



U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

SEP 22 1998

Mr. Eric Cook
Saf-T-Pak, Inc.
101, 17872-106 Avenue
Edmonton, Alberta T5S 1V4
CANADA

Ref. No. 98-0131

Dear Mr. Cook:

This is in response to your letter dated June 2, 1998, regarding the marking requirements for infectious substance packagings manufactured in the United States. Your questions have been paraphrased and answered as follows.

- Q1. Is it correct that a UN specification mark is not required on packaging manufactured or used in the United States for infectious substances?
- A1. Yes. Infectious substance packagings manufactured in the United States are not required to have package specification markings under the Hazardous Materials Regulations (HMR; 49 CFR Part 171-180). As you state in your letter, § 178.609(i) excepts packagings that meet the test requirements in that section from the marking requirements of § 178.503 and all other requirements of Subpart N of Part 178, except for § 178.608 (the vibration standard).

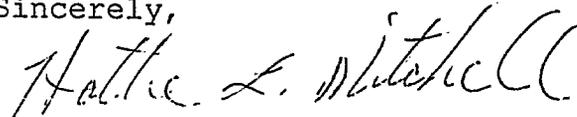
Infectious substance packages transported in the United States by aircraft under § 171.11, or by vessel under 171.12, must be marked with the appropriate UN specification mark. International markings for such packagings, including the markings required under the International Civil Aviation Organizations Technical Instructions for the Transport of Dangerous Goods by Air (ICAO Technical Instructions) and the International Maritime Dangerous Goods Code (IMDG Code), are acceptable to the DOT provided test records show that the test requirements of § 178.609 have been met.

- Q2. If a hazardous materials packaging manufacturer in the United States were to put a UN specification mark on an infectious substance packaging manufactured in the United States, what would this marking designate?

A2. If the mark is as prescribed in the ICAO Technical Instructions or the IMDG Code, the mark designates that the packaging conforms to the UN specification packaging criteria contained in those regulations. Also, enclosed is a recently published advance notice of proposed rulemaking concerning infectious substance requirements.

I hope this satisfies your request.

Sincerely,

A handwritten signature in cursive script that reads "Hattie L. Mitchell". The signature is written in dark ink and is positioned below the word "Sincerely,".

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

Enclosure



June 2, 1998

Ed Mazzullo
US Department of Transportation
Research and Special Programs Administration
Office of Hazardous Materials Standards
400 Seventh Street, S.W.,
Washington, D.C. 20590

mack
File 173.196

Dear Mr. Mazzullo:

Saf-T-Pak, Inc. manufactures UN Specification packaging for transporting Class 6.2 dangerous goods. Currently we are preparing to set up a manufacturing facility in the US and plan to have a US facility test our packaging. I wish to inquire about US requirements for specification markings on packaging for Class 6.2 dangerous goods manufactured and used in the US. My question is in two parts:

1. I am aware of UN and ICAO requirements for specification marking however, **is it correct that a UN specification mark is not required on packaging manufactured and or used in the US for Class 6.2 Dangerous Goods?**

49 CFR 173.196 outlines the components of authorized packagings and indicates that each package must be capable of passing the tests specified in 178.609. 178.609(i) stipulates that packagings subject to this section are not subject to the specification marking requirements of 178.503. As long as a package met all the requirements in 173.196 and was capable of passing the tests in 178.609, would it require the UN specification mark in order to transport infectious substances legally in the US?

2. **If a US manufacturer were to put a UN specification mark on such packaging what would it designate?**

178.3(b) outlines two options for marking of UN standard packagings: one in which the UN standard is set forth in the HMR and the other in which a UN standard is not set forth. Is the UN standard set forth in 178.609 or would a manufacturer be required to establish that the packaging conforms to the applicable ICAO standards? In other words, does the UN specification mark, on packaging for infectious substances manufactured in the US, indicate conformance to 178.609 or conformance to the ICAO standards set out in Packing Instruction 602 and Part 7 Chapter 6 of the ICAO Technical Instructions?

Thank you for taking the time to respond at your earliest convenience so that we may plan our production strategy. Please call me at 1-800-814-7484 if any further clarification is needed.

Sincerely,

Eric Cook
Biological Technical Specialist
Saf-T-Pak, Inc.

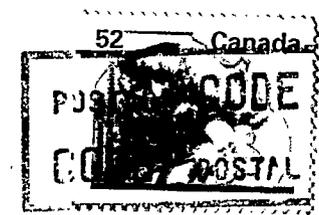


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