U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

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

AUG 2 7 2014

Mr. David Creighton
Regulatory and Training Manager
Saf-T-Pak, Inc.
17827-111 Ave
Edmonton, AB T5S 2X3
CANADA

Reference No. 14-0060

Dear Mr. Creighton:

This is in response to your March 26, 2014 e-mail requesting clarification of the packaging requirements for "UN 3373, Biological substance, Category B, 6.2 (infectious substance)" under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask several questions concerning how these requirements would apply if the packaging is composed of components from sources that are different than those of the original tested packaging. We have paraphrased your questions and answered them in the order provided.

Q1. Is it possible to alter, add, remove, or mix packaging components of a Category B packaging from its tested design without performing a new drop test?

A1. The answer is yes. As specified in § 173.199, a Category B packaging must be capable of successfully passing the drop tests prescribed in paragraph (d) of § 178.609 at a drop height of at least 1.2 meters (3.9 feet) but is not required to be tested using this method. Capability may be demonstrated using a number of methods, including actual previous handling and transportation experience, design specification, or, even though not required, performance testing. Category B packagings authorized under exceptions prescribed in § 173.134(b) are also not required to be drop tested. However, depending on the type of exception used, such packagings must meet one or more of the following: the general packaging requirements prescribed in §§ 173.24 and 173.24a, the packaging provisions of § 173.199, and/or the Department of Labor's Occupational Safety and Health Administration bloodborne pathogen requirements prescribed in 29 CFR 1910.1030.

Q2. If a shipper alters the components of a packaging that has met a tested design, is the shipper responsible for ensuring that the altered packaging is capable of passing the drop test prescribed in § 173.199(a)(4)?

A2. The answer is yes. Although performance testing is not required for a packaging meeting the requirements of § 173.199, the responsibility remains in effect under the HMR for the person who authorizes that the packaging is in compliance with that standard to demonstrate it is capable of meeting a 1.2 meter drop test.

Q3. Is the shipper responsible for creating new closure instructions as prescribed in § 173.199(a)(10) for packagings with components that have been added, removed, or mixed?

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.

I hope this satisfies your request.

Sincerely,

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

Edmonson
§ 173.199
Category B Infectious Substances
14-0060

Edmonson, Eileen (PHMSA)

From: David Creighton <DavidCreighton@saftpak.com>
Sent: Wednesday, March 26, 2014 3:13 PM
To: Edmonson, Eileen (PHMSA)
Subject: Letter of Interpretation

Hello Eileen

I wanted to add my appreciation for your attendance and assistance at the ABSA shipping discussion earlier this month. There was an item from the meeting that I wanted to discuss with you. In the packaging section the question was raised about mixing and matching components of Category B packages from different manufacturers, or adding or removing components that are not part of the approved package design as outlined in the closure instructions. As a packaging manufacturer, we have come across a number of shippers who do not understand the importance of following the closure instructions, especially in relation to drop test requirement. As such I was wondering if it is possible to receive a PHMSA letter of interpretation on the following questions.

Is it possible to alter (mix for different manufacturers, add or remove) components of a Category B package from its tested design without performing a new drop test? If the shipper alters the components from the package design, is the shipper responsible to ensure the altered package design is capable of passing the drop test as outlined in 173.199 (a) (4) and is the shipper responsible to create new closure instructions as outlined in 173.199 (a) (10)?

Thank you

David Creighton

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