



U.S. Department
of Transportation

**Research and
Special Programs
Administration**

400 Seventh Street, 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 of 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

Edmonson
173,134
Regulated Medical Waste
Beyond Trails

Hospitec Inc.

203 - 502 Bow Valley Trail
Canmore Alberta
Canada T1W 1N9
Tel: 403-609-4330
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Toll Free: 1-800-337-2885
Email: office@hospitecinc.com

FAX COVER

Attention: EDWARD MAZZULLO 00-0296

Company: D.O.T.

Fax: 202-366-3012

Pages (Including Cover): 2

Date: 10/13/00

From: CHRIS HAHN

Reference: QUESTION REGARDING REQUESTED MEDICAL WASTE

THIS FAX CONTAINS INFORMATION THAT IS PRIVILEGED AND CONFIDENTIAL. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR OR THE INFORMATION IS UNCLEAR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE.

DEAR MR. MAZZULLO,

THIS IS MY SECOND TIME RESUBMITTING THE ATTACHED QUESTION. I ORIGINALLY SUBMITTED THIS QUESTION TO KILLEN EDMONSON ON JULY 26, 2000 AND HAVE NOT RECEIVED A RESPONSE BACK. WOULD YOU BE KIND ENOUGH TO GIVE ME A RESPONSE AT YOUR EARLIEST CONVENIENCE. IT IS IMPORTANT THAT I HAVE THIS INFORMATION AS SOON AS POSSIBLE, SO I CAN PROVIDE SOMETHING IN WRITING TO MY CUSTOMERS THAT ARE REQUESTING IT. D.O.T. HAS ALREADY VERBALLY TOLD ME THAT THE BAG IS NOT NECESSARY, BUT I NEED SOMETHING IN WRITING TO SATISFY MY CUSTOMERS. THANK YOU.
BEST REGARDS,
CHRIS


Hospitec

Edmonson
-8 173.134
Regulated Medical Waste

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October 13, 2000

Mr. Edward Mazzullo
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. Mazzullo:

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