



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

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

JUL 3 2009

Ms. Julie Park
Sr. Safety & Environmental Professional
Roche Molecular Systems, Inc.
1080 U.S. Highway 202 South
Branchburg, NJ 08876

Ref. No. 09-0094

Dear Ms. Park:

This responds to your April 22, 2009, request for clarification of the requirements for transporting small quantities of hazardous materials under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you request clarification concerning whether packages that pass the tests specified in the International Safe Transit Association (ISTA) Procedure 2A conform to the testing requirements specified in § 173.4(a)(6).

According to your letter, your company manufactures and ships a variety of medical chemical testing kits that are tested in accordance with ISTA Procedure 2A. The ISTA Procedure 2A test protocols include vibration, free fall drop, and compressive load tests. The chemical kits are overpacked into double wall corrugated cardboard boxes for shipment.

Section 173.4 sets forth the conditions under which certain hazardous materials may be transported utilizing the exception for small quantities. Section 173.4(a)(6) requires each completed package, as demonstrated by prototype testing, to be capable of sustaining each of the drop tests in § 173.4(a)(6)(i) (A) through (E) and the compression test in § 173.4(a)(6)(ii). It is the opinion of this Office that the ISTA Procedure 2A testing protocols demonstrate that a package is capable of sustaining the drop tests and compression test if the drop height is adjusted to the 1.8m (5.9 feet) required by §173.4(a)(6)(i). Thus, packages that pass the ISTA 2A tests may be transported in accordance with the small quantity exception in § 173.4 provided all other listed conditions are met.

I hope this answers your inquiry.

Sincerely,

Charles E. Betts
Chief, Standards Development
Office of Hazardous Materials Standards

April 22, 2009

U.S. DOT PHMSA Office of Hazardous Materials Standards
Attn: PHH-10
East Building
1200 New Jersey Avenue, SE.
Washington, DC 20590-0001

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§173.4
Small Quantity Exceptions
09-0094



Subject: REQUEST FOR INTERPRETATION

Dear Sir or Madam

This letter requests your formal interpretation as to whether ISTA Procedure 2A package testing can be used to meet the requirement for package testing specified in 49 CFR 173.4(a)(6).

Roche Molecular Systems, Inc. manufactures and ships a variety (approximately 100) different medical testing kits all of which contain several small vials of non hazardous materials and one to three vials or cassettes containing 7-14 mls (maximum of 21 mls total) of either isopropanol, sodium hydroxide or sulfuric acid, depending on the specific kit. Kits containing the vials of hazardous material are classified as UN3316 Chemical Kits.

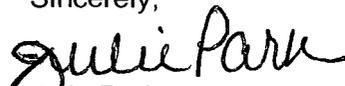
When shipped within the United States, we offer the chemical kits for transportation in accordance with the Small Quantity Exception in 49 CFR 173.4. Paragraph (a)(6) of this exception requires that the completed package, as demonstrated by prototype testing, be capable of sustaining, drop and compressive load tests as specified in that section. We believe that ISTA Procedure 2A fulfills that requirement.

ISTA Procedure 2A tests are conducted on every chemical kit manufactured by Roche Molecular. Every kit undergoes this testing before it is offered for transportation and any time a change is made either to the components of the kit, the number of vials in the kit or the package design, the test is repeated. No kit is shipped until the kits pass the test. ISTA Procedure 2A test protocols, which are attached for your review, include a vibration, free fall drop test and compressive load test. Kits which pass these tests are then overpacked into double wall corrugated cardboard boxes for shipment.

We believe the ISTA Procedure 2A testing coupled with the overpacking of the test kits prior to shipment meets the requirement to ensure packages can pass the tests included in 49 CFR 173.4(a)(6). It is our belief therefore that additional testing of our chemical kits is not necessary.

We look forward to your response.

Sincerely,


Julie Park

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