



U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

JAN 12 1998

Mr. Jay Johnson
Partners in Compliance, Inc.
100 Dominion Drive Suite 102
Morrisville, NC 27560

Dear Mr. Johnson:

This is in response to your letter of July 28, 1997, and August 11, 1997 telephone conversation with Ms. Eileen Edmonson of my staff asking if multiple primary packagings of a Division 6.2 material must be separated by a material that is both cushioning and capable of absorbing their entire contents.

The answer is no. Section 173.196(a)(1)(iii) requires that multiple primary packagings of a Division 6.2 material be wrapped individually by a material, absorbent or non-absorbent, sufficient to ensure contact between the receptacles is prevented and the packaging complies with the performance tests in § 178.609. However, this section does require that material sufficient to absorb the entire liquid contents of the inner packagings be placed between the primary and secondary packagings.

You stated the current design for your packaging has each primary receptacle surrounded with an absorbent foam that prevents contact between the receptacles. You questioned whether separating these packagings with fiberboard or plastic dividers and placing an absorbent strip at the bottom of the secondary packaging would fulfill the requirements in § 173.196. Provided the packaging meets the performance tests required in § 178.609, this configuration would be acceptable. However, please be aware that these performance tests require the packaging to be dropped on its bottom, top, sides, and corner, cold-conditioned and immersed in water with no leakage from the primary receptacle. Placing the absorbent material only at the bottom of the packaging may prove insufficient to meet these criteria.

Thank you for inquiry. If we can assist you further, please let us know.

Sincerely,

Hattie L. Mitchell, Chief
Exemptions and Regulations Terminations
Office of Hazardous Materials Standards



U.S. Department
of Transportation

Research and
Special Programs
Administration

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

APR 9 1993

Mr. Barry Sibley
Environmental Packaging Systems Ltd.
1 Research Drive
Dartmouth, N.S.
Canada B2Y 4M9

Dear Mr. Sibley:

This is in response to your February 18 telefax to Mr. James Jones, and additional information dated March 3, 1993, concerning the suitability of the packaging you described for the shipment of infectious substances and diagnostic specimens. The packaging you described consists of a plastic inner packaging and a fiberboard outer packaging.

New packaging requirements for infectious substances are not mandatory within the United States until January 1, 1994. From the information you presented, your packaging does not meet the requirements for packagings for infectious substances specified in 49 CFR 173.196 and 178.609 and the Seventh Revised Edition of the United Nations Recommendations on the Transport of Dangerous Goods for the following reasons:

First, paragraph 173.196(a)(ii) (and UN 6.13.(a)(iii)) requires that absorbent material be placed between the primary and secondary receptacles, enough to absorb the entire liquid contents of all primary receptacles. The absorbency test result noted in your test report from Nova Scotia Research Foundation Corporation shows an absorbency of 50 ml. One of the packages tested contained 14 "Vacutainers" of 5 ml capacity each. The 70 ml liquid contents is more than the absorbent material is capable of absorbing.

Second, the testing requirements of 49 CFR 178.609 (and UN 6.14.3 and 6.14.4) for a plastic inner packaging in a fiberboard outer packaging include two drop tests. For the first drop test, the packaging (assembled as for shipment) must be fully immersed for at least 5 minutes and then conditioned at 23°C and 50+/-2 percent relative humidity. There is no indication in the test report that the immersion was conducted. For the second drop, the packaging must be conditioned in an atmosphere of -18°C or less for at least 24 hours. There is no indication in the test report that this cold conditioning was performed.

A packaging used to transport infectious substances after January 1, 1994 must comply with all other applicable requirements of 49 CFR 173.196 and Part 178. There is an exception from these requirements in paragraph 173.196(h) for certain diagnostic specimens.

As stated above, the requirements for infectious substances contained in §§ 173.196 and 178.609 are not mandatory until January 1, 1994. Voluntary compliance with the new requirements is currently authorized. Prior to January 1, 1994, packagings for infectious substances which are "etiologic agents," as defined in 49 CFR 173.386 (of the of the regulations in effect on September 30, 1990) must meet the requirements of 49 CFR 173.387 (of the same date). From the information presented in your letter, it appears that your packaging meets those requirements.

You also asked whether your company would qualify for an "M" number to place on the outer packaging. If your packaging will be certified and marked as a UN packaging, part of the marking is an indication of the country authorizing allocation of the mark. The letters "USA" may only be marked on a packaging manufactured and marked in the United States. The "M" numbers issued by our Office of Hazardous Materials Exemptions and Approvals are only issued for packagings manufactured and marked in the United States.

Sincerely,



Edward T. Mazzullo
Director
Office of Hazardous
Materials Standards



100 Dominion Drive, Suite 102, Morrisville, NC 27560
Phone: 919-468-0333 Fax: 919-468-0311

Edmanson
File: 173.196(a)(1)(iii)
Sc: 300,

July 28, 1997

Edward T. Mazzullo
Director, Office of Hazardous Materials Standards
U.S. Department of Transportation
Research & Special Programs Administration
DHM-10, Room 8100
400 Seventh Street, SW
Washington, DC 20590-0001

SUBJECT: Request for Interpretation

49 CFR, Section 173.196(a)(1)(iii) *an absorbent material must be placed between the primary receptacle and the secondary packaging. If multiple-primary receptacles are placed in a single secondary packaging they must be wrapped individually to ensure that contact between them is prevented. The absorbent material, such as cotton wool, must be sufficient to absorb the entire contents of all primary receptacles.*

Partners In Compliance, Inc. is committed to compliance with the regulations governing the transportation of hazardous materials. We are currently developing a packaging system for the transport of infectious substances. Each individual primary receptacle will be surrounded in an absorbent foam rack that protects and prevents contact.

Based on a conversation with Helen Engrum of the DOT/RSPA and our understanding of the regulations, multiple primary receptacles placed in a single secondary packaging must be individually surrounded by material that is **both** absorbent and cushioning to prevent breakage or leakage and control movement. We feel that the use of corrugate or plastic dividers to separate primary receptacles with an absorbent strip at the bottom of the secondary packaging does not meet the requirements for individual wrapping stated in the regulations. Please respond with your concurrence/non-concurrence.

Sincerely,


Mr. Jay Johnson
Partners In Compliance, Inc.

TELEPHONIC CONVERSATION RECORD

<i>Specialist Receiving Call:</i> Eileen Edmonson	ROUTING	
<i>Date of Call:</i> 8/11/97	SYMBOL	INT
<i>Person(s) Contacted:</i> Mr. Jay Johnson		
<i>Their Organization:</i> Partners in Compliance, Inc		
<i>Date of Incoming Letter:</i> 7/28/97		
<i>Specific Subject (including section #'s and key words):</i> Mr. Johnson is designing an infectious substance packaging. He wanted to know if § 173.196(a)(1)(iii) was instructing him to wrap each primary packaging with an absorbent material that would simultaneously separate each primary packaging to prevent damage and absorb its entire contents.		
<p><i>Summary:</i> On August 7, 1997, I faxed Mr. Johnson a related letter (Barry Sibley, Environmental Packaging Systems Ltd., 4/9/93) we did on absorbent material for infectious substance packagings as an example of the type of information we needed about his packaging to provide him with a response. Mr. Johnson called me on August 11 and stated he has only begun to design his packaging and, as a result, has no drawing or test results to send me. I told him that the dividers between the primary receptacles did not have to meet the absorbent criteria in § 173.609(a)(1)(iii), but that they could if he wished to design it that way. I told him the dividers must prevent the inner packagings from being damaged. I told him however he designed the packaging, it would have to pass the performance tests located in § 178.609. He requested this response in writing.</p>		
<p><i>Comments for Further Action:</i> I drafted the response on August 11, 1997, and forwarded it for review.</p>		
<p><i>Specialist Signature:</i> </p>		
<p><i>Date:</i> 8/11/97</p>		

OFFICE OF HAZARDOUS MATERIALS STANDARDS
CORRESPONDENCE TRACKING SHEET

DATE	COMPANY	SPECIALIST
<u>07/28/97</u>	<u>PARTNERS IN COMPLIANCE INC</u> /FROM: JAY JOHNSON	<u>EDMONSON</u>

RECEIVED:
ASSIGNED: 08/07/97
DUE: 09/04/97
SUBJECT 173.196

SIGNED:
COMMENTS:

SUMMARY:

COMPLEXITY: H M L

SIGNATURE:
DRAFTS:

8/7/97 Faxed question for
more info to Mr Johnson

8/11/97 telephone conversation w/ Johnson