



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

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

APR 16 2009

Mr. Stephen C. Powell
Lab Director
Container-Quinn Testing Laboratories, Inc.
170 Shepard Avenue
Wheeling, IL 60090

Ref. No.: 09-0062

Dear Mr. Powell:

This in response to your March 18, 2009 letter regarding the drop test requirements specified in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) for a combination packaging intended for the transportation of regulated medical waste (RMW). The combination packaging consists of a UN 4H2 plastic container with an inner 3-mil polyethylene bag. You ask for clarification of the failure criteria in § 178.603(f)(4) and specifically if it is acceptable for the inner packaging to develop punctures and ¼" to ½" holes upon impact if there is no leakage of the filling substance.

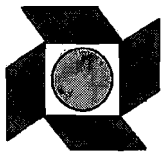
The answer is no. As you correctly noted in your letter, §178.603(f)(4) states a combination packaging passes the drop test if there is no damage to the outer packaging likely to adversely affect the packaging during transport, and there is no leaking of substance from the inner packaging. It is the opinion of this Office that an inner packaging of a combination packaging that develops punctures and ¼" to ½" holes after the drop test does not meet the requirements in §178.603(f)(4) and, therefore, does not pass the drop test. The inner packaging's inability to resist punctures and holes during testing can be indicative of its integrity under transportation conditions.

Please note that, in accordance with § 173.197(e)(1), plastic film bags used as inner packagings for solid RMW must be marked and certified by the manufacturer as having passed the tests for tear resistance in ASTM D 1922, "Standard for Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method," and for impact resistance in ASTM D 1709, "Standard for Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method." The film bag must meet an impact resistance of 165 grams and a tear resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag.

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

Sincerely,

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards



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Andrews
§ 178.603(f)(4)
Testing
09-0062

18 March 2009

Mr. Edward T. Mazzullo
Director, Office of Hazardous Materials Standards
US DOT / PHMSA (PHH-10)
1200 New Jersey Avenue, SE
East Building, 2nd Floor (PH)
Washington, DC 20590

Mr. Mazzullo;

Re. SA-9009004, ID Code +AX
RMW testing of a combination package

After discussion with Anthony Lima, USDOT and at his suggestion, I am requesting an interpretation and clarification of pass/fail criteria in the testing of a Regulated Medical Waste (RMW) container. With Mr Lima as an observer, I conducted testing of a 4H2 plastic container, for use with RMW.

Description is as follows: UN 4H2 17-gallon oblong openhead plastic container with sliding transport cover containing one (1) 3-mil polyethylene red bag. Bag is secured by twisting the top and then tightly knotting it. Container is secured with cable ties. Test weight is 15.9kg. Drop height was 1.2M

During the testing, the redbag is removed and inspected after each individual drop. There were some holes (1/4" to 1/2") and punctures found in the bag after the drops but bag integrity was intact (bag was lifted completely out of the container and inspected). As per 49CFR, 178.603(f)(4), "For a composite or combination packaging, there is no damage to the outer packaging likely to adversely affect safety during transport, and there is no leakage of the filling substance from the inner packaging;" Under this section, as the bag was able to contain all product within and the outer container showed no damage, I considered this to be a pass. Mr Lima raised a concern with the holes in the bag and whether this compromised the test. This is the area that is under question, whether these holes and punctures are acceptable and, as the bag does contain all the inner product, if this should be considered a pass in accordance with the Criteria for Passing the Test as listed above.

Thank you for your assistance in this matter.

Sincerely

Stephen C. Powell
Lab Director
Container-Quinn Testing Laboratories, Inc.

Cc: Mr. Anthony Lima, US DOT/PHMSA

Don Moore