



U.S. Department  
of Transportation

**Pipeline and Hazardous  
Materials Safety  
Administration**

1200 New Jersey Avenue SE  
Washington, DC 20590

DEC 21 2011

Mr. James Campbell Kean, JD, LLM  
Master of Laws, Environment and Energy Law  
Law Offices of James Kean  
2 Hilshire Oaks Court  
Houston, TX 77055

Ref. No. 11-0204

Dear Mr. Kean:

This responds to your August 17, 2011 request for clarification of the Hazardous Materials Regulation's (HMR; 49 CFR Parts 171-180) exception for biological products or medical preparations in § 173.306(b)(3). In your letter, you present your specific interpretations of conditions specified in the exception applicable to a particular scenario. You ask that we comment on the accuracy of each of your interpretations. Your interpretations of § 173.306(b)(3) and PHMSA's responses are as follows:

- (1) Scenario: Division 2.1 (Flammable gas) medicinal aerosols and inhalers (each of which meet the exception criteria) are covered under this provision, even though the metal aerosols and inhalers may contain flammable gases.

Response: Your understanding is correct, provided the medicinal aerosols and inhalers otherwise meet all of the conditions as described in the exception in § 173.306(b)(3). Division 2.1 (Flammable gas) materials may not be transported in plastic containers under this exception.

- (2) Scenario: The capacity limitation (not to exceed 35 cubic inches (19.3 fluid ounces)) applies separately to each individual container. There is no limit to the number of separate containers that may be placed together inside one outer container. In other words, multiple individual Division 2.1 medicinal aerosols and/or inhalers (each of which meet the exception criteria) may be placed within one outer container.

Response: Your understanding that the capacity limitation applies separately to each individual container is correct. Your understanding that there is no limit to the number of separate containers that may be placed together inside one outer packaging is incorrect. The introductory paragraph to § 173.306(b) states that for transportation by aircraft the net quantity per package may not exceed the quantity specified in column (9A) of the Hazardous Materials Table in § 172.101. Further, the gross weight of the

completed package must not exceed 30 kg (66 pounds) for any mode of transportation (§ 173.306(a)).

- (3) Scenario: Where the exception criteria specify “strong outside packaging,” any outer container that meets the general packaging requirements of 49 CFR 173.24 will suffice.

Response: Your understanding is incorrect. “Strong outer packaging,” synonymous with “strong outside packaging,” is defined in § 171.8 as the outermost enclosure that provides protection against the unintentional release of its contents. It is a packaging that is sturdy, durable, and constructed so that it will retain its contents under normal conditions of transportation. In addition, a strong outer packaging must meet the general requirements of subpart B of part 173. For transportation by aircraft, a strong outer packaging is subject to § 173.27.

- (4) Scenario: Other than the reference to “strong outside packaging” there are no special labeling or packaging requirements that apply to Division 2.1 (Flammable gas) medicinal aerosols and inhalers (each of which meet the exclusion criteria).

Response: Your understanding is incorrect. When transporting materials in accordance with the exception in § 173.306(b)(3) by aircraft, the package must be labeled as specified in Part 172, Subpart E. The package must be marked in accordance with § 172.315. For packaging requirements, please see the Response to Scenario 3 provided above.

I hope this answers your inquiry. If you need additional assistance, please contact this office at (202) 366-8553.

Sincerely,

A handwritten signature in black ink, appearing to read "Ben Supko", with a long horizontal flourish extending to the right.

Ben Supko  
Acting Chief, Standards Development  
Standards and Rulemaking Division

**James Kean, JD, LLM***Master of Laws  
Environment, Energy and  
Natural Resources*

8/17/11

Mr. T. Glenn Foster  
Chief, Regulatory Review and Reinvention Branch  
Standards and Rulemaking Division  
US Department of Transportation  
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East Building, 2<sup>nd</sup> Floor  
1200 New Jersey Avenue, SE  
Washington, DC 20590

Eichenlaub  
§ 173.306(b)(3)  
§ 173.24  
Cylinders  
11-0204

Re: Request for a Formal Letter of Interpretation 49 CFR Section 173.306(b)(3)

Dear Mr. Foster,

This is a request for a formal letter of interpretation regarding the exclusion of certain limited quantities of compressed gases from certain labeling and packaging requirements.

49 173.306(b)(3) states:

“Nonrefillable metal or plastic containers charged with a Division 6.1 Packing Group III or nonflammable solution containing biological products or a medical preparation which could be deteriorate by heat, and compressed gas or gases. Plastic containers must only contain 2.2 nonflammable soluble or emulsified compressed gas. The capacity of each container may not exceed 35 cubic inches (19.3 fluid ounces). The pressure in the container may not exceed 140 psig at 130 [deg]F, and the liquid content of the product and gas must not completely fill the containers at 130 [deg]F. One completed container out of each lot of 500 or less, filled for shipment, must be heated, until the pressure in the container is equivalent to equilibrium pressure of the contents at 130 [deg]F. There must be no evidence of leakage, distortion, or other defect. The container must be packed in strong outside packagings.”

For clarity’s sake, we request written interpretation on each of the following points:

1. Class 2.1 medicinal aerosols and inhalers (each of which meet the exclusion criteria) are covered under this provision, even though the metal aerosols and inhalers may contain flammable gases.

2. The capacity limitation (not to exceed 35 cubic inches (19.3 fluid ounces)) applies separately to each individual container. There is no limit to the number of separate containers that may be placed together inside one outer container. In other words, multiple individual Class 2.1 medicinal aerosols and/or inhalers (each of which meet the exclusion criteria) may be placed within one outer container.
3. Where the exclusion criteria specify "strong outside packaging", any outer container that meets the general packaging requirements at 49 CFR 173.24 will suffice.
4. Other than the reference to "strong outside packaging" there are no special labeling or packaging requirements that apply to Class 2.1 medicinal aerosols and inhalers (each of which meet the exclusion criteria).

Please feel free to contact me if you have any questions, concerns or are in need of further clarifications.

Very truly yours,



James Kean