U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration

1200 New Jersey Ave, S.E.
Washington, D.C. 20590

MAR 2 5 2013

Mr. Ben Hellming
Minigrip
161 Kimball Bridge Road
Alpharetta, GA 30009

Ref No.: 13-0031

Dear Mr. Hellming:

This is a response to your January 25, 2013 email and subsequent telephone conversation with a member of my staff requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-185) with regard to general packaging requirements. Specifically, you request confirmation that a packaging that your company has designed, which will not contain hazardous materials, voluntarily complies with the venting requirements for packaging specified in § 173.24(g)(2).

In your email, you include a description of your packaging and pictures of the packaging configuration. The packaging is considered a combination packaging and consists of a primary leak-proof container to hold specimens, packed in a secondary bag that has been fitted with a pressure release patch, which is further placed in a rigid outer container. The package is marked with orientation arrows. Additionally, the bag has printed language stating "do not cover pressure release patch." You indicate that the primary leak-proof cups as well as the secondary bag have both been tested to withstand a 95 kPa internal pressure test.

Based on the telephone conversation with my staff, these packages are meant to hold specimens (e.g. blood and urine) that do not meet the definition of any hazard class, including Division 6.2, Infectious Substance and are not subject to the HMR. While these materials are not required to be shipped in conformance with the HMR, you intend for your packaging to voluntarily comply with the general packaging requirements in § 173.24(g)(2). It should be noted that the venting requirement in § 173.24(g)(2) is not a standalone requirement. In order for a packaging to fully comply with the venting requirements of the HMR, the packaging must conform to all requirements of § 173.24(g).

The purpose of § 173.24(g) is to allow for the venting of packages to reduce internal pressure, which may develop by the evolution of gas from the contents. For all non-bulk packaging venting is only permitted under the following conditions: (1) except for shipments of cryogenic liquids as specified in § 173.320(c) and of carbon dioxide, solid (dry

ice), transportation by aircraft is not involved; (2) except as otherwise provided in this the HMR, the evolved gases are not poisonous, likely to create a flammable mixture with air or be an asphyxiant under normal conditions of transportation; and (3) the packaging is designed so as to preclude an unintentional release of hazardous materials from the receptacle.

It also be should be noted that if the packaging is intended to contain materials classified as Division 6.2 (infectious substances), the requirements of the applicable packaging section for the specific category of infectious substance (§§ 173.196, 173.197, and 173.199) must also be met. Furthermore, § 173.134 provides exceptions from the HMR for potentially infectious substances such as blood and urine.

I hope this information is helpful. If you have any more questions, please do not hesitate to contact this office.

Sincerely,

Robert Benedict
Chief, Standards Development
Standards and Rulemaking Division

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§173.24

Drakeford, Carolyn (PHMSA)

Packagings
13-0031

From: INFOCNTR (PHMSA)
Sent: Monday, January 28, 2013 1:45 PM
To: Drakeford, Carolyn (PHMSA)
Subject: FW: letter of Interpretation 173.24 G2
Attachments: Minigrip Image Slide Show - 95kPA Bags - 25Jan13.wmv

Hi Carolyn,

We received the following request for a formal letter of interpretation.

Thanks,
Victoria

From: Bennett Hellming [mailto:ben.hellming@minigrip.com]
Sent: Friday, January 25, 2013 4:25 PM
To: INFOCNTR (PHMSA)
Subject: letter of Interpretation 173.24 G2

To U.S. Department of Transportation:

We are launching a new 95 kPa specimen transport bag for air transportation of blood and laboratory samples and want to be sure we understand the regulations with respect to our product and application.

We are a provider of liquid bio-hazard shipping bags used for blood vials and urine cups. Our package is a **secondary package** – see attached picture. The primary container (blood vial and urine cup) is leak proof (and many times 95 kPa rated). The primary container goes into our secondary package (used to tie patient paperwork to sample) and then goes into a rigid outer container. Our shipping bag survives the 95 kPa internal pressure test by use of a pressure release patch that allows the bag to vent when the bag expands and contracts during pressure changes during air transportation.

In the worst case scenario that the primary leak proof container leaks, out-gassing from the contents would be non-flammable, non-poisonous and not an asphyxiate. The pressure release patch also contains an antimicrobial agent. Any liquid leaking from the primary leak proof container would be contained in our absorbent system designed to absorb more liquid then would be transported in the bag.

To prohibit blockage of pressure release patch during shipping, the outer rigid container has 'this side up arrows' to ensure that the pressure release patch is oriented correctly and the bag has printed language stating 'do not cover pressure release patch' during shipping.

Our bag passed a 95 kPa internal pressure test conducted by Southeast Testing & Engineering, Lawrenceville, GA, a DOT certified 3rd party certification lab.

We are requesting a DOT Letter of Interpretation that states that Minigrip 95 kPa bag is compliant with 49 CFR 173.24 G2 for our product.

Thank you,

Ben Hellming
General Manager

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