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

1200 New Jersey Avenue, SE
Washington, DC 20590

May 26, 2021

Bill Greene
Burlington Products, Inc.
70 East Sunrise Highway
Suite 500
Valley Stream, NY 11581

Reference No. 21-0019

Dear Mr. Greene:

This letter is in response to your March 1, 2021, email, and subsequent phone conversation and email, requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the packaging requirements for infectious substances.

We have paraphrased and answered your questions as follows:

Q1. You ask whether a plastic bag used as the primary receptacle or secondary packaging for the packaging of a Category A or B infectious substance is required to have a certified lab test the plastic bag to determine that it meets the capability performance standard of not leaking at an internal pressure of 95 kPa (0.95 bar, 14 psi).

A1. The answer is no. Laboratory certification is not a specific condition of meeting the capability standard associated with the internal pressure requirement for primary or secondary packaging.

Q2. You ask what a bag manufacturer must do to satisfy the "must be capable of" requirement concerning a plastic bag's ability to meet a pressure requirement.

A2. The internal pressure requirement for a primary receptacle or secondary packaging used for Category A or Category B infectious substances is a capability performance standard. The HMR does not specify the manner in which this performance standard must be met. The bag manufacturer should use its expertise and knowledge regarding the design and materials used in the production of the packaging when making this determination in the absence of choosing to perform tests.

Q3. You ask what temperature must the plastic bag be conditioned to prior to pressure testing the primary or secondary plastic bag packaging used to ship infectious substances (Category A or B) by ground or air.

A3. The HMR does not specify temperature conditioning requirements associated with the performance of an internal pressure test for these packagings. However, with respect to Category A infectious substance packaging standards, the primary receptacle or secondary packaging must be capable of withstanding, without leakage, temperatures in the range of −40 °C to + 55 °C (−40 °F to + 131 °F) (see § 173.196(a)(7)). Furthermore, Category A infectious substance packaging must meet the test standards of § 178.609 for the completed package and is subject to conditioning requirements (see paragraphs (b) and (f)) for performance of certain tests. For Category B infectious substance packages, there is a standard that the effectiveness of the completed package must not be substantially reduced for minimum and maximum temperatures, normally encountered during transportation, as well as an integrity requirement associated with refrigerated or frozen specimens.

Q4. You ask whether a pressure-sustaining bag used as a component in a combination packaging can be altered per § 178.601(g)(4) without further testing.

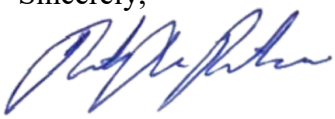
A4. The selective testing and packaging variations of § 178.601(g), including paragraph (g)(4), are not applicable. Infectious substance packagings are subject to test requirements in § 178.609, which outlines authorized variations in the primary receptacle of a tested package in § 178.609(i).

Q5. What is the distinction in the regulations between a “leak-tight bag” and a “leakproof bag?”

A5. For the purposes of the HMR, there is a no distinction. The term “leakproof” is commonly used in the HMR in association with a test (i.e., leakproofness test) used to detect leaks in a packaging to ensure a package is free from leakage. “Leaktight” is another term that is used to describe a packaging, including its closures or valves, which is free from leakage.

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

Sincerely,



Dirk Der Kinderen
Chief, Standards Development Branch
Standards and Rulemaking Division

Ciccarone

21-0019

From: INFOCNTR (PHMSA)
To: Dodd, Alice (PHMSA); Hazmat Interps
Subject: FW: Request for Letter of Interpretation
Date: Monday, March 1, 2021 12:02:17 PM

Hi Alice,

Please see below for a letter of interpretation request. When speaking with Breanna this morning, he stated that he would like a three week turnaround on the letter. Please contact our office with any questions.

Thank you,

Sarah (HMIC)

From: service@burlingtonproducts.com [mailto:service@burlingtonproducts.com]
Sent: Monday, March 1, 2021 10:23 AM
To: INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov>
Subject: RE: Request for Letter of Interpretation

Jonathon -
Thank you for your prompt acknowledgment of receipt.

The information you requested:
William Greene
Burlington Products
70 East Sunrise Highway, Suite 500
Valley Stream, NY 11581
718-797-4940

Bill Greene

BURLINGTON PRODUCTS, INC.

UN Standard & Custom Containers for Hazardous Materials
718.797.4940
service@burlingtonproducts.com

From: "INFOCNTR (PHMSA)" <INFOCNTR.INFOCNTR@dot.gov>
Sent: 3/1/21 10:14 AM
To: "service@burlingtonproducts.com" <service@burlingtonproducts.com>
Subject: RE: Request for Letter of Interpretation

Dear Bill,

We have received your request for a written letter of interpretation regarding the hazardous materials regulations (49 CFR Parts 171-180). The hazardous materials regulations are available at the following URL:

https://www.phmsa.dot.gov/phmsa-regulations

However, before we can submit your request for processing, please respond to this email with:

- Full Name
- Physical Mailing Address
- Telephone Number

Sincerely,

Jonathon, Hazardous Materials Specialist

An e-mail response from this office is considered informal guidance. Formal guidance may be requested in accordance with 49 CFR 105.20. https://www.phmsa.dot.gov/standards-rulemaking/hazmat/hazardous-materials-information-center

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From: service@burlingtonproducts.com [mailto:service@burlingtonproducts.com]
Sent: Monday, March 1, 2021 10:08 AM
To: INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov>
Subject: Request for Letter of Interpretation

I am writing to request a Letter of Interpretation concerning the questions addressed below.

At issue is a plastic bag that has been pressure tested to 95kPa so that it can be used as the primary or secondary
packaging to ship diagnostic specimens, infectious substances and other biohazards (Class A and Class B) via ground or air.

1 Does the insertion of an absorbent pad into the bag thereby disqualify the bag's pressure certification?

2 Must the bag be tested with the absorbent pad inserted into the bag in order to be properly qualified?

3 If the second question is answered affirmatively, must the bag be tested with each different type or different size
of absorbent pad or are there permitted substitutions or exceptions?

4 If the third question is answered affirmatively, what are the permitted substitutions?

5 If a plastic bag that has been pressure tested to 95kPa to qualify as a primary or secondary packaging, does the
rule expressed in §178.601(g)(4)(i) apply, assuming all other criteria in (4) Variation 4 are met?

There is some urgency to these issues and a reply at your earliest convenience would be greatly appreciated.

Thank you very much for your help with this matter.

William Greene
Burlington Products

Bill Greene

BURLINGTON PRODUCTS, INC.

UN Standard & Custom Containers for Hazardous Materials

718.797.4940

service@burlingtonproducts.com