



U.S. Department  
of Transportation

**Research and  
Special Programs  
Administration**

**DEC 7 2004**

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

Mr. John Edmunson  
EnviroMed, Inc.  
Safety and Compliance  
848 W. Danforth Road  
Edmond, Oklahoma 73003

Ref. No. 04-0211

Dear Mr. Edmunson:

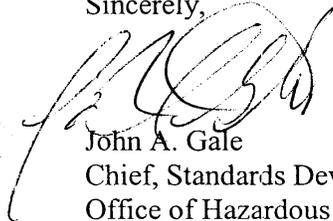
This responds to your September 8, 2004 letter requesting clarification on packaging requirements in § 173.199(d) for the shipment of used healthcare products under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask whether your packaging meets the requirements in § 173.199(d).

According to your letter, you designed a packaging for shipment of used healthcare products in accordance with § 173.199(d) requirements. You further state that this packaging has been tested and certified by an independent laboratory in accordance with testing criteria in §§ 178.604, 178.606, 178.608, and 178.609(e)(f)(h). You ask for confirmation from this Office that your packaging meets all the requirements for the transportation of used health care products according to § 173.199(d).

Based on the information and diagram provided in your letter, if the inner watertight bag liner is used in the primary container, your packaging does meet § 173.199(d) requirements.

I hope this answers your inquiry.

Sincerely,

  
John A. Gale  
Chief, Standards Development  
Office of Hazardous Materials Standards



040211

173.199(d)



**EnviroMed**  
Safety and Compliance

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email: [enviomed@cox.net](mailto:enviomed@cox.net)

Boothe  
§173.199(d)  
Diagnostic Specimens  
04-0211

September 8, 2004

Mr. Edward Mazzullo  
Director, Office of Material Standards  
USDOT / RSP (DHM-10)  
400 7<sup>th</sup> Street, SW  
Washington, DC 20590-0001

Re: EnviroMed packaging for Used Healthcare Products

Dear Mr. Mazzullo,

This letter is to confirm the correct packaging for Used Healthcare products as specified by the USDOT in 49 CFR 173.199(d).

According to 49 173.199(d), Used Healthcare Products assigned to Risk Group 1-3 are transportable if the packaging meets the following specifications:

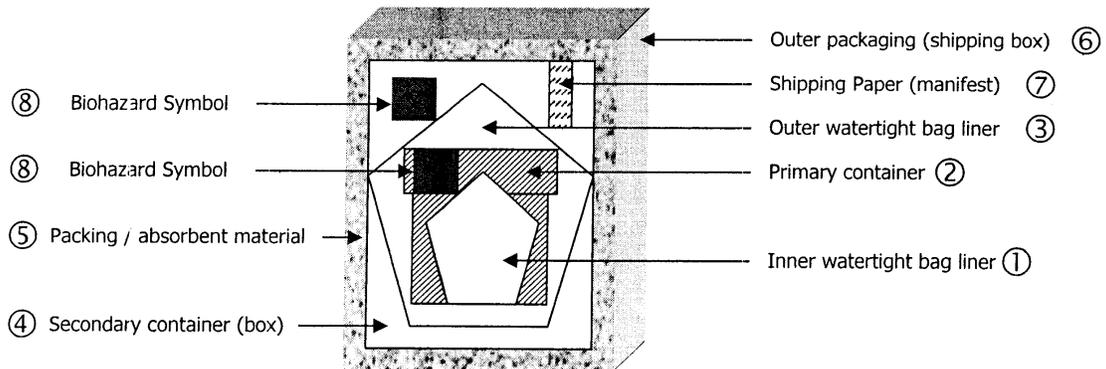
- 1) Used healthcare products are to be drained of free liquids and packed in a watertight primary container. For sharps items, the primary container must be capable of retaining the waste without puncture.
- 2) Each primary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030 (g)(1)(i).
- 3) Primary containers must be placed inside a watertight secondary container, which also must be marked with a BIOHAZARD marking.
- 4) The secondary container must be placed inside an outer packaging with sufficient cushioning to prevent movement.
- 5) An itemized list, or manifest, of the contents must be placed between the secondary container and outer packaging.
- 6) No outer markings are required for the outer packaging.

EnviroMed has designed packaging pursuant to these requirements and has had the packaging certified by an independent laboratory to the following standards:

- Leakproof Test (49 CFR 178.604)
- Stacking Test (49 CFR 178.606)
- Vibration Test (49 CFR 178.608)
- Infectious Substances (49 CFR 609-e, -f, and -h)

Please see the below packaging drawing as an example of our packaging components. Our packaging consists of the following components:

- Primary container consisting of a puncture proof watertight container (2) combined with an interior leakproof 0.4mil plastic liner (1), properly marked with a universal Biohazard symbol (8).
- Secondary containment system consisting of a 0.4mil leakproof liner (3) and strong fiberboard box (4), properly marked with a universal Biohazard symbol (8).
- Outer packaging consisting of a strong fiberboard box (6) with sufficient cushioning and absorbent material (5) to prevent movement and leakage during shipment.
- Shipping paper (Manifest) (7) placed between the secondary containment system and outer packaging.



We would like to confirm that the packaging described above as produced by EnviroMed consists of the necessary components and meets USDOT requirements for transportation of Used Healthcare Products. Please respond with your opinion of acceptability. We understand that it is the responsibility of the shipper to properly pack, label and ship this material.

Please contact me at 405-340-2430 with any questions or for more information on our packaging. Thank you for your attention.

Very best regards,

  
 John Edmunson  
 EnviroMed, Inc.