



U.S. Department
of Transportation

1200 New Jersey Avenue SE
Washington, DC 20590

**Pipeline and Hazardous
Materials Safety
Administration**

FEB 01 2015

Mr. Jay Johnson
Regulatory Compliance Manager
Inmark Packaging, Inc.
675 Hartman Road, Suite 100
Austell, GA 30168

Reference No. 15-0154

Dear Mr. Johnson:

This is in response to your July 27, 2015 email and subsequent telephone conversation with a member of my staff concerning packaging requirements for Category B infectious substances contained in the Hazardous Materials Regulations (HMR: 49 CFR Parts 171-180). Specifically, you ask whether a Category B packaging is required to meet the conditions specified in §§ 178.609(e) and 178.609(f) for water spray and cold conditioning, respectively, before subjecting the packaging to the drop test in § 178.609(d).

As specified in § 173.199(a)(4), a Category B packaging must be capable of successfully passing the drop test in § 178.609(d) at a drop height of at least 1.2 meters (3.9 feet) but is not required to be tested using this method. Further, as stated in the preamble to a final rule issued under Docket No. PHMSA-2004-16895 (71 FR 32244), a § 173.199 packaging need not be capable of passing a puncture or other performance tests. Therefore, the HMR do not require that a Category B infectious substance packaging be subjected to the conditions prescribed in §§ 178.609(e) and 178.609(f) in preparation for the drop test prescribed in § 178.609(d).

I hope this information is helpful. Please contact this office if we can be of further assistance.

Sincerely,

Duane A. Pfund
International Standards Coordinator
Standards and Rulemaking Division

Suchak
§173.199
Category B infectious
Substances

15-0154

Dodd, Alice (PHMSA)

From: Foster, Glenn (PHMSA)
Sent: Tuesday, July 28, 2015 8:33 AM
To: Dodd, Alice (PHMSA); Goodall, Shante CTR (PHMSA)
Subject: Question about Category B Infectious Packaging

Alice and Shante,

Please check in the email below as a request for letter of interpretation.

Thanks,
Glenn

From: Foster, Glenn (PHMSA)
Sent: Tuesday, July 28, 2015 7:40 AM
To: 'Jay Johnson'
Cc: Betts, Charles (PHMSA); Supko, Ben (PHMSA)
Subject: RE: Question about Category B Infectious Packaging

Hello Jay,

Your inquiry below will be logged in as a request for Interpretation and responded accordingly.

Thanks,
Glenn

From: Jay Johnson [<mailto:jayj@inmarkinc.com>]
Sent: Monday, July 27, 2015 4:42 PM
To: Foster, Glenn (PHMSA)
Cc: Betts, Charles (PHMSA); Supko, Ben (PHMSA)
Subject: RE: Question about Category B Infectious Packaging

Hello Glenn,

While you are working on this, I have another question on 173.199 package performance capability.

Does Category B packaging that is being dropped according to 178.609(d) subject to the cold conditioning and water spray conditioning as defined in 178.609(b) and 178.609(c)?

Kind Regards,

Jay Johnson, DGSA | Regulatory Compliance Manager





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From: Glenn.Foster@dot.gov [<mailto:Glenn.Foster@dot.gov>]
Sent: Wednesday, June 24, 2015 11:48 AM
To: Jay Johnson
Cc: charles.betts@dot.gov; Ben.Supko@dot.gov
Subject: RE: Question about Category B Infectious Packaging

Jay,

In the meantime, here is a PDF of the NPRM under HM-218 "Miscellaneous Amendments" where the revision was proposed. I will have the final rule forwarded to you when it is published, as well.

Thanks,
Glenn

From: Foster, Glenn (PHMSA)
Sent: Wednesday, June 24, 2015 10:56 AM
To: 'Jay Johnson '
Cc: Betts, Charles (PHMSA); Supko, Ben (PHMSA)
Subject: FW: Question about Category B Infectious Packaging

Hello Jay,

Thanks for the follow-up. Our plan is to include this revision in an upcoming rulemaking. We will send you a notification/link to the rule when it is published.

Thanks,
Glenn

From: Jay Johnson [<mailto:jayj@inmarkinc.com>]
Sent: Wednesday, June 24, 2015 6:21 AM
To: Betts, Charles (PHMSA); Supko, Ben (PHMSA)
Subject: FW: Question about Category B Infectious Packaging

Hello Ben and Charles,

I am curious how things are progressing with two questions I asked Del Billings back in 2011.
Has there been any changes regarding this topic?

Thanks
Jay Johnson
Inmark

From: Jay Johnson
Sent: Wednesday, August 03, 2011 12:21 PM
To: 'delmer.billings@dot.gov'
Subject: Question about Category B Infectious Packaging

Hello Del,

I have two questions about the package testing for Biological Substance, Category B and I hope you can help me with this. Currently §§173.199(a)(4) states that packages must be capable of successfully passing the drop tests in §§178.609(d) and (h) of this subchapter.

173.199(a)(4) The completed package must be designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. Package effectiveness must not be substantially reduced for minimum and maximum temperatures, changes in humidity and pressure, and shocks, loadings and vibrations normally encountered during transportation. The packaging must be capable of successfully passing the drop tests in §§178.609(d) and (h) of this subchapter at a drop height of at least 1.2 meters (3.9 feet). Following the drop tests, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).

PHMSA clarified this requirements in an interpretation (PHMSA Interpretation #07-0018) that:

A packaging used to transport a Category B infectious substance must be capable of passing the drop test prescribed in § 178.609(d). The packaging is not required to also be capable of passing the steel rod impact test in § 178.609(h). We will correct this error in a future rulemaking.

Question 1: Do you know when the rulemaking to correct this error is going to occur?

Question 2: When conduction the drop testing in §§178.609(d) to establish if the packages are capable of passing the drop test, do the samples have to be conditioned as described in the requirements of §§178.609(e), §§178.609(f), and §§178.609(g)?

§§178.609(e) The samples must be subjected to a water spray to simulate exposure to rainfall of approximately 50 mm (2 inches) per hour for at least one hour. They must then be subjected to the test described in paragraph (d) of this section.

§§178.609(f) The sample must be conditioned in an atmosphere of -18 [deg]C (0 [deg]F) or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the test described in paragraph (d) of this section. Where the sample contains dry ice, the conditioning period may be reduced to 4 hours.

§§178.609(g) Where packaging is intended to contain dry ice, a test additional to that specified in paragraph (d) or (e) or (f) of this section must be carried out. One sample must be stored so that all the dry ice dissipates and then be subjected to the test described in paragraph (d) of this section.

Thanks for your clarification on the matter.

Best regards,

Jay Johnson DGSA, Regulatory Compliance Manager | Inmark | 675 Hartman Road, Suite 100, Austell, GA 30168 |
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www.inmarkinc.com

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