



U.S. Department  
of Transportation

**Research and  
Special Programs  
Administration**

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

DEC 16 1999

Ref. No. 99-0192

Ms. Samantha Burdick  
Office Manager  
Bio-Safe America, Inc.  
4301 32<sup>nd</sup> Street West, Suite C-16  
Bradenton, Florida 34205

Dear Ms. Burdick:

This is in response to your letter dated July 12, 1999, requesting clarification of the packaging exceptions in 49 CFR 173.134(b)(3) for "Regulated Medical Waste, 6.2, UN 3291, PG II" in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

Your understanding of the exceptions in § 173.134(b)(3) is correct. As provided by § 173.134(b)(3), a regulated medical waste that is transported by a private or contract carrier is excepted from: (1) the "INFECTIOUS SUBSTANCE" label, if the outer packaging is marked with a "BIOHAZARD" marking conforming to 29 CFR 1910.1030, and (2) for other than a waste culture or stock of an infectious substance, the specific packaging requirements in § 173.197, if packaged in a rigid, non-bulk package conforming to §§ 173.24 and 173.24a, and 29 CFR 1910.1030.

I hope this satisfies your request.

Sincerely,

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



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July 12, 1999

Mr. Edward Mazzullo, Director  
US DOT/RSPA  
400 7<sup>th</sup> Street S.W.  
Washington, D.C. 20590

Dear Mr. Mazzullo:

I am writing in reference to the US DOT regulations pertaining to containers manufactured for the transportation of regulated medical waste. I was referred to you by Mr. Arthur Pollack in the standards division in regard to obtaining a letter from your office regarding certain exceptions to the packaging requirements.

CFR 49 Parts 100-185 set forth the regulations for transportation of all hazardous materials, including regulated medical waste. Bio-Safe America, Inc. is a medical waste transporter and, therefore, must comply with these regulations. However, there are exceptions to the packaging and marking requirements for various types of carriers and different types of substances being transported.

Part 173.197 sets forth the packaging regulations for regulated medical waste. In this section, minimum construction standards are established, testing and certification procedures are discussed (specific testing procedures are located in parts 173.24 and 173.24a), and UN Standard Packaging (UN markings, numbers) is defined. However, part 173.134 sets forth EXCEPTIONS to the packaging requirements for regulated medical waste in part 173.197. Based on our interpretation of the regulations, we believe that our boxes do not require testing or certification based on several of these exceptions. I have indicated below those that apply to Bio-Safe America, Inc. directly. The specific exceptions are as follows:

#### 173.134 Packaging Exceptions

A Regulated Medical Waste that is transported by a private or contract carrier (Bio-Safe America is a contract carrier) is excepted from:

1. Infectious Substance label, if the outer packaging is marked with a "biohazard" marking (Bio-Safe America's boxes have always been printed with the international biohazard symbol and the word "biohazard").
2. For other than a waste culture or stock of an infectious substance (Bio-Safe America does not contract with facilities that produce these types of items for disposal), the specific packaging requirements of 173.197, if packaged in a rigid, non-bulk package conforming to 173.24 and 173.24a, and CFR 29 1910.130 (these are OSHA safety requirements that Bio-Safe America's containers comply with).

BIO-SAFE AMERICA, INC.  
4301 32ND STREET WEST, SUITE C-16  
BRADENTON, FL 34205

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§ 173.134  
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July 12, 1999

Parts 173.24 and 173.24a set forth General Non-Specification and Specification Packaging Requirements for hazardous materials:

1. There will be no identifiable leakage.
2. The effectiveness of the package will not be substantially reduced due to temperature changes or weather conditions.
3. Inner packaging (bags) must be secured to prevent leakage.

Under normal use and conditions, Bio-Safe America's boxes meet all of the above specifications.

Based on this information, it is our understanding that our containers are not subject to UN Standard Packaging requirements, including testing and certification, UN markings, and identification numbers.

As part of my research in this matter, I have had several telephone conversations with individuals in your department, including Ms. Helen Engrum and Mr. Arthur Pollack, both regulatory specialists. I also spoke with Mr. Phil Olsen at the office of the Associate Administrator, Mr. Alan Roberts. After I had explained our situation to them, each of these individuals verbally agreed with our interpretation of the exceptions in the regulations. I am now, however, in need of written clarification of this information from your office.

Please call me at 941-755-1921 with any questions or comments regarding this matter. If possible, please fax your response to this inquiry to my attention at 941-753-1416.

Thank you for your time and attention in this matter.

Sincerely,



Samantha Burdick  
Office Manager