



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

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

NOV - 9 2000

Mr. Christopher Hahn
Vice-President, Sales
Hospitec
285 Granada Road
West Palm Beach, FL 33401

Reference No. 00-0296

Dear Mr. Hahn:

This is in response to your letters and conversations with members of my staff concerning the requirements for a regulated medical waste packaging under § 173.197 of the Hazardous Materials Regulations (49 CFR 171-180). Specifically, you asked if a plastic sharps container that is puncture-resistant, leakproof, and has passed requirements in 49 CFR Part 178 at the Packing Group II performance level is required to have a polyethylene liner (red bag). You state that the liner was shredded during each test.

If the use a plastic liner is not necessary to that packaging's performance, such as to satisfy the moisture or leak resistance criteria, there is no requirement under § 173.197 to use a liner.

I hope this satisfies your request.

Sincerely,

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



00-0296

173.197

Hospitec

Edmonson
- 173.134
Regulated Medical Waste

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October 13, 2000

Mr. Edward Mazullo
Director of Hazardous Materials Standard
U.S. Department of Transportation
Research and Special Programs Administration
400 Seventh St., S.W.
DHM-10
Washington, DC 20590-0001

Dear Mr. Mazullo:

I would appreciate some clarification in writing regarding the testing protocol used for the testing of Group II Packaging of Regulated Medical Waste. Is it required that a polyethylene plastic liner (red bag) be placed inside a puncture-resistant, leak-proof plastic sharps container that has passed the Packaging Group II Performance Standards?

I would like to add, that when the testing of our containers was completed by Ten-E Packaging Services, it was reported to us that the plastic liners served no purpose, since the inside liner would always fail, due to the fact, that it always shredded from the sharps material inside. I was also informed by two D.O.T. Enforcement Specialists that the inner liner was not written into the protocol, and was not necessary. Unfortunately, I found this out after the testing was completed.

Please send response to the following address: 285 Granada Road, W. Palm Beach, FL 33401.
Thank you for your help.

Sincerely,



Christopher Hahn
Vice-President of Sales

Innovations in Healthcare