



U.S. Department  
of Transportation

**Pipeline and Hazardous  
Materials Safety  
Administration**

1200 New Jersey Avenue, SE  
Washington, D.C. 20590

MAR 02 2016

Jay Johnson, DGSA  
Inmark Packaging  
Regulatory Compliance Manager  
675 Hartman Road, Suite 100  
Austell, GA 30168

Ref. No.: 15-0092

Dear Mr. Johnson:

This letter is in response to your e-mail and attached letter requesting the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to closure instructions for Category B infectious substance packagings. Specifically, you ask if the closure instructions on filling and closing a Category B packaging that are prescribed in § 173.199(a)(10) differ from the closure instruction requirements prescribed in § 178.2(c).

While the packaging closure instructions prescribed in §§ 173.199(a)(10) and 178.2(c) use similar language, the instructions differ in that those prescribed in § 178.2(c) apply to hazardous materials subject to the requirements of 49 CFR Subtitle B, Chapter I, Subchapter C. The HMR excepts Category B infectious substances prepared and offered for transportation in conformance with the requirements prescribed in § 173.199 from having to conform to the remainder of 49 CFR Subchapter C, except those requirements specifically prescribed in § 173.199 (see § 173.199(a)). Therefore, the packaging closure instructions prescribed in § 173.199(a)(10) apply only to Category B infectious substances.

You also refer to a letter the Pipeline and Hazardous Materials Safety Administration (PHMSA) issued under Reference No. 14-0060 that stated the HMR does not require closure instructions for Category B infectious substances that conform to § 173.199. For clarification, the HMR does require closure instructions under § 173.199(a)(10) for Category B infectious substances but does not require these materials to conform to the closure instructions prescribed in § 178.2(c).

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

T. Glenn Foster  
Chief, Regulatory Review and Reinvention Branch  
Standards and Rulemaking Division

Edmonson  
§173.199  
Category B Infectious Sub.  
15-0092

**Dodd, Alice (PHMSA)**

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**From:** INFOCNTR (PHMSA)  
**Sent:** Tuesday, May 05, 2015 4:22 PM  
**To:** Hazmat Interps  
**Subject:** FW: Question regarding 173.199  
**Attachments:** Interp Request on 173.199.pdf

Dear Shante & Alice, please assign to Eileen Edmonson.  
Thanks,

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**From:** Jay Johnson [<mailto:jayj@inmarkinc.com>]  
**Sent:** Tuesday May 5, 2015 9:45 AM  
**To:** PHMSA HM InfoCenter  
**Subject:** Question regarding 173.199

Please see attached document for a request for a formal letter of interpretation of 49 CFR 173.199.

Kind Regards,

Jay Johnson, DGSA  
Regulatory Compliance Manager  
675 Hartman Road, Suite 100  
Austell GA 30168

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Mr. Charles E. Betts  
Director, Standards and Rulemaking Division  
U.S. DOT/PHMSA (PHH-10)  
1200 New Jersey Avenue, SE East Building, 2nd Floor  
Washington, DC 20590

Dear PHMSA:

In your recent interpretation (Reference No. 14-0060) you stated that 173.199 do not require closure instructions.

*A3. The answer is no. The HMR requires packaging closure instructions for DOT specification and UN standard packagings that comply with the requirements in 49 CFR Part 178 (see § 178.2(c)(1)(ii)(B)). The HMR does not require closure instructions for packagings that comply with § 173.199.*

**How do the requirements in § 173.199(a)(10) for “Clear instructions on filling and closing a packaging used to transport a Category B infectious” differ from the closure requirements found in § 178.2(c)?**

*-§173.199(a)(10) Clear instructions on filling and closing a packaging used to transport a Category B infectious substance must be provided by the packaging manufacturer and subsequent distributors to the consignor or person who prepares the package to enable the package to be correctly prepared for transport. A copy or electronic image of these instructions must be retained by the manufacturer and subsequent distributors for at least one year from the date of issuance, and made available for inspection by a Federal or state government representative upon request. Packagings must be filled and closed in accordance with the information provided by the packaging manufacturer or subsequent distributor.*

*-§178.2(c)(1)(i)(B) With information specifying the type(s) and dimensions of the closures, including gaskets and any other components needed to ensure that the packaging is capable of successfully passing the applicable performance tests. This information must include any procedures to be followed, including closure instructions for inner packagings and receptacles, to effectively assemble and close the packaging for the purpose of preventing leakage in transportation. Closure instructions must provide for a consistent and repeatable means of closure that is sufficient to ensure the packaging is closed in the same manner as it was tested. For packagings sold or represented as being in conformance with the requirements of this subchapter applicable to transportation by aircraft, this information must include relevant guidance to ensure that the packaging, as prepared for transportation, will withstand the pressure differential requirements in §173.27 of this subchapter.*

*-§178.2(c)(1)(ii) Retain copies of each written notification for at least one year from date of issuance; and  
-§178.2(c)(1)(iii) Make copies of all written notifications available for inspection by a representative of the Department.*

Kind Regards,

Jay Johnson, DGSA | Regulatory Compliance Manager  
675 Hartman Road, Suite 100  
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