



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

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

MAY 23 2003

Mr. Victor B. Anderson  
Solutions, Inc.  
5948 Timber Ridge Drive, Ste. 102  
Prospect, Kentucky 40059

Reference No. 02-0222

Dear Mr. Anderson:

This is in further response to your letter and telephone conversations with Ms. Eileen Edmonson of my staff. You asked if a hazardous materials carrier may transport sharps described as "Regulated medical waste, 6.2 (infectious), UN 3291, PG II," packaged in UN standard or non-DOT specification packagings under the Hazardous Materials Regulations (HMR; 49 CFR Part 171-180) that do not meet the sharps packaging requirements of the U.S. Food and Drug Administration (FDA).

We recently revised the requirements in the HMR for infectious substances, including sharps meeting the definition of RMW, to harmonize them with international standards and incorporate several RMW exemptions (67 FR 53118, August 14, 2002). While certain of these revised requirements, some of which are discussed below, refer to FDA requirements for sharps containers, the FDA is the lead agency in approving single-use and reusable medical devices, such as sharps containers. The HMR do not supercede these requirements. For more information on the FDA's requirements, you may wish to contact Ms. Diane Goldsberry or Ms. Carolyn Niebauer of the FDA's Centers for Devices and Radiological Health, Office of Compliance, Division of Enforcement, General Hospital Devices Branch, HFZ-333, 2094 Gaither Road, Rockville, MD, 20850, at (301) 594-4618.

Under the new HMR requirements, the following RMW packagings are authorized for Division 6.2 (infectious) sharps that are not a Risk Group 4 material: (1) a non-bulk, puncture-resistant packaging that meets the Packing Group II performance level requirements in 49 CFR Part 178, Subpart M, as specified in § 173.197(b); (2) a puncture-resistant Large packaging capable of retaining liquids that meets the testing requirements for an intermediate bulk container prescribed in 49 CFR Part 178, Subpart O, as specified in § 173.197(c); (3) a non-specification wheeled cart (Cart) as specified in § 173.197(d)(1) and (d)(2); or 4) a bulk outer packaging (BOP) as specified in § 173.197(d)(1) and (d)(3). Inner packagings used in a Large packaging, Cart, or BOP must conform to the requirements in § 173.197(e).

You also asked if an inner packaging containing sharps and a polyethylene bag containing RMW may be placed in the same outer packaging under the HMR. For non-bulk packagings, the



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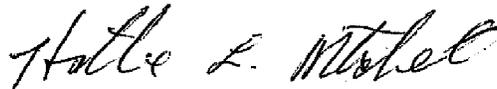
173.197

answer is yes. However, inner packagings in a Cart or BOP must be restricted in a manner that minimizes breakage. See §§ 173.197(d)(2)(iv) and 173.197(d)(3)(v). Further, in a BOP, a rigid packaging must be separated from a plastic-film bag with rigid barriers or dividers that will prevent damage to inner packagings from load shifts. See § 173.197(d)(3)(v).

Sharps may be transported as RMW in a non-specification, non-bulk packaging by a private or contract carrier under the provisions in §§ 173.134(c)(1) and (2). A sharps container intended for reuse in a Large packaging, Cart, or BOP must be approved and certified as a medical device for reuse by the FDA and meet additional requirements under § 173.197(e)(3). Sharps meeting the definition of a Risk Group 4 material must be classed and transported as a UN 2814 or UN 2900 infectious substance in packagings tested and marked as required under §§ 173.196 and 173.503(f), respectively. See § 173.134(a)(4).

I hope this satisfies your request.

Sincerely,

A handwritten signature in cursive script that reads "Hattie L. Mitchell".

Hattie L. Mitchell  
Chief, Regulatory Review and Reinvention  
Office of Hazardous Materials Standards



Corbin

§ 173.197

Regulated Medical  
Waste

02-0222

August 22, 2002

US Department of Transportation  
RSPA  
400 7<sup>th</sup> Street, S.W.  
Washington, DC. 20590  
DHM-10  
Ed Mazzulo, Director of Office of Hazardous Materials

Dear Mr. Mazzulo;

I am a packaging provider for the medical waste industry. I have a customer that needs to ship sharps in D.O.T. approved containers without the FDA approved collection container. Please advise me if my understanding is correct and that procedure is legal and conforms to the intent of the regulations.

Please reply back to me by fax or mail as soon as possible. Fax # 502-228-2931, You may reply by mail to;

Solutions Inc.  
5948 Timber Ridge Drive, Suite 102  
Prospect, KY. 40059

If you have any questions please feel free to call me at 502-228-2901

Thank you.

A handwritten signature in black ink, appearing to read "Victor B. Anderson", written over a white background.

Victor B. Anderson