



U.S. Department
of Transportation

**Pipeline and
Hazardous Materials Safety
Administration**

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

Lisa Hardesty, MA, CHCC, HEM
Healthcare Support Services
14593 North Barton Lake Drive
Vicksburg, MI 49097

Reference No. 06-0267

Dear Ms. Hardesty:

This is in response to your November 17, 2006 e-mail and recent telephone conversations with a member of my staff asking how to transport Division 6.2 (infectious) and non-infectious pathological wastes preserved in a 10% buffered formalin solution under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You state different hospitals around the United States offer these wastes for transport mixed with formalin containing various concentrations of formaldehyde up to but not exceeding 10%, described herein as "10% buffered formalin." You also state the wastes exhibit corrosive and toxic characteristics and are subject to the hazardous waste manifest requirements of the U.S. Environmental Protection Agency (EPA). I have paraphrased your questions and answered them in the order provided.

- Q1. Is a 10% buffered formalin solution considered a hazardous material under the HMR? If so, does § 173.24a(c)(2)(iii) apply to a formalin solution placed in an inner packaging with a Division 6.2 material that meets the definition for a regulated medical waste?
- A1. As provided in § 173.22 of the HMR, it is the shipper's responsibility to properly class a hazardous material. This Office does not perform that function. However, it is our opinion that formalin containing 10% formaldehyde placed in an inner packaging with non-hazardous material meets the definition for a Class 9 (miscellaneous) material and should be described as "UN 3334, Aviation regulated liquid, n.o.s. (formaldehyde), 9" for transportation by aircraft, or "NA 3082, Other regulated substances, liquid, n.o.s. (formaldehyde), 9, PG III" for domestic transportation in all modes. See § 172.202(b). Formalin containing less than 10% formaldehyde does not meet the definition for a hazardous material under the HMR.

Class 9 formalin packaged with regulated medical waste (RMW) as a preservative or stabilizing material under the provisions of § 173.24a(c)(2)(iii) must conform to the requirements in § 173.197 and the material must be described as "UN 3291, Regulated medical waste, n.o.s, 6.2, PG II." Section 173.24a(c) permits the transportation of more than one hazardous material in a non-bulk outer packaging



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173.24a(c)(2)(iii)

paragraph (c)(2), a packaging containing inner packagings of Division 6.2 material may also contain refrigerants, anticoagulants used to stabilize blood or plasma, or small quantities of Class 3, 8, 9 or other materials used to stabilize or prevent degradation of the sample provided the quantity of such materials does not exceed 30 mL or 30 g for each inner packaging and 4 L or 4 kg for each outer packaging.

- Q2. Is a formalin solution that is subject to the EPA hazardous waste manifest requirements considered a hazardous material under the HMR?
- A2. Yes. For purposes of the HMR, a hazardous waste is a material that is subject to the EPA hazardous waste manifest requirements in 40 CFR Part 262. Provided the material does not meet the definition for any other hazard class, a waste formalin solution may be described as “UN 3334, Waste aviation regulated liquid, n.o.s. (formaldehyde), 9” for transportation by aircraft, or “NA 3082, Waste other regulated substances, liquid, n.o.s. (formaldehyde), 9, PG III” for domestic transportation in all modes.

For a formalin solution meeting the definition for a hazardous waste under the HMR that is contained in the same inner packaging as RMW, the packaging must conform to the requirements in § 173.197 and the material must be described as “UN 3291, Regulated medical waste, n.o.s., 6.2, PG II.” If the shipper determines that enough formalin is placed in the package such that 100 pounds of formaldehyde is present at a concentration by weight of 0.2 percent or 2000 ppm, its contents also meets the definition of a hazardous substance and must be described as “RQ, UN 3291, Regulated medical waste, n.o.s. (formaldehyde), 6.2, PG II.”

- Q3. Does the 30 mL limit for formalin in § 173.24a(c)(2)(iii) apply to RMW or all infectious substances?
- A3. Yes. The 30 mL limit in § 173.24a(c)(2)(iii) applies to all infectious substances, including RMW. See answer A1 above.
- Q4. In a letter of interpretation your agency issued on April 10, 2003, (Reference No. 02-0292) you state the appropriate proper shipping name for biological samples preserved with a 10% buffered formalin solution transported by aircraft is “NA 3082, Other regulated substances, n.o.s. (formaldehyde), 9, PG III.” Does the same proper shipping description apply to ground transportation?
- A4. Yes, provided the biological samples or pathological materials packaged with the formalin solution do not meet the definition for a Division 6.2 material and the material is transported domestically. However, please note that on October 1, 1999, we added the proper shipping description “UN 3334, Aviation regulated liquid, n.o.s. (formaldehyde), 9” to the Hazardous Materials Table to align the HMR with international requirements for transporting hazardous materials (Docket

No. HM-215C; 64 FR 10741 and 64 FR 44426). As stated in our July 13, 2001 letter of interpretation (Reference No. 01-0120), this is the preferred proper shipping name for 10% buffered formalin solutions that meet no other hazard class and are offered for domestic and international transportation by aircraft. See answer A1 above.

I hope this information is helpful.

Sincerely,

A handwritten signature in black ink, appearing to read 'Hattie L. Mitchell', written in a cursive style.

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

November 17, 2006

Eileen Edmonson
PHH-10
400 7th St., S.W.
Washington, DC 20590-0001

Edmonson
§173.24a(c)(2)(iii)
Applicability
06-0267

Dear Ms. Edmonson,

I am writing to request an interpretation of 49 CFR 173.24a(c)(2)(iii) regarding the transport of pathological materials preserved in 10% buffered formalin.

I consult with a company that transports regulated medical waste and pathological waste that requires formalin to be decanted prior to shipment. I have heard that there are some entities that accept for shipment containers where the inner packagings exceed the 30 ml exception for a preservative material in hazard Classes 3, 8, 9. My questions are:

1. Is 10% buffered formalin considered a hazardous material as stated in §173.24a(c)(2)(iii)?
2. Would the shipment of pathological materials in 10% buffered formalin in amounts greater than 30ml in each inner package constitute a hazardous waste shipment? Does the 30ml apply to regulated medical waste or only infectious substances?
3. And finally, in a letter of interpretation dated April 10, 2003 the proper shipping description (for air transport) of biological samples preserved with a 10% buffered formalin solution was given as "**Other Regulated Substances, n.o.s., 9, NA 3082, PGIII**". Would the same proper shipping description apply for ground transportation of 10% buffered formalin solution used to preserve pathological tissues that have now become a waste?

Based upon my knowledge of DOT and EPA regulations, a 10% buffered formalin solution may exhibit the characteristics of corrosivity, and toxicity and would typically be classified in this instance as a hazardous waste. I appreciate your attention to this matter on my behalf and await your direction.

Should you have any additional questions, please contact me at (269)-649-1623

Sincerely,

Lisa Hardesty, MA, CHCC, HEM
Healthcare Support Services

Edmonson, Eileen <PHMSA>

From: Lisa Hardesty [lisahardesty@comcast.net]
Sent: Saturday, November 18, 2006 9:49 PM
To: Edmonson, Eileen <PHMSA>
Subject: Request for interpretation
Attachments: Formalin Interp_11_17_06.doc

Hello Eileen,

My name is Lisa Hardesty and I'm a healthcare compliance consultant based in the Midwest. I was given your name and e-mail information as a contact for USDOT interpretations. I've been struggling for a number of years over proper shipment of 10% buffered formalin. Regulated medical waste vendors seem to have conflicting opinions regarding the transportation of pathological waste immersed in a 10% formalin preservative. Some haulers require the hospital to decant the formalin before shipping the pathological waste as regulated medical waste while other haulers encourage the hospitals **not** to decant the formalin. Please review **my** questions as outlined in the attached letter. I sincerely appreciate any direction you can offer.

Best regards,

Lisa Hardesty, MA, CHCC, HEM
Healthcare Support Services
269-649-1623 phone
269-649-4076 fax

11/21/2006