



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

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

AUG 11 2003

Mr. Paul H. Brinton
Assistant Vice President, Transportation and Logistics
ARUP Laboratories
500 Chipeta Way
Salt Lake City, Utah 84108

Ref. No. 03-0161

Dear Mr. Brinton:

This responds to your email of July 2, 2003, concerning the applicability the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to the transportation of infectious substances. Specifically, you ask about shipping paper and package labeling requirements for a shipment containing multiple pathogens.

According to your email, you ship specimens in containers that are placed inside plastic bags and then placed within pressure vessels. Each specimen container may contain a different pathogen. Several pressure vessels are then placed with temperature media inside a secondary packaging that consists of a layer of fiberboard, a layer of urethane, and an additional layer of fiberboard that is coated with waterproofing. The secondary packagings are then placed within an outside packaging. You provide an example of a shipping paper for a single package that contains three 5-ml tubes of Hepatitis C and one 5-ml tube of Human immunodeficiency virus packed with 2.2 kg of dry ice. You ask how the different hazardous materials contained in the package should be listed on the shipping paper.

Your shipping paper entry for the infectious substances packed with dry ice should read as follows:

Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and type of packaging
Infectious substance, affecting humans (Hepatitis C, Human immunodeficiency virus)	6.2	UN 2814			20 ml
AND					
Carbon dioxide, solid	9	UN 1845	III		2.2kg Packed in 1 plastic box



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As an alternative, you may elect to list each pathogen separately. In that case, your shipping paper entry should read as follows:

Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and type of packaging
Infectious substance, affecting humans (Hepatitis C) AND	6.2	UN 2814			15 ml
Infectious substance, affecting humans (Human immunodeficiency virus) AND	6.2	UN 2814			5 ml
Carbon dioxide, solid	9	UN 1845	III		<u>2.2kg</u> Packed in 1 plastic box

With your email, you provided a copy of the label that you propose to utilize to meet the package marking requirements of § 172.301 of the HMR. Paragraph (b) of § 172.301 requires a package to be marked with the technical name of the hazardous material in parentheses in association with the proper shipping name. On the label you provided, the technical names of the material are not listed in parentheses in association with the proper shipping name. To conform with § 172.301(b), the package must be marked "Infectious substance, affecting humans (Hepatitis C, Human immunodeficiency virus)".

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,


Edward T. Mazzullo
Director, Office of Hazardous
Materials Standards

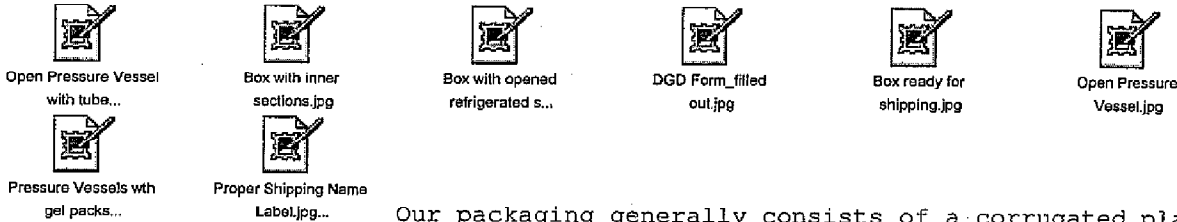
Gorsky, Susan

Gorsky
§ 173.194

§ 173.199
Infectious Substance

From: Brinton, Paul [brintoph@aruplab.com]
Sent: Wednesday, July 02, 2003 12:09 PM
To: Gorsky, Susan
Subject: RE: DOT Infectious Substance/Diagnostic Specimen Transport Regulations

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Our packaging generally consists of a corrugated plastic outer, and then three possible configurations of inner containers, one for each temperature of specimen being shipped. The inner containers consist of a layer of fiberboard, a one inch layer of urethane, an additional layer of fiberboard, and that layer is coated with a waterproofing coating. The temperature medium, either cold gel packs, or dry ice is interspersed with the pressure vessels inside the inner container. The specimens are generally in specimen containers, inside plastic bags and then inside the pressure vessels. The system, from the outer plastic jacket was certified as a package, and the certification markings are on the plastic outer layer. Since the entire package was certified as a whole, the package is not considered an over pack. I am including some pictures of our process. I hope you can receive them. If not, I would be happy to print them and send them to you. The pictures have brief explanations as to what they show. If you have questions, please call or contact me. In addition, I would like to request an official letter supporting our position on the format of the DGD and the labeling of the shipping container with the names of the organisms. We call that label the Proper Shipping Name (PSN) label. Thank you for any help you may be able to give us.

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-----Original Message-----

From: Gorsky, Susan [mailto:Susan.Gorsky@rspa.dot.gov]
Sent: Monday, June 30, 2003 10:01
To: 'brintoph@aruplab.com'
Subject: RE: DOT Infectious Substance/Diagnostic Specimen Transport Regulations

Paul,

I have consulted with several of my colleagues in the Hazmat Standards office. The answer to your question depends on how you package your multiple organisms in one shipment. If by one shipment you mean a single box, then you may list "Infectious substance, affecting humans" once on the shipping paper and list the different organisms in parentheses after the shipping name. However, if your one shipment consists of several different boxes, then you must separately list the contents of each box on the shipping paper (thus, if five boxes, then five separate entries for "Infectious substance, affecting humans" followed by the technical name of

the specific organism after each entry). I hope this is helpful.

Susan

-----Original Message-----

From: Brinton, Paul [mailto:brintonph@aruplab.com]

Sent: Wednesday, June 18, 2003 3:44 PM

To: Gorsky, Susan

Subject: RE: DOT Infectious Substance/Diagnostic Specimen Transport Regulations

Susan, I am wrestling with an issue as to how a Dangerous Goods Declaration must be filled out. If you are not the appropriate person, perhaps you could forward this to that person. We frequently ship multiple organisms in one shipment. It has been our procedure to list "Infectious Substance, Affecting Humans" once, and then list the different organism names below that, placed inside parentheses. Recently, we were told that we could no longer use that format, and must repeat the Infectious statement for each organism. This seems overly complex to us, and will cause an increase in the opportunity for errors and extra forms to no good purpose. Can you give me information to help alleviate this situation, or direct me to someone that may be able to help? Thank you very much.

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<<Open Pressure Vessel with tubes.jpg>> <<Box with inner sections.jpg>>
<<Box with opened refrigerated section.jpg>> <<DGD Form filled out.jpg>>
<<Box ready for shipping.jpg>> <<Open Pressure Vessel.jpg>> <<Pressure
Vessels wth gel packs.jpg>> <<Proper Shipping Name Label.jpg>>