol and which are sold to consumers at retail. In addition, Vapor-Sterilant would present no greater risks when transported in limited quantities than would alcohol-based household products.

The status of Vapo-Sterilant under the HazMat regulations has very significant and time-sensitive commercial implications for its manufacturer. For this reason, we respectfully ask that OHMS confirm as soon as possible in writing that, based on the facts presented, Vapo-Steril would qualify as a consumer commodity under section 171.8. We also ask that you advise us at once if you believe the foregoing analysis of the regulations, or the conclusion we reach, is incorrect in any material way.

Sincerely,


Carolina L. Mederos

Duane Siler/CCW
Duane A. Siler

Attachments

