



U.S. Department  
of Transportation

**Research and  
Special Programs  
Administration**

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

FEB 25 1998

Ms. Susan Morrissey  
Environmental Services Consultant  
Pall Corporation  
25 Harbor Park Drive  
Port Washington, NY 11050

Dear Ms. Morrissey:

This is in response to your letter of May 5, 1997, requesting clarification of requirements for transporting used medical devices and human donor blood under the Hazardous Material Regulations (HMR; 49 CFR Parts 171-180). You stated in your letter and in a subsequent telephone conversation, on September 17, 1997, with Mr. Charles Betts of my staff that neither the medical devices or the human donor blood contained known infectious agents.

The HMR define an "infectious substance" in § 173.134 (a)(1) as a viable microorganism, or its toxin, which causes or may cause disease in humans or animals. This includes agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services and any other agent that causes or may cause severe, disabling, or fatal disease. Biological products (i.e., human donor blood) and medical equipment (i.e., used medical devices that conforms to 29 CFR 1910.1030 of the regulations of the Occupational Safety and Health Administration of the Department of Labor) are excepted, under §§ 173.134 (b)(1)(i) and 173.134 (b)(1)(iii) respectively, from the requirements of the HMR if the items as packaged do not contain any material that would otherwise be subject to any other Department of Transportation hazard class. Therefore, based on the information you provided, it appears that the medical devices and human donor blood would not be subject to the HMR.

I hope this information is helpful. Should you have further questions, do not hesitate to contact us.

Sincerely,

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

*Betto*  
*File: 173.134*  
*SC: 133, 132*

Pall Corporation

25 Harbor Park Drive • Port Washington, NY 11050 • USA  
Phone 516-484-3600 • FAX 516-484-3651

May 5, 1997

Mr. Edward T. Mazzullo  
RSPA  
U.S. Department of Transportation  
Attention: DHM-10  
400 7<sup>th</sup> Street SW  
Washington, D.C., 20590

Re: Pall Corporation  
Request for Determination of a Hazardous Material

Dear Mr. Mazzullo:

We are writing to your attention to request guidance on forming a hazardous material determination for transporting: (1) returned medical devices and (2) human donor blood. These medical devices are potentially infectious because they are returned goods from hospitals used in patient care and may have been in contact with potentially infectious materials such as human blood, platelets and intravenous fluids. The human donor blood is tested and screened for infectious disease markers. Neither of these materials contain known infectious agents.

Please advise how these materials should be classified and packaged for transport via truck and air. If there is further information that we may provide, please contact me at (516) 484-3600, extension 6371.

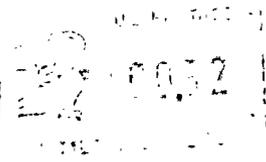
*What does this mean?*

Sincerely,  
PALL CORPORATION

*Susan Morrissey*

Susan Morrissey  
Environmental Services Consultant

Scientific & Laboratory Services Dept.  
Pall Corporation • 25 Harbor Park Drive  
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Mr. Edward T. Mazzullo  
RSPA  
U.S. Department of Transportation  
ATTN: DHM-10  
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